

# Prescription Benefit Medication Prior Authorization Criteria

# QuartzBenefits.com

These criteria apply to drugs picked up at the pharmacy.

These medication prior authorization criteria do not apply to drugs picked up at the pharmacy for State and Local Government members or BadgerCare Plus and/or Medicaid SSI members.

State and Local Government members should call **Navitus** at **(866)** 333-2757 or visit <u>navitus.com</u> for information about your prescription drug benefits.

Quartz BadgerCare Plus and/or Medicaid SSI members must call the **Wisconsin Department of Health and Family Services** at **(800)** 362-3002 or visit <u>forwardhealth.wi.gov</u> for information about your prescription drug benefits.



# April 1, 2024 Pharmacy Benefit Drug Prior Authorization Criteria

A medication prior authorization request may be started by members, providers, or designated representatives by fax, electronically on Quartz's website, telephone, mail. Or, for medical benefit medications, also by Health Link, Plan Link, MyQuartzTools, or electronic prior authorization (e-PA) within the electronic medical record. Electronic (e-PA) via Surescripts verifies member eligibility and member benefit information. Quartz sends back e-PA criteria questions to the provider staff which can be answered, and medical records can be attached to the request.

Quartz strongly recommends that the health care provider initiate the prior authorization request process on behalf of the member. This is because the health care provider will be able to include the medical history necessary for a timely decision to be made based on all of the relevant information, including any case specific circumstances that can be considered. Once a request and the supporting documentation have been submitted, a pharmacist or appropriate staff review the prior authorization criteria and exception requirements separately to make a coverage decision.

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| Actemra (tocilizumab)            |   |                             |  |  |  |
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# **Prior Authorization Guideline**

| Guideline ID                         | GL-134598 |
|--------------------------------------|-----------|
| Guideline Name Actemra (tocilizumab) |           |
| Formulary                            | Quartz    |

# **Guideline Note:**

| Effective Date: |
|-----------------|
|-----------------|

# 1. Criteria

| Product Name: Actemra                                      |  |  |
|--|--|--|
| Diagnosis Moderate to Severely Active Rheumatoid Arthritis |  |  |
| Approval Length 12/31/2039                                 |  |  |
| Guideline Type   | Prior Authorization - All Plans Except IL and MN Plans |  |

| Product<br>Name | Generic Name   | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| _               | TOCILIZUMAB SUBCUTANEOUS SOLN AUTO-<br>INJECTOR 162 MG/0.9ML | 6650007000D520 | Brand         |
| ACTEMRA         | TOCILIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 162 MG/0.9ML | 6650007000E520 | Brand         |

# **Approval Criteria**

| 1 - Diagnosis of modera   | ate to severely active rheumatoid arthritis (RA)   |
|---|--|
|   | AND  |
|   | cal records (e.g., chart notes) documenting a 3-month trial and failure, dication to ONE of the following:                                   |
| <ul><li>methotrexate (N</li><li>leflunomide</li><li>hydroxychloroqu</li><li>sulfasalazine</li></ul>   |  |
|   | AND  |
| <b>3</b> - Trial and failure, cor   | straindication or intolerance to TWO of the following:   |
| <ul> <li>adalimumab</li> <li>certolizumab</li> <li>etanercept</li> <li>golimumab</li> <li>tofacitinib (ER)</li> <li>upadacitinib</li> </ul> |  |
|   | AND  |
| 4 - Medication must be  | self-administered (not in clinic or provider office)   |
|   | AND  |
| <b>5</b> - Prescribed by or in o  | consultation with a rheumatologist   |
|   | AND  |
|   | e used in combination with other biologic disease modifying anti-<br>D) (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist,   |
| Notes   | *Member new to the plan (as evidenced by coverage effective date of I ess than or equal to 90 days) who initiated therapy using a manufactur |
|   |  |

| er-sponsored free drug program, provider samples, and/or vouchers will go through initial criteria, otherwise for continuation of therapy for new to plan, reauthorization criteria applies  **Absolute contraindications to methotrexate are pregnancy nursing all |
|---|
| **Absolute contraindications to methotrexate are pregnancy, nursing, al coholism, alcoholic liver disease or other chronic liver disease, immunodeficiency syndromes, bone marrow hyp erplasia, leukopenia, thrombocytopenia or                                     |
| significant anemia, or hypersensitivity to methotrexate.  |

| Product Name: Actemra                                      |                                       |
|--|---------------------------------------|
| Diagnosis Moderate to Severely Active Rheumatoid Arthritis |                                       |
| Approval Length  | 12 month(s)                           |
| Therapy Stage  | Initial Authorization                 |
| Guideline Type   | Prior Authorization - IL and MN Plans |

| Product<br>Name   | Generic Name   | GPI            | Brand/Generic |
|-------------------|--|----------------|---------------|
| ACTEMRA<br>ACTPEN | TOCILIZUMAB SUBCUTANEOUS SOLN AUTO-<br>INJECTOR 162 MG/0.9ML | 6650007000D520 | Brand         |
| ACTEMRA           | TOCILIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 162 MG/0.9ML | 6650007000E520 | Brand         |

1 - Diagnosis of moderate to severely active rheumatoid arthritis (RA)

#### AND

- 2 Submission of medical records (e.g., chart notes) documenting a 3-month trial and failure, intolerance, or contraindication to ONE of the following:
  - methotrexate (MTX)\*\*
  - leflunomide
  - hydroxychloroquine sulfasalazine

#### **AND**

**3** - Trial and failure, contraindication or intolerance to TWO of the following:

- adalimumab
- certolizumab
- etanercept
- golimumab
- tofacitinib (ER)
- upadacitinib

#### **AND**

**4** - Medication must be self-administered (not in clinic or provider office)

#### **AND**

**5** - Prescribed by or in consultation with a rheumatologist

#### AND

**6** - Therapy must not be used in combination with other biologic disease modifying antirheumatic drug (DMARD) (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

| Notes | *Member new to the plan (as evidenced by coverage effective date of I ess than or equal to 90 days) who initiated therapy using a manufactur er-sponsored free drug program, provider samples, and/or vouchers wil I go through initial criteria, otherwise for continuation of therapy for new to plan, reauthorization criteria applies  **Absolute contraindications to methotrexate are pregnancy, nursing, al coholism, alcoholic liver disease or other chronic liver disease, immunodeficiency syndromes, bone marrow hyp erplasia, leukopenia, thrombocytopenia or significant anemia, or hypersensitivity to methotrexate. |
|-------|---|
|-------|---|

| Product Name: Actemra                                |            |  |     |               |
|--|------------|--|-----|---------------|
| Diagnosis  |            | Moderate to Severely Active Rheumatoid Arthritis |     |               |
| Approval Le  | ength      | 12 month(s)                                      |     |               |
| Therapy Sta  | age        | Reauthorization                                  |     |               |
| Guideline Type Prior Authorization - IL and MN Plans |            |  |     |               |
| Product  | Generic Na | me   | GPI | Brand/Generic |

| Name              |  |                |       |
|-------------------|--|----------------|-------|
| ACTEMRA<br>ACTPEN | TOCILIZUMAB SUBCUTANEOUS SOLN AUTO-<br>INJECTOR 162 MG/0.9ML | 6650007000D520 | Brand |
| ACTEMRA           | TOCILIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 162 MG/0.9ML | 6650007000E520 | Brand |

**1** - Submission of medical records (e.g., chart notes), documenting the member's response to therapy within the past 12 months including individual improvements in functional status

| *Member new to the plan (as evidenced by coverage effective date of I ess than or equal to 90 days) who initiated therapy using a manufactur er-sponsored free drug program, provider samples, and/or vouchers wil I go through initial criteria, otherwise for continuation of therapy for new |
|---|
| to plan, reauthorization criteria applies   |

| Product Name: Actemra |  |
|-----------------------|--|
| Diagnosis             | Systemic Juvenile Idiopathic Arthritis (SJIA)          |
| Approval Length       | 12/31/2039   |
| Guideline Type        | Prior Authorization - All Plans Except IL and MN Plans |

| Product<br>Name   | Generic Name   | GPI            | Brand/Generic |
|-------------------|--|----------------|---------------|
| ACTEMRA<br>ACTPEN | TOCILIZUMAB SUBCUTANEOUS SOLN AUTO-<br>INJECTOR 162 MG/0.9ML | 6650007000D520 | Brand         |
| ACTEMRA           | TOCILIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 162 MG/0.9ML | 6650007000E520 | Brand         |

#### **Approval Criteria**

1 - Member is 2 years of age or older

#### **AND**

- 2 Trial and failure, contraindication\*\* or intolerance to ONE of the following for 3 months:
  - corticosteroids
  - methotrexate

• nonsteroidal anti-inflammatories

#### **AND**

**3** - Medication must be self-administered (not in clinic or provider office)

#### **AND**

**4** - Prescribed by or in consultation with a rheumatologist

#### **AND**

**5** - Therapy must not be used in combination with other biologic disease modifying antirheumatic drug (DMARD) (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

| Notes | *Member new to the plan (as evidenced by coverage effective date of I ess than or equal to 90 days) who initiated therapy using a manufactur er-sponsored free drug program, provider samples, and/or vouchers wil I go through initial criteria, otherwise for continuation of therapy for new to plan, reauthorization criteria applies  **Absolute contraindications to methotrexate are pregnancy, nursing, al coholism, alcoholic liver disease or other chronic liver disease, immunodeficiency syndromes, bone marrow hyperplasia, leuk openia, thrombocytopenia or significant anemia, or hypersensitivity to methotrexate |
|-------|--|
|-------|--|

| Product Name: Actemra |   |
|-----------------------|---|
| Diagnosis             | Systemic Juvenile Idiopathic Arthritis (SJIA) |
| Approval Length       | 12 month(s)                                   |
| Therapy Stage         | Initial Authorization                         |
| Guideline Type        | Prior Authorization - IL and MN Plans         |

| ACTEMRA TOCILIZUMAB SUBCUTANEOUS SOLN AUTO- INJECTOR 162 MG/0.9ML  ACTEMRA TOCILIZUMAB SUBCUTANEOUS SOLN PREFILLED 6650007000E520 Brand  SYRINGE 162 MG/0.9MI | Product<br>Name | Generic Name   | GPI            | Brand/Generic |
|---|-----------------|--|----------------|---------------|
| 0000007000L020  |                 |  | 6650007000D520 | Brand         |
| OTAMOE TO MOJO.SWIE   | ACTEMRA         | TOCILIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 162 MG/0.9ML | 6650007000E520 | Brand         |

1 - Member is 2 years of age or older

#### **AND**

- 2 Trial and failure, contraindication\*\* or intolerance to ONE of the following for 3 months:
  - corticosteroids
  - methotrexate
  - nonsteroidal anti-inflammatories

#### **AND**

**3** - Medication must be self-administered (not in clinic or provider office)

#### **AND**

4 - Prescribed by or in consultation with a rheumatologist

#### **AND**

**5** - Therapy must not be used in combination with other biologic disease modifying anti-rheumatic drug (DMARD) (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

| Notes | *Member new to the plan (as evidenced by coverage effective date of I ess than or equal to 90 days) who initiated therapy using a manufactur er-sponsored free drug program, provider samples, and/or vouchers wil I go through initial criteria, otherwise for continuation of therapy for new to plan, reauthorization criteria applies  **Absolute contraindications to methotrexate are pregnancy, nursing, al coholism, alcoholic liver disease or other chronic liver disease, immunodeficiency syndromes, bone marrow hyperplasia, leuk openia, thrombocytopenia or significant anemia, or hypersensitivity to methotrexate |
|-------|--|

Product Name: Actemra

| Diagnosis       | Systemic Juvenile Idiopathic Arhtritis (SJIA) |
|-----------------|---|
| Approval Length | 12 month(s)                                   |
| Therapy Stage   | Reauthorization                               |
| Guideline Type  | Prior Authorization - IL and MN Plans         |

| Product<br>Name   | Generic Name   | GPI            | Brand/Generic |
|-------------------|--|----------------|---------------|
| ACTEMRA<br>ACTPEN | TOCILIZUMAB SUBCUTANEOUS SOLN AUTO-<br>INJECTOR 162 MG/0.9ML | 6650007000D520 | Brand         |
| ACTEMRA           | TOCILIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 162 MG/0.9ML | 6650007000E520 | Brand         |

**1** - Submission of medical records (e.g., chart notes), documenting the member's response to therapy within the past 12 months including individual improvements in functional status

| Notes | *Member new to the plan (as evidenced by coverage effective date of I ess than or equal to 90 days) who initiated therapy using a manufactur er-sponsored free drug program, provider samples, and/or vouchers wil I go through initial criteria, otherwise for continuation of therapy for new |
|-------|---|
|       | to plan, reauthorization criteria applies   |

| Product Name: Actemra |  |  |
|-----------------------|--|--|
| Diagnosis             | Polyarticular Juvenile Idiopathic Arthritis (PJIA)     |  |
| Approval Length       | 12/31/2039   |  |
| Guideline Type        | Prior Authorization - ALL Plans Except IL and MN Plans |  |

| Product<br>Name   | Generic Name   | GPI            | Brand/Generic |
|-------------------|--|----------------|---------------|
| ACTEMRA<br>ACTPEN | TOCILIZUMAB SUBCUTANEOUS SOLN AUTO-<br>INJECTOR 162 MG/0.9ML | 6650007000D520 | Brand         |
| ACTEMRA           | TOCILIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 162 MG/0.9ML | 6650007000E520 | Brand         |

# **Approval Criteria**

**1** - Diagnosis of polyarticular juvenile idiopathic arthritis (PJIA)

#### AND

- **2** Submission of medical records (e.g., chart notes) documenting documenting a 3-month trial and failure, intolerance, or contraindication to ONE of the following
  - methotrexate (MTX)\*\*
  - leflunomide
  - hydroxychloroquine
  - sulfasalazine

#### **AND**

- 3 Trial and failure, contraindication or intolerance to TWO of the following:
  - adalimumab
  - etanercept
  - tofacitinib

#### **AND**

**4** - Medication must be self-administered (not in clinic or provider office)

#### **AND**

**5** - Prescribed by or in consultation with a rheumatologist

#### **AND**

**6** - Therapy must not be used in combination with other biologic disease modifying antirheumatic drug (DMARD) (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

| Notes | *Member new to the plan (as evidenced by coverage effective date of I ess than or equal to 90 days) who initiated therapy using a manufactur er-sponsored free drug program, provider samples, and/or vouchers wil I go through initial criteria, otherwise for continuation of therapy for new to plan, reauthorization criteria applies  **Absolute contraindications to methotrexate are pregnancy, nursing, al coholism, alcoholic liver disease or other chronic liver disease, immunodeficiency syndromes, bone marrow hyp |
|-------|--|
|-------|--|

| erplasia, leukopenia, thrombocytopenia or                |
|--|
| significant anemia, or hypersensitivity to methotrexate. |

| Product Name: Actemra |  |
|-----------------------|--|
| Diagnosis             | Polyarticular Juvenile Idiopathic Arthritis (PJIA) |
| Approval Length       | 12 month(s)  |
| Therapy Stage         | Initial Authorization                              |
| Guideline Type        | Prior Authorization - IL and MN Plans              |

| Product<br>Name   | Generic Name   | GPI            | Brand/Generic |
|-------------------|--|----------------|---------------|
| ACTEMRA<br>ACTPEN | TOCILIZUMAB SUBCUTANEOUS SOLN AUTO-<br>INJECTOR 162 MG/0.9ML | 6650007000D520 | Brand         |
| ACTEMRA           | TOCILIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 162 MG/0.9ML | 6650007000E520 | Brand         |

1 - Diagnosis of polyarticular juvenile idiopathic arthritis (PJIA)

#### **AND**

- **2** Submission of medical records (e.g., chart notes) documenting a 3-month trial and failure, intolerance, or contraindication to ONE of the following:
  - methotrexate (MTX)\*\*
  - leflunomide
  - hydroxychloroquine
  - sulfasalazine

#### **AND**

- **3** Trial and failure, contraindication or intolerance to TWO of the following:
  - adalimumab
  - etanercept
  - tofacitinib

#### **AND**

4 - Medication must be self-administered (not in clinic or provider office)

#### AND

**5** - Prescribed by or in consultation with a rheumatologist

#### **AND**

**6** - Therapy must not be used in combination with other biologic disease modifying antirheumatic drug (DMARD) (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

|  | *Member new to the plan (as evidenced by coverage effective date of I ess than or equal to 90 days) who initiated therapy using a manufactur er-sponsored free drug program, provider samples, and/or vouchers wil I go through initial criteria, otherwise for continuation of therapy for new to plan, reauthorization criteria applies  **Absolute contraindications to methotrexate are pregnancy, nursing, al coholism, alcoholic liver disease or other chronic liver disease, immunodeficiency syndromes, bone marrow hyp erplasia, leukopenia, thrombocytopenia or significant anemia, or hypersensitivity to methotrexate. |
|--|---|
|--|---|

| Product Name: Actemra |  |  |  |
|-----------------------|--|--|--|
| Diagnosis             | Polyarticular Juvenile Idiopathic Arthritis (PJIA) |  |  |
| Approval Length       | 12 month(s)  |  |  |
| Therapy Stage         | Reauthorization                                    |  |  |
| Guideline Type        | Prior Authorization - IL and MN Plans              |  |  |

| Product<br>Name   | Generic Name   | GPI            | Brand/Generic |
|-------------------|--|----------------|---------------|
| ACTEMRA<br>ACTPEN | TOCILIZUMAB SUBCUTANEOUS SOLN AUTO-<br>INJECTOR 162 MG/0.9ML | 6650007000D520 | Brand         |
| ACTEMRA           | TOCILIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 162 MG/0.9ML | 6650007000E520 | Brand         |

# **Approval Criteria**

| 1 - Submission of medical records (e.g., chart notes), documenting the member's response to therapy within the past 12 months including individual improvements in functional status |   |  |
|--|---|--|
| Notes  | *Member new to the plan (as evidenced by coverage effective date of I ess than or equal to 90 days) who initiated therapy using a manufactur er-sponsored free drug program, provider samples, and/or vouchers wil I go through initial criteria, otherwise for continuation of therapy for new to plan, reauthorization criteria applies |  |

| Product Name: Actemra   |  |  |
|---|--|--|
| Diagnosis Giant Cell Arteritis (GCA)                                  |  |  |
| Approval Length 12/31/2039  |  |  |
| Guideline Type Prior Authorization - All Plans Except IL and MN Plans |  |  |

| Product<br>Name   | Generic Name   | GPI            | Brand/Generic |
|-------------------|--|----------------|---------------|
| ACTEMRA<br>ACTPEN | TOCILIZUMAB SUBCUTANEOUS SOLN AUTO-<br>INJECTOR 162 MG/0.9ML | 6650007000D520 | Brand         |
| ACTEMRA           | TOCILIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 162 MG/0.9ML | 6650007000E520 | Brand         |

1 - Diagnosis of Giant Cell Arteritis (GCA)

**AND** 

- 2 ONE of the following:
- **2.1** Symptoms relapsed despite use of corticosteroids or methotrexate

OR

2.2 Contraindication\*\* to methotrexate

OR

2.3 Inability to taper corticosteroids

#### **AND**

**3** - Medication must be self-administered (not in clinic or provider office)

#### **AND**

**4** - Prescribed by or in consultation with a rheumatologist

#### **AND**

**5** - Therapy must not be used in combination with other biologic disease modifying antirheumatic drug (DMARD) (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

| Notes | *Member new to the plan (as evidenced by coverage effective date of I ess than or equal to 90 days) who initiated therapy using a manufactur er-sponsored free drug program, provider samples, and/or vouchers wil I go through initial criteria, otherwise for continuation of therapy for new to plan, reauthorization criteria applies  **Absolute contraindications to methotrexate are pregnancy, nursing, al coholism, alcoholic liver disease or other chronic liver disease, immunodeficiency syndromes, bone marrow hyperplasia, leuk openia, thrombocytopenia or significant anemia, or hypersensitivity to methotrexate |
|-------|--|
|-------|--|

| Product Name: Actemra                                |                                    |  |
|--|------------------------------------|--|
| Diagnosis Giant Cell Arteritis (GCA)                 |                                    |  |
| Approval Length                                      | 12 month(s)                        |  |
| Therapy Stage  | nerapy Stage Initial Authorization |  |
| Guideline Type Prior Authorization - IL and MN Plans |                                    |  |

| Product<br>Name   | Generic Name   | GPI            | Brand/Generic |
|-------------------|--|----------------|---------------|
| ACTEMRA<br>ACTPEN | TOCILIZUMAB SUBCUTANEOUS SOLN AUTO-<br>INJECTOR 162 MG/0.9ML | 6650007000D520 | Brand         |
| ACTEMRA           | TOCILIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 162 MG/0.9ML | 6650007000E520 | Brand         |

| Approval Criteria   |  |  |  |
|---|--|--|--|
| 1 - Diagnosis of Giant C  | 1 - Diagnosis of Giant Cell Arteritis (GCA)  |  |  |
|   | AND  |  |  |
|   | AND  |  |  |
| 2 - ONE of the following  | ı:   |  |  |
| 2.1 Symptoms relapse  | ed despite use of corticosteroids or methotrexate  |  |  |
|   | OR   |  |  |
| 2.2 Contraindication**  | to methotrexate  |  |  |
|   | OR   |  |  |
| 2.3 Inability to taper co   | orticosteroids   |  |  |
|   | AND  |  |  |
| 3 - Medication must be  | self-administered (not in clinic or provider office)   |  |  |
|   | AND  |  |  |
| 4 - Prescribed by or in consultation with a rheumatologist  |  |  |  |
| AND   |  |  |  |
| <b>5</b> - Therapy must not be used in combination with other biologic disease modifying anti-rheumatic drug (DMARD) (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.) |  |  |  |
| Notes   | *Member new to the plan (as evidenced by coverage effective date of I ess than or equal to 90 days) who initiated therapy using a manufactur er-sponsored free drug program, provider samples, and/or vouchers wil |  |  |

| I go through initial criteria, otherwise for continuation of therapy for new to plan, reauthorization criteria applies  **Absolute contraindications to methotrexate are pregnancy, nursing, al coholism, alcoholic liver disease or other chronic liver disease, immunodeficiency syndromes, bone marrow hyperplasia, leuk |
|---|
| openia, thrombocytopenia or significant<br>anemia, or hypersensitivity to methotrexate  |

| Product Name: Actemra                                |                            |  |
|--|----------------------------|--|
| Diagnosis Giant Cell Arteritis (GCA)                 |                            |  |
| Approval Length                                      | 12 month(s)                |  |
| Therapy Stage  | rapy Stage Reauthorization |  |
| Guideline Type Prior Authorization - IL and MN Plans |                            |  |

| Product<br>Name   | Generic Name   | GPI            | Brand/Generic |
|-------------------|--|----------------|---------------|
| ACTEMRA<br>ACTPEN | TOCILIZUMAB SUBCUTANEOUS SOLN AUTO-<br>INJECTOR 162 MG/0.9ML | 6650007000D520 | Brand         |
| ACTEMRA           | TOCILIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 162 MG/0.9ML | 6650007000E520 | Brand         |

**1** - Submission of medical records (e.g., chart notes), documenting the member's response to therapy within the past 12 months including individual improvements in functional status

|  | *Member new to the plan (as evidenced by coverage effective date of I ess than or equal to 90 days) who initiated therapy using a manufactur er-sponsored free drug program, provider samples, and/or vouchers wil I go through initial criteria, otherwise for continuation of therapy for new to plan, reauthorization criteria applies |
|--|---|
|--|---|

| Product Name: Actemra |   |
|-----------------------|---|
| Diagnosis             | Systemic Sclerosis - Associated Interstitial Lung Disease (SSc-ILD) |
| Approval Length       | 12/31/2039  |
| Guideline Type        | Prior Authorization - ALL Plans Except IL and MN Plans              |

| Product<br>Name   | Generic Name   | GPI            | Brand/Generic |
|-------------------|--|----------------|---------------|
| ACTEMRA<br>ACTPEN | TOCILIZUMAB SUBCUTANEOUS SOLN AUTO-<br>INJECTOR 162 MG/0.9ML | 6650007000D520 | Brand         |

| ACTEMRA TOCILIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 162 MG/0.9ML | 6650007000E520 | Brand |
|--|----------------|-------|
|--|----------------|-------|

1 - Diagnosis of Systemic Sclerosis – Associated Interstitial Lung Disease (SSc-ILD)

#### AND

- 2 Submission of medical records (e.g., chart notes), documenting one of the following:
- **2.1** Decline in pulmonary function despite use of one of the following standard treatments:
  - mycophenolate
  - cyclophosphamide
  - azathioprine

#### OR

- **2.2** Contraindication to one of the following standard agents:
  - mycophenolate
  - cyclophosphamide
  - azathioprine

#### AND

**3** - Medication must be self-administered (not in clinic or provider office)

#### AND

- **4** Prescribed by or in consultation with one of the following:
  - rheumatologist
  - pulmonologist

#### **AND**

5 - Therapy must not be used in combination with other biologic disease modifying antirheumatic drug (DMARD) (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

\*Member new to the plan (as evidenced by coverage effective date of I ess than or equal to 90 days) who initiated therapy using a manufactur er-sponsored free drug program, provider samples, and/or vouchers wil I go through initial criteria, otherwise for continuation of therapy for new to plan, reauthorization criteria applies

| Product Name: Actemra |   |
|-----------------------|---|
| Diagnosis             | Systemic Sclerosis - Associated Interstitial Lung Disease (SSc-ILD) |
| Approval Length       | 12 month(s)   |
| Therapy Stage         | Initial Authorization   |
| Guideline Type        | Prior Authorization - IL and MN Plans                               |

| Product<br>Name   | Generic Name   | GPI            | Brand/Generic |
|-------------------|--|----------------|---------------|
| ACTEMRA<br>ACTPEN | TOCILIZUMAB SUBCUTANEOUS SOLN AUTO-<br>INJECTOR 162 MG/0.9ML | 6650007000D520 | Brand         |
| ACTEMRA           | TOCILIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 162 MG/0.9ML | 6650007000E520 | Brand         |

#### **Approval Criteria**

1 - Diagnosis of Systemic Sclerosis – Associated Interstitial Lung Disease (SSc-ILD)

#### **AND**

- 2 Submission of medical records (e.g., chart notes), documenting one of the following:
- **2.1** Decline in pulmonary function despite use of one of the following standard treatments:
  - mycophenolate
  - cyclophosphamide
  - azathioprine

OR

- **2.2** Contraindication to one of the following standard agents:
  - mycophenolate
  - cyclophosphamide
  - azathioprine

#### **AND**

**3** - Medication must be self-administered (not in clinic or provider office)

#### **AND**

- 4 Prescribed by or in consultation with one of the following:
  - rheumatologist
  - pulmonologist

#### **AND**

**5** - Therapy must not be used in combination with other biologic disease modifying anti-rheumatic drug (DMARD) (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

| Notes | *Member new to the plan (as evidenced by coverage effective date of I ess than or equal to 90 days) who initiated therapy using a manufactur er-sponsored free drug program, provider samples, and/or vouchers wil I go through initial criteria, otherwise for continuation of therapy for new |
|-------|---|
|       | to plan, reauthorization criteria applies   |

| Product Name: Actemra |   |
|-----------------------|---|
| Diagnosis             | Systemic Sclerosis - Associated Interstitial Lung Disease (SSc-ILD) |
| Approval Length       | 12 month(s)   |
| Therapy Stage         | Reauthorization   |
| Guideline Type        | Prior Authorization - IL and MN Plans                               |

| Product<br>Name   | Generic Name   | GPI            | Brand/Generic |
|-------------------|--|----------------|---------------|
| ACTEMRA<br>ACTPEN | TOCILIZUMAB SUBCUTANEOUS SOLN AUTO-<br>INJECTOR 162 MG/0.9ML | 6650007000D520 | Brand         |

| ACTEMRA           | TOCILIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 162 MG/0.9ML | 6650007000E520 | Brand |
|-------------------|--|----------------|-------|
|                   |  |                |       |
| Approval Criteria |  |                |       |

**1** - Submission of medical records (e.g., chart notes), documenting the member's response to therapy within the past 12 months including individual improvements in functional status

|  | *Member new to the plan (as evidenced by coverage effective date of I ess than or equal to 90 days) who initiated therapy using a manufactur er-sponsored free drug program, provider samples, and/or vouchers wil I go through initial criteria, otherwise for continuation of therapy for new to plan, regulthorization criteria applies. |
|--|---|
|  | to plan, reauthorization criteria applies   |

| Product Name: Actemra |   |
|-----------------------|---|
| Diagnosis             | Moderate to Severely Active Rheumatoid Arthritis      |
| Approval Length       | 12/31/2039  |
| Guideline Type        | Quantity Exception - All Plans Except IL and MN Plans |

| Product<br>Name   | Generic Name   | GPI            | Brand/Generic |
|-------------------|--|----------------|---------------|
| ACTEMRA<br>ACTPEN | TOCILIZUMAB SUBCUTANEOUS SOLN AUTO-<br>INJECTOR 162 MG/0.9ML | 6650007000D520 | Brand         |
| ACTEMRA           | TOCILIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 162 MG/0.9ML | 6650007000E520 | Brand         |

# **Approval Criteria**

**1** - Failure of an adherent 3-month trial of standard maintenance dosing with concomitant methotrexate (unless contraindicated or not appropriate for indication being requested)

| Notes | *Member new to the plan (as evidenced by coverage effective date of I ess than or equal to 90 days) who initiated therapy using a manufactur er-sponsored free drug program, provider samples, and/or vouchers wil I go through initial criteria, otherwise for continuation of therapy for new |
|-------|---|
|       | to plan, reauthorization criteria applies   |

| Product Name: Actemra |  |  |
|-----------------------|--|--|
| Diagnosis             | Moderate to Severely Active Rheumatoid Arthritis |  |
| Approval Length       | 12 month(s)                                      |  |

| Guideline T  | уре   | Quantity Exception - IL and MN Plans |                |               |
|--|---|--------------------------------------|----------------|---------------|
| Product<br>Name  | Name  ACTEMRA TOCILIZUMAB SUBCUTANEOUS SOLN AUTO- |                                      | GPI            | Brand/Generic |
| ACTEMRA<br>ACTPEN  |   |                                      | 6650007000D520 | Brand         |
| ACTEMRA TOCILIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 162 MG/0.9ML |   | 6650007000E520                       | Brand          |               |

**1** - Failure of an adherent 3-month trial of standard maintenance dosing with concomitant methotrexate (unless contraindicated or not appropriate for indication being requested)

| *Member new to the plan (as evidenced by coverage effective date of I ess than or equal to 90 days) who initiated therapy using a manufactur er-sponsored free drug program, provider samples, and/or vouchers will go through initial criteria, otherwise for continuation of therapy for new to plan, regulthorization criteria applies. |
|--|
| to plan, reauthorization criteria applies  |

# 2. Definitions

| Definition          | Description  |
|---------------------|--|
| Steroid Dependence: | Demonstrated steroid dependence (defined as equivalent to prednisone 10mg daily for >3 months) with the inability to taper or when tapering of dose leads to loss of symptom control |

# 3. Revision History

| Date      | Notes                   |
|-----------|-------------------------|
| 12/1/2023 | 2024 New Implementation |

| Actiq (Fentanyl)  |
|---|
| The billion frequency to the fine to be the second, consider and fine fine fine free free constitution. |
|   |

# **Prior Authorization Guideline**

| Guideline ID          | GL-129620        |
|-----------------------|------------------|
| <b>Guideline Name</b> | Actiq (Fentanyl) |
| Formulary             | Quartz           |

# **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

# 1. Criteria

| Product Name: Fentanyl                               |                       |  |
|--|-----------------------|--|
| Approval Length                                      | 12 month(s)           |  |
| Therapy Stage  | Initial Authorization |  |
| Guideline Type Prior Authorization - IL and MN Plans |                       |  |
|  |                       |  |

| Product Name                             | Generic Name                                    | GPI            | Brand/Generic |
|--|---|----------------|---------------|
| FENTANYL<br>CITRATE ORAL<br>TRANSMUCOSAL | FENTANYL CITRATE LOZENGE ON A HANDLE 200 MCG    | 65100025108450 | Generic       |
| FENTANYL<br>CITRATE ORAL<br>TRANSMUCOSAL | FENTANYL CITRATE LOZENGE ON A HANDLE<br>400 MCG | 65100025108455 | Generic       |
| FENTANYL<br>CITRATE ORAL<br>TRANSMUCOSAL | FENTANYL CITRATE LOZENGE ON A HANDLE<br>600 MCG | 65100025108460 | Generic       |
| FENTANYL                                 | FENTANYL CITRATE LOZENGE ON A HANDLE            | 65100025108465 | Generic       |

| CITRATE ORAL<br>TRANSMUCOSAL             | 800 MCG  |                |         |
|--|--|----------------|---------|
| FENTANYL<br>CITRATE ORAL<br>TRANSMUCOSAL | FENTANYL CITRATE LOZENGE ON A HANDLE<br>1200 MCG | 65100025108475 | Generic |
| FENTANYL<br>CITRATE ORAL<br>TRANSMUCOSAL | FENTANYL CITRATE LOZENGE ON A HANDLE<br>1600 MCG | 65100025108485 | Generic |

| 1 - All of the following |
|--------------------------|
|--------------------------|

1.1 Prescribed by, or in consultation with, an Oncologist or specialty in Pain Management

#### **AND**

1.2 Medication is limited to the treatment of breakthrough cancer pain

#### **AND**

- **1.3** Person is already tolerant to opioids, defined as:
- **1.3.1** oral morphine 60mg daily for one week

OR

1.3.2 transdermal fentanyl 25mcg/hr for one week

OR

1.3.3 oxycodone 30mg daily for one week

OR

1.3.4 oral hydromorphone 8mg daily for one week

OR

**1.3.5** equianalgesic dose of another opioid for at least one week

#### AND

- **1.4** Person has failed an adequate trial of one of the following:
- 1.4.1 immediate release oxycodone

OR

1.4.2 immediate release oral hydromorphone

OR

1.4.3 immediate release morphine

OR

**2** - (Minnesota plans only) – person has stage four metastatic cancer and the requested drug is being used to treat cancer-related pain

| Product Name: Fentanyl |                                       |
|------------------------|---------------------------------------|
| Approval Length        | 12 month(s)                           |
| Therapy Stage          | Reauthorization                       |
| Guideline Type         | Prior Authorization - IL and MN Plans |

| Product Name                             | Generic Name                                    | GPI            | Brand/Generic |
|--|---|----------------|---------------|
| FENTANYL<br>CITRATE ORAL<br>TRANSMUCOSAL | FENTANYL CITRATE LOZENGE ON A HANDLE 200 MCG    | 65100025108450 | Generic       |
| FENTANYL<br>CITRATE ORAL<br>TRANSMUCOSAL | FENTANYL CITRATE LOZENGE ON A HANDLE<br>400 MCG | 65100025108455 | Generic       |

| FENTANYL<br>CITRATE ORAL<br>TRANSMUCOSAL | FENTANYL CITRATE LOZENGE ON A HANDLE<br>600 MCG  | 65100025108460 | Generic |
|--|--|----------------|---------|
| FENTANYL<br>CITRATE ORAL<br>TRANSMUCOSAL | FENTANYL CITRATE LOZENGE ON A HANDLE<br>800 MCG  | 65100025108465 | Generic |
| FENTANYL<br>CITRATE ORAL<br>TRANSMUCOSAL | FENTANYL CITRATE LOZENGE ON A HANDLE<br>1200 MCG | 65100025108475 | Generic |
| FENTANYL<br>CITRATE ORAL<br>TRANSMUCOSAL | FENTANYL CITRATE LOZENGE ON A HANDLE<br>1600 MCG | 65100025108485 | Generic |

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug.

| Product Name: Fentanyl |  |
|------------------------|--|
| Approval Length        | 12/31/2039                                       |
| Guideline Type         | Prior Authorization - All plans except IL and MN |

| Product Name                             | Generic Name                                     | GPI            | Brand/Generic |
|--|--|----------------|---------------|
| FENTANYL<br>CITRATE ORAL<br>TRANSMUCOSAL | FENTANYL CITRATE LOZENGE ON A HANDLE 200 MCG     | 65100025108450 | Generic       |
| FENTANYL<br>CITRATE ORAL<br>TRANSMUCOSAL | FENTANYL CITRATE LOZENGE ON A HANDLE<br>400 MCG  | 65100025108455 | Generic       |
| FENTANYL<br>CITRATE ORAL<br>TRANSMUCOSAL | FENTANYL CITRATE LOZENGE ON A HANDLE<br>600 MCG  | 65100025108460 | Generic       |
| FENTANYL<br>CITRATE ORAL<br>TRANSMUCOSAL | FENTANYL CITRATE LOZENGE ON A HANDLE<br>800 MCG  | 65100025108465 | Generic       |
| FENTANYL<br>CITRATE ORAL<br>TRANSMUCOSAL | FENTANYL CITRATE LOZENGE ON A HANDLE<br>1200 MCG | 65100025108475 | Generic       |
| FENTANYL<br>CITRATE ORAL<br>TRANSMUCOSAL | FENTANYL CITRATE LOZENGE ON A HANDLE<br>1600 MCG | 65100025108485 | Generic       |

#### **Approval Criteria**

| 1 - Prescribed by, or in consultation with, an Oncologist or specialty in Pain Management |
|---|
| AND   |
| 2 - Medication is limited to the treatment of breakthrough cancer pain                    |
| AND   |
| 3 - Person is already tolerant to opioids, defined as:                                    |
| 3.1 oral morphine 60mg daily for one week   |
| OR  |
| 3.2 transdermal fentanyl 25mcg/hr for one week  |
| OR  |
| 3.3 oxycodone 30mg daily for one week   |
| OR  |
| 3.4 oral hydromorphone 8mg daily for one week   |
| OR  |
| 3.5 equianalgesic dose of another opioid for at least one week                            |
| AND   |
| 4 - Person has failed an adequate trial of one of the following:                          |
| 4.1 immediate release oxycodone   |

OR
4.2 immediate release oral hydromorphone
OR
4.3 immediate release morphine

# 2. Revision History

| Date      | Notes       |
|-----------|-------------|
| 11/6/2023 | New Program |

| , | Actonel (risedronate)  |  |
|---|--|--|
| 1 | The second seco |  |
|   |  |  |

# **Prior Authorization Guideline**

| Guideline ID          | GL-129870             |
|-----------------------|-----------------------|
| <b>Guideline Name</b> | Actonel (risedronate) |
| Formulary             | Quartz                |

# **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

# 1. Criteria

| Product Name: risedronate 5 mg |                                       |  |
|--------------------------------|---------------------------------------|--|
| Approval Length                | 12 month(s)                           |  |
| Therapy Stage                  | Initial Authorization                 |  |
| Guideline Type                 | Prior Authorization - IL and MN Plans |  |

| Product<br>Name       | Generic Name                | GPI            | Brand/Generic |
|-----------------------|-----------------------------|----------------|---------------|
| RISEDRONATE<br>SODIUM | RISEDRONATE SODIUM TAB 5 MG | 30042065100305 | Generic       |

# **Approval Criteria**

1 - One of the following:

- **1.1** Both of the following:
  - Diagnosis of osteoporosis due to corticosteroid use
  - Trial and failure, contraindication, or intolerance to alendronate

#### OR

- **1.2** For diagnoses other than osteoporosis due to corticosteroid use, trial and failure, contraindication, or intolerance to ALL of the following:
  - alendronate
  - ibandronate
  - other strengths of risedronate (i.e., 35 mg, 150 mg)

| Product Name: risedronate 5 mg |                                       |  |
|--------------------------------|---------------------------------------|--|
| Approval Length 12 month(s)    |                                       |  |
| Therapy Stage Reauthorization  |                                       |  |
| Guideline Type                 | Prior Authorization - IL and MN Plans |  |
|                                |                                       |  |

| Product<br>Name       | Generic Name                | GPI            | Brand/Generic |
|-----------------------|-----------------------------|----------------|---------------|
| RISEDRONATE<br>SODIUM | RISEDRONATE SODIUM TAB 5 MG | 30042065100305 | Generic       |

## **Approval Criteria**

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug

| Product Name: risedronate 5 mg |  |  |
|--------------------------------|--|--|
| Approval Length 12/31/2039     |  |  |
| Guideline Type                 | Prior Authorization - All Plans Except IL and MN Plans |  |

| RISEDRONATE RISEDRONATE SODIUM TAB 5 MG 30042065100305 General SODIUM | ric |
|---|-----|

- **1** One of the following:
  - **1.1** Both of the following:
    - Diagnosis of osteoporosis due to corticosteroid use
    - Trial and failure, contraindication, or intolerance to alendronate

OR

- **1.2** For diagnoses other than osteoporosis due to corticosteroid use, trial and failure, contraindication, or intolerance to ALL of the following:
  - alendronate
  - ibandronate
  - other strengths of risedronate (i.e., 35 mg, 150 mg)

# 2. Revision History

| Date       | Notes                   |
|------------|-------------------------|
| 10/12/2023 | 2024 New Implementation |

| Acute Migraine Tr  | eatments |
|--|----------|
| The State of Language common to definite at Time State on the Common of contents of the Common of th | and a    |
|  |          |

# **Prior Authorization Guideline**

| Guideline ID          | GL-127880                 |  |
|-----------------------|---------------------------|--|
| <b>Guideline Name</b> | Acute Migraine Treatments |  |
| Formulary             | Quartz                    |  |

# **Guideline Note:**

| Effective Date: |
|-----------------|
|-----------------|

# 1. Criteria

| Product Name: Generic Frovatriptan, Brand Reyvow |                       |  |
|--|-----------------------|--|
| Approval Length 12 month(s)                      |                       |  |
| Therapy Stage                                    | Initial Authorization |  |
| Guideline Type Step Therapy - IL and MN Plans    |                       |  |

| Product<br>Name           | Generic Name  | GPI            | Brand/Generic |
|---------------------------|---|----------------|---------------|
| FROVATRIPTAN<br>SUCCINATE | FROVATRIPTAN SUCCINATE TAB 2.5 MG (BASE EQUIVALENT) | 67406030100320 | Generic       |
| REYVOW                    | LASMIDITAN SUCCINATE TAB 50 MG                      | 67406540600310 | Brand         |
| REYVOW                    | LASMIDITAN SUCCINATE TAB 100 MG                     | 67406540600320 | Brand         |

- 1 Trial and failure of at least 2 of the following:
  - sumatriptan
  - naratriptan
  - rizatriptan
  - eletriptan
  - zolmitriptan
  - almotriptan
  - frovatriptan (not required for request for frovatriptan)

### OR

**2** - If the member has contraindication to triptan, than trial and failure of 2 non-triptan, prescription strength analgesics that are listed as effective for treatment of migraines by the American Headache Society treatment guidelines is required (ex. nonsteroidal anti-inflammatory drugs (NSAIDs), ergotamine derivatives, etc.)

| Product Name: Generic Frovatriptan, Brand Reyvow |  |  |
|--|--|--|
| Approval Length                                  | 12 month(s)                                  |  |
| Therapy Stage                                    | Reauthorization                              |  |
| Guideline Type                                   | uideline Type Step Therapy - IL and MN Plans |  |

| Product<br>Name           | Generic Name  | GPI            | Brand/Generic |
|---------------------------|---|----------------|---------------|
| FROVATRIPTAN<br>SUCCINATE | FROVATRIPTAN SUCCINATE TAB 2.5 MG (BASE EQUIVALENT) | 67406030100320 | Generic       |
| REYVOW                    | LASMIDITAN SUCCINATE TAB 50 MG                      | 67406540600310 | Brand         |
| REYVOW                    | LASMIDITAN SUCCINATE TAB 100 MG                     | 67406540600320 | Brand         |

## **Approval Criteria**

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug

| Product Name: Generic Frovatriptan, Brand Reyvow  Approval Length 12/31/2039 |  |
|--|--|
|  |  |

| Product<br>Name           | Generic Name  | GPI            | Brand/Generic |
|---------------------------|---|----------------|---------------|
| FROVATRIPTAN<br>SUCCINATE | FROVATRIPTAN SUCCINATE TAB 2.5 MG (BASE EQUIVALENT) | 67406030100320 | Generic       |
| REYVOW                    | LASMIDITAN SUCCINATE TAB 50 MG                      | 67406540600310 | Brand         |
| REYVOW                    | LASMIDITAN SUCCINATE TAB 100 MG                     | 67406540600320 | Brand         |

- 1 Trial and failure of at least 2 of the following:
  - sumatriptan
  - naratriptan
  - rizatriptan
  - eletriptan
  - zolmitriptan
  - almotriptan
  - frovatriptan (not required for request for frovatriptan)

#### OR

**2** - If the member has contraindication to triptan, than trial and failure of 2 non-triptan, prescription strength analgesics that are listed as effective for treatment of migraines by the American Headache Society treatment guidelines is required (ex. nonsteroidal anti-inflammatory drugs (NSAIDs), ergotamine derivatives, etc.)

| Product Name: Generic Frovatriptan, Brand Reyvow            |  |  |
|---|--|--|
| Approval Length 12/31/2039                                  |  |  |
| Guideline Type Quantity Limits - All Plans except IL and MN |  |  |

| Product<br>Name           | Generic Name  | GPI            | Brand/Generic |
|---------------------------|---|----------------|---------------|
| FROVATRIPTAN<br>SUCCINATE | FROVATRIPTAN SUCCINATE TAB 2.5 MG (BASE EQUIVALENT) | 67406030100320 | Generic       |
| REYVOW                    | LASMIDITAN SUCCINATE TAB 50 MG                      | 67406540600310 | Brand         |
| REYVOW                    | LASMIDITAN SUCCINATE TAB 100 MG                     | 67406540600320 | Brand         |

1 - Member has greater than or equal to 2 migraine headaches per week

### **AND**

2 - Member is on migraine headache prophylaxis treatment

| Product Name: Generic Frovatriptan, Brand Reyvow |                                   |
|--|-----------------------------------|
| Approval Length                                  | 12 month(s)                       |
| Guideline Type                                   | Quantity Limits - IL and MN Plans |

| Product<br>Name           | Generic Name  | GPI            | Brand/Generic |
|---------------------------|---|----------------|---------------|
| FROVATRIPTAN<br>SUCCINATE | FROVATRIPTAN SUCCINATE TAB 2.5 MG (BASE EQUIVALENT) | 67406030100320 | Generic       |
| REYVOW                    | LASMIDITAN SUCCINATE TAB 50 MG                      | 67406540600310 | Brand         |
| REYVOW                    | LASMIDITAN SUCCINATE TAB 100 MG                     | 67406540600320 | Brand         |

## **Approval Criteria**

1 - Member has greater than or equal to 2 migraine headaches per week

### **AND**

2 - Member is on migraine headache prophylaxis treatment

# 2. Revision History

| Date      | Notes       |
|-----------|-------------|
| 8/25/2023 | New Program |

| Aczone (dapsone)   |  |  |  |  |
|--|--|--|--|--|
| [2] The blad in long control to displayed. The firm op has been record, or added, sholly that the big place is the amount of added, sholly that the big place is the amount of added, and in a second or added in the amount of added |  |  |  |  |
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|  |  |  |  |  |

# **Prior Authorization Guideline**

| Guideline ID          | GL-128132        |
|-----------------------|------------------|
| <b>Guideline Name</b> | Aczone (dapsone) |
| Formulary             | Quartz           |

# **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

# 1. Criteria

| Product Name: Generic Dapsone 5% |                                |
|----------------------------------|--------------------------------|
| Approval Length                  | 12 month(s)                    |
| Therapy Stage                    | Initial Authorization          |
| Guideline Type                   | Step Therapy - IL and MN Plans |

| Product<br>Name | Generic Name   | GPI            | Brand/Generic |
|-----------------|----------------|----------------|---------------|
| DAPSONE         | DAPSONE GEL 5% | 90051015004020 | Generic       |

- 1 Trial and failure of two different prior treatments for acne
  - tretinoin 0.01% gel, 0.025% cream/gel, 0.05% cream/gel, 0.1% cream

- adapalene (0.1% gel/cream, 0.3% gel)
- azelaic acid
- tazarotene
- oral minocycline
- oral doxycycline
- clindamycin 1% gel
- clindamycin 1.2%/benzoyl peroxide 5% gel
- erythromycin 2% topical

| Product Name: Generic Dapsone 7.5% |                                |
|------------------------------------|--------------------------------|
| Approval Length                    | 12 month(s)                    |
| Therapy Stage                      | Initial Authorization          |
| Guideline Type                     | Step Therapy - IL and MN Plans |

| Product<br>Name | Generic Name     | GPI            | Brand/Generic |
|-----------------|------------------|----------------|---------------|
| DAPSONE         | DAPSONE GEL 7.5% | 90051015004030 | Generic       |

- 1 Trial and failure of two different prior treatments for acne
  - tretinoin 0.01% gel, 0.025% cream/gel, 0.05% cream/gel, 0.1% cream
  - adapalene (0.1% gel/cream, 0.3% gel)
  - azelaic acid
  - tazarotene
  - oral minocycline
  - oral doxycycline
  - clindamycin 1% gel
  - clindamycin 1.2%/benzoyl peroxide 5% gel
  - erythromycin 2% topical

## AND

2 - Trial and failure of generic dapsone 5%

| Product Name: Generic Dapsone 5%, Generic Dapsone 7.5% |                 |
|--|-----------------|
| Approval Length  | 12 month(s)     |
| Therapy Stage  | Reauthorization |

| Guideline T     | уре              | Step Therapy - IL and MN Plans |                |               |
|-----------------|------------------|--------------------------------|----------------|---------------|
| Product<br>Name | Generic Name     |                                | GPI            | Brand/Generic |
| DAPSONE         | DAPSONE GEL 5%   |                                | 90051015004020 | Generic       |
| DAPSONE         | DAPSONE GEL 7.5% |                                | 90051015004030 | Generic       |

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug

| Product Name: Generic Dapsone 5% |  |                                       |               |  |
|----------------------------------|--|---------------------------------------|---------------|--|
| Approval Length 12/31/2039       |  |                                       |               |  |
| Guideline Type                   |  | Step Therapy - All plans except IL an | d MN Plans    |  |
| Product Generic Name             |  | GPI                                   | Brand/Generic |  |

| Product<br>Name | Generic Name   | GPI            | Brand/Generic |
|-----------------|----------------|----------------|---------------|
| DAPSONE         | DAPSONE GEL 5% | 90051015004020 | Generic       |

- **1** Trial and failure of two different prior treatments for acne
  - tretinoin 0.01% gel, 0.025% cream/gel, 0.05% cream/gel, 0.1% cream
  - adapalene (0.1% gel/cream, 0.3% gel)
  - azelaic acid
  - tazarotene
  - oral minocycline
  - oral doxycycline
  - clindamycin 1% gel
  - clindamycin 1.2%/benzoyl peroxide 5% gel
  - erythromycin 2% topical

| Product Name: Generic Dapsone 7.5% |   |
|------------------------------------|---|
| Approval Length                    | 12/31/2039                                      |
| Guideline Type                     | Step Therapy - All plans except IL and MN Plans |

| Product<br>Name | Generic Name     | GPI            | Brand/Generic |
|-----------------|------------------|----------------|---------------|
| DAPSONE         | DAPSONE GEL 7.5% | 90051015004030 | Generic       |

- 1 Trial and failure of two different prior treatments for acne
  - tretinoin 0.01% gel, 0.025% cream/gel, 0.05% cream/gel, 0.1% cream
  - adapalene (0.1% gel/cream, 0.3% gel)
  - azelaic acid
  - tazarotene
  - oral minocycline
  - oral doxycycline
  - clindamycin 1% gel
  - clindamycin 1.2%/benzoyl peroxide 5% gel
  - erythromycin 2% topical

#### **AND**

2 - Trial and failure of generic dapsone 5%

# 2. Revision History

| Date      | Notes       |
|-----------|-------------|
| 8/25/2023 | New Program |

| Adalimumab biosimilars   |  |  |
|--|--|--|
| The third process of the training and control of the training and and training and training and and an articular and an articula |  |  |

# **Prior Authorization Guideline**

| Guideline ID          | GL-144721              |
|-----------------------|------------------------|
| <b>Guideline Name</b> | Adalimumab biosimilars |
| Formulary             | Quartz                 |

# **Guideline Note:**

| Effective Date: | 3/21/2024 |
|-----------------|-----------|
|-----------------|-----------|

## Note:

Member new to the plan (as evidenced by coverage effective date of less than or equal to 90 days) who initiated therapy using a manufacturer-sponsored free drug program, provider samples, and/or vouchers will go through initial criteria, otherwise for continuation of therapy for new to plan, reauthorization criteria applies.

## 1. Criteria

| Product Name: Humira, Hadlima, Adalimumab-fkjp, Hyrimoz, Adalimumab-adaz |      |                                       |       |               |
|--|------|---------------------------------------|-------|---------------|
| Diagnosis  |      | Plaque Psoriasis                      |       |               |
| Approval Length  |      | 12 month(s)                           |       |               |
| Therapy Stage  |      | Initial Authorization                 |       |               |
| Guideline Type   |      | Prior Authorization – IL and MN Plans |       |               |
| Product Name   | Gene | eric Name                             | GPI   | Brand/Generic |
| HUMIRA PEN-<br>PS/UV STARTER ADALIMUMAB PEN-INJECTOR KIT 40 MG/0.8ML     |      | 6627001500F420                        | Brand |               |

| HUMIRA PEN   | ADALIMUMAB PEN-INJECTOR KIT 40 MG/0.8ML                    | 6627001500F420 | Brand |
|--|--|----------------|-------|
| HUMIRA PEN-<br>CD/UC/HS<br>STARTER                       | ADALIMUMAB PEN-INJECTOR KIT 40 MG/0.8ML                    | 6627001500F420 | Brand |
| HUMIRA PEN   | ADALIMUMAB PEN-INJECTOR KIT 40 MG/0.4ML                    | 6627001500F430 | Brand |
| HUMIRA PEN-<br>PEDIATRIC UC<br>STARTER PACK              | ADALIMUMAB PEN-INJECTOR KIT 80 MG/0.8ML                    | 6627001500F440 | Brand |
| HUMIRA PEN   | ADALIMUMAB PEN-INJECTOR KIT 80 MG/0.8ML                    | 6627001500F440 | Brand |
| HUMIRA PEN-<br>CD/UC/HS<br>STARTER                       | ADALIMUMAB PEN-INJECTOR KIT 80 MG/0.8ML                    | 6627001500F440 | Brand |
| HUMIRA PEN-<br>PS/UV STARTER                             | ADALIMUMAB PEN-INJECTOR KIT 80 MG/0.8ML & 40 MG/0.4ML      | 6627001500F450 | Brand |
| HUMIRA   | ADALIMUMAB PREFILLED SYRINGE KIT 10 MG/0.1ML               | 6627001500F804 | Brand |
| HUMIRA   | ADALIMUMAB PREFILLED SYRINGE KIT 20 MG/0.2ML               | 6627001500F809 | Brand |
| HUMIRA   | ADALIMUMAB PREFILLED SYRINGE KIT 40 MG/0.8ML               | 6627001500F820 | Brand |
| HUMIRA   | ADALIMUMAB PREFILLED SYRINGE KIT 40 MG/0.4ML               | 6627001500F830 | Brand |
| HUMIRA<br>PEDIATRIC<br>CROHNS<br>DISEASE<br>STARTER PACK | ADALIMUMAB PREFILLED SYRINGE KIT 80 MG/0.8ML               | 6627001500F840 | Brand |
| HUMIRA PEDIATRIC CROHNS DISEASE STARTER PACK             | ADALIMUMAB PREFILLED SYRINGE KIT 80 MG/0.8ML & 40 MG/0.4ML | 6627001500F880 | Brand |
| HADLIMA<br>PUSHTOUCH                                     | ADALIMUMAB-BWWD SOLN AUTO-INJECTOR<br>40 MG/0.4ML          | 6627001520D510 | Brand |
| HADLIMA<br>PUSHTOUCH                                     | ADALIMUMAB-BWWD SOLN AUTO-INJECTOR<br>40 MG/0.8ML          | 6627001520D520 | Brand |
| HADLIMA  | ADALIMUMAB-BWWD SOLN PREFILLED<br>SYRINGE 40 MG/0.4ML      | 6627001520E510 | Brand |
| HADLIMA  | ADALIMUMAB-BWWD SOLN PREFILLED<br>SYRINGE 40 MG/0.8ML      | 6627001520E520 | Brand |
| ADALIMUMAB-<br>FKJP                                      | ADALIMUMAB-FKJP AUTO-INJECTOR KIT 40<br>MG/0.8ML           | 6627001535F520 | Brand |
| ADALIMUMAB-<br>FKJP                                      | ADALIMUMAB-FKJP PREFILLED SYRINGE KIT<br>20 MG/0.4ML       | 6627001535F810 | Brand |
| ADALIMUMAB-<br>FKJP                                      | ADALIMUMAB-FKJP PREFILLED SYRINGE KIT<br>40 MG/0.8ML       | 6627001535F820 | Brand |

| l  |   |                |       |
|--|---|----------------|-------|
| ADALIMUMAB-<br>ADAZ  | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40<br>MG/0.4ML               | 6627001504D515 | Brand |
| ADALIMUMAB-<br>ADAZ  | ADALIMUMAB-ADAZ SOLN PREFILLED<br>SYRINGE 40 MG/0.4ML           | 6627001504E515 | Brand |
| HYRIMOZ  | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40 MG/0.4ML                  | 6627001504D515 | Brand |
| HYRIMOZ  | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40 MG/0.8ML                  | 6627001504D520 | Brand |
| HYRIMOZ<br>CROHN'S<br>DISEASE AND<br>ULCERATIVE<br>COLITIS STARTER<br>PACK | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80<br>MG/0.8ML               | 6627001504D540 | Brand |
| HYRIMOZ  | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML                  | 6627001504D540 | Brand |
| HYRIMOZ<br>PLAQUE<br>PSORIASIS<br>STARTER PACK                             | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80<br>MG/0.8ML & 40 MG/0.4ML | 6627001504D560 | Brand |
| HYRIMOZ  | ADALIMUMAB-ADAZ SOLN PREFILLED<br>SYRINGE 10 MG/0.1ML           | 6627001504E508 | Brand |
| HYRIMOZ  | ADALIMUMAB-ADAZ SOLN PREFILLED<br>SYRINGE 20 MG/0.2ML           | 6627001504E513 | Brand |
| HYRIMOZ  | ADALIMUMAB-ADAZ SOLN PREFILLED<br>SYRINGE 40 MG/0.4ML           | 6627001504E515 | Brand |
| HYRIMOZ  | ADALIMUMAB-ADAZ SOLN PREFILLED<br>SYRINGE 40 MG/0.8ML           | 6627001504E520 | Brand |
| HYRIMOZ<br>PEDIATRIC<br>CROHNS<br>DISEASE<br>STARTER PACK                  | ADALIMUMAB-ADAZ SOLN PREFILLED<br>SYRINGE 80 MG/0.8ML           | 6627001504E540 | Brand |
| HYRIMOZ<br>PEDIATRIC<br>CROHN'SDISEASE<br>STARTER PACK                     | ADALIMUMAB-ADAZ SOLN PREFILLED SYR 80<br>MG/0.8ML & 40 MG/0.4ML | 6627001504E560 | Brand |

- **1** One of the following:
- **1.1** All of the following:
- **1.1.1** Diagnosis of moderate to severe plaque psoriasis

AND

## **1.1.2** One of the following:

- · Significant functional disability
- Body surface area (BSA) involvement of greater than or equal to 3%
- Debilitating palmer/plantar psoriasis or other vulnerable areas that are difficult to treat (e.g. nails, scalp, genitals, or intertriginous areas

#### **AND**

**1.1.3** Prescribed by or in consultation with a dermatologist

#### AND

**1.1.4** Trial and failure, contraindication, or intolerance to topical treatment (e.g., topical corticosteroids, calcipotriene, retinoids)

#### **AND**

**1.1.5** Not used in combination with other biologic DMARDs (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

#### OR

| Notes *Place authoriza | tion at a GPI 8 with an Ignore Drug Status of I |
|------------------------|---|
|------------------------|---|

| Product Name: Humira, Hadlima, Adalimumab-fkjp, Hyrimoz, Adalimumab-adaz |            |  |
|--|------------|--|
| Diagnosis Plaque Psoriasis   |            |  |
| Approval Length  | 12/31/2039 |  |
| Guideline Type Prior Authorization – All Plans Except IL and MN Plans    |            |  |

| Product Name                 | Generic Name                            | GPI            | Brand/Generic |
|------------------------------|---|----------------|---------------|
| HUMIRA PEN-<br>PS/UV STARTER | ADALIMUMAB PEN-INJECTOR KIT 40 MG/0.8ML | 6627001500F420 | Brand         |
| HUMIRA PEN                   | ADALIMUMAB PEN-INJECTOR KIT 40 MG/0.8ML | 6627001500F420 | Brand         |

| HUMIRA PEN-<br>CD/UC/HS<br>STARTER           | ADALIMUMAB PEN-INJECTOR KIT 40 MG/0.8ML                    | 6627001500F420 | Brand |
|--|--|----------------|-------|
| HUMIRA PEN                                   | ADALIMUMAB PEN-INJECTOR KIT 40 MG/0.4ML                    | 6627001500F430 | Brand |
| HUMIRA PEN-<br>PEDIATRIC UC<br>STARTER PACK  | ADALIMUMAB PEN-INJECTOR KIT 80 MG/0.8ML                    | 6627001500F440 | Brand |
| HUMIRA PEN                                   | ADALIMUMAB PEN-INJECTOR KIT 80 MG/0.8ML                    | 6627001500F440 | Brand |
| HUMIRA PEN-<br>CD/UC/HS<br>STARTER           | ADALIMUMAB PEN-INJECTOR KIT 80 MG/0.8ML                    | 6627001500F440 | Brand |
| HUMIRA PEN-<br>PS/UV STARTER                 | ADALIMUMAB PEN-INJECTOR KIT 80 MG/0.8ML & 40 MG/0.4ML      | 6627001500F450 | Brand |
| HUMIRA                                       | ADALIMUMAB PREFILLED SYRINGE KIT 10 MG/0.1ML               | 6627001500F804 | Brand |
| HUMIRA                                       | ADALIMUMAB PREFILLED SYRINGE KIT 20<br>MG/0.2ML            | 6627001500F809 | Brand |
| HUMIRA                                       | ADALIMUMAB PREFILLED SYRINGE KIT 40<br>MG/0.8ML            | 6627001500F820 | Brand |
| HUMIRA                                       | ADALIMUMAB PREFILLED SYRINGE KIT 40<br>MG/0.4ML            | 6627001500F830 | Brand |
| HUMIRA PEDIATRIC CROHNS DISEASE STARTER PACK | ADALIMUMAB PREFILLED SYRINGE KIT 80<br>MG/0.8ML            | 6627001500F840 | Brand |
| HUMIRA PEDIATRIC CROHNS DISEASE STARTER PACK | ADALIMUMAB PREFILLED SYRINGE KIT 80 MG/0.8ML & 40 MG/0.4ML | 6627001500F880 | Brand |
| HADLIMA<br>PUSHTOUCH                         | ADALIMUMAB-BWWD SOLN AUTO-INJECTOR<br>40 MG/0.4ML          | 6627001520D510 | Brand |
| HADLIMA<br>PUSHTOUCH                         | ADALIMUMAB-BWWD SOLN AUTO-INJECTOR<br>40 MG/0.8ML          | 6627001520D520 | Brand |
| HADLIMA                                      | ADALIMUMAB-BWWD SOLN PREFILLED<br>SYRINGE 40 MG/0.4ML      | 6627001520E510 | Brand |
| HADLIMA                                      | ADALIMUMAB-BWWD SOLN PREFILLED<br>SYRINGE 40 MG/0.8ML      | 6627001520E520 | Brand |
| ADALIMUMAB-<br>FKJP                          | ADALIMUMAB-FKJP AUTO-INJECTOR KIT 40<br>MG/0.8ML           | 6627001535F520 | Brand |
| ADALIMUMAB-<br>FKJP                          | ADALIMUMAB-FKJP PREFILLED SYRINGE KIT<br>20 MG/0.4ML       | 6627001535F810 | Brand |
| ADALIMUMAB-<br>FKJP                          | ADALIMUMAB-FKJP PREFILLED SYRINGE KIT<br>40 MG/0.8ML       | 6627001535F820 | Brand |
| ADALIMUMAB-<br>ADAZ                          | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40 MG/0.4ML             | 6627001504D515 | Brand |

| ADALIMUMAB-<br>ADAZ  | ADALIMUMAB-ADAZ SOLN PREFILLED<br>SYRINGE 40 MG/0.4ML           | 6627001504E515 | Brand |
|--|---|----------------|-------|
| HYRIMOZ  | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40<br>MG/0.4ML               | 6627001504D515 | Brand |
| HYRIMOZ  | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40 MG/0.8ML                  | 6627001504D520 | Brand |
| HYRIMOZ<br>CROHN'S<br>DISEASE AND<br>ULCERATIVE<br>COLITIS STARTER<br>PACK | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80<br>MG/0.8ML               | 6627001504D540 | Brand |
| HYRIMOZ  | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80<br>MG/0.8ML               | 6627001504D540 | Brand |
| HYRIMOZ<br>PLAQUE<br>PSORIASIS<br>STARTER PACK                             | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80<br>MG/0.8ML & 40 MG/0.4ML | 6627001504D560 | Brand |
| HYRIMOZ  | ADALIMUMAB-ADAZ SOLN PREFILLED<br>SYRINGE 10 MG/0.1ML           | 6627001504E508 | Brand |
| HYRIMOZ  | ADALIMUMAB-ADAZ SOLN PREFILLED<br>SYRINGE 20 MG/0.2ML           | 6627001504E513 | Brand |
| HYRIMOZ  | ADALIMUMAB-ADAZ SOLN PREFILLED<br>SYRINGE 40 MG/0.4ML           | 6627001504E515 | Brand |
| HYRIMOZ  | ADALIMUMAB-ADAZ SOLN PREFILLED<br>SYRINGE 40 MG/0.8ML           | 6627001504E520 | Brand |
| HYRIMOZ<br>PEDIATRIC<br>CROHNS<br>DISEASE<br>STARTER PACK                  | ADALIMUMAB-ADAZ SOLN PREFILLED<br>SYRINGE 80 MG/0.8ML           | 6627001504E540 | Brand |
| HYRIMOZ<br>PEDIATRIC<br>CROHN'SDISEASE<br>STARTER PACK                     | ADALIMUMAB-ADAZ SOLN PREFILLED SYR 80<br>MG/0.8ML & 40 MG/0.4ML | 6627001504E560 | Brand |

- **1** One of the following:
- **1.1** All of the following:
- **1.1.1** Diagnosis of moderate to severe plaque psoriasis

## AND

### **1.1.2** One of the following:

- Significant functional disability
- Body surface area (BSA) involvement of greater than or equal to 3%
- Debilitating palmer/plantar psoriasis or other vulnerable areas that are difficult to treat (e.g. nails, scalp, genitals, or intertriginous areas

#### **AND**

1.1.3 Prescribed by or in consultation with a dermatologist

#### **AND**

**1.1.4** Trial and failure, contraindication, or intolerance to topical treatment (e.g., topical corticosteroids, calcipotriene, retinoids)

#### **AND**

**1.1.5** Not used in combination with other biologic DMARDs (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

### OR

| Product Name: Humira, Hadlima, Adalimumab-fkjp, Hyrimoz, Adalimumab-adaz |                                       |  |  |
|--|---------------------------------------|--|--|
| Diagnosis  | Hidradenitis Suppurativa (HS)         |  |  |
| Approval Length  | 12 month(s)                           |  |  |
| Therapy Stage  | Initial Authorization                 |  |  |
| Guideline Type   | Prior Authorization – IL and MN Plans |  |  |

| Product Name                 | Generic Name                            | GPI            | Brand/Generic |
|------------------------------|---|----------------|---------------|
| HUMIRA PEN-<br>PS/UV STARTER | ADALIMUMAB PEN-INJECTOR KIT 40 MG/0.8ML | 6627001500F420 | Brand         |

| HUMIRA PEN   | ADALIMUMAB PEN-INJECTOR KIT 40 MG/0.8ML                    | 6627001500F420 | Brand |
|--|--|----------------|-------|
| HUMIRA PEN-<br>CD/UC/HS<br>STARTER                       | ADALIMUMAB PEN-INJECTOR KIT 40 MG/0.8ML                    | 6627001500F420 | Brand |
| HUMIRA PEN   | ADALIMUMAB PEN-INJECTOR KIT 40 MG/0.4ML                    | 6627001500F430 | Brand |
| HUMIRA PEN-<br>PEDIATRIC UC<br>STARTER PACK              | ADALIMUMAB PEN-INJECTOR KIT 80 MG/0.8ML                    | 6627001500F440 | Brand |
| HUMIRA PEN   | ADALIMUMAB PEN-INJECTOR KIT 80 MG/0.8ML                    | 6627001500F440 | Brand |
| HUMIRA PEN-<br>CD/UC/HS<br>STARTER                       | ADALIMUMAB PEN-INJECTOR KIT 80 MG/0.8ML                    | 6627001500F440 | Brand |
| HUMIRA PEN-<br>PS/UV STARTER                             | ADALIMUMAB PEN-INJECTOR KIT 80 MG/0.8ML & 40 MG/0.4ML      | 6627001500F450 | Brand |
| HUMIRA   | ADALIMUMAB PREFILLED SYRINGE KIT 10 MG/0.1ML               | 6627001500F804 | Brand |
| HUMIRA   | ADALIMUMAB PREFILLED SYRINGE KIT 20 MG/0.2ML               | 6627001500F809 | Brand |
| HUMIRA   | ADALIMUMAB PREFILLED SYRINGE KIT 40 MG/0.8ML               | 6627001500F820 | Brand |
| HUMIRA   | ADALIMUMAB PREFILLED SYRINGE KIT 40 MG/0.4ML               | 6627001500F830 | Brand |
| HUMIRA<br>PEDIATRIC<br>CROHNS<br>DISEASE<br>STARTER PACK | ADALIMUMAB PREFILLED SYRINGE KIT 80 MG/0.8ML               | 6627001500F840 | Brand |
| HUMIRA PEDIATRIC CROHNS DISEASE STARTER PACK             | ADALIMUMAB PREFILLED SYRINGE KIT 80 MG/0.8ML & 40 MG/0.4ML | 6627001500F880 | Brand |
| HADLIMA<br>PUSHTOUCH                                     | ADALIMUMAB-BWWD SOLN AUTO-INJECTOR<br>40 MG/0.4ML          | 6627001520D510 | Brand |
| HADLIMA<br>PUSHTOUCH                                     | ADALIMUMAB-BWWD SOLN AUTO-INJECTOR<br>40 MG/0.8ML          | 6627001520D520 | Brand |
| HADLIMA  | ADALIMUMAB-BWWD SOLN PREFILLED<br>SYRINGE 40 MG/0.4ML      | 6627001520E510 | Brand |
| HADLIMA  | ADALIMUMAB-BWWD SOLN PREFILLED<br>SYRINGE 40 MG/0.8ML      | 6627001520E520 | Brand |
| ADALIMUMAB-<br>FKJP                                      | ADALIMUMAB-FKJP AUTO-INJECTOR KIT 40 MG/0.8ML              | 6627001535F520 | Brand |
| ADALIMUMAB-<br>FKJP                                      | ADALIMUMAB-FKJP PREFILLED SYRINGE KIT 20 MG/0.4ML          | 6627001535F810 | Brand |
| ADALIMUMAB-<br>FKJP                                      | ADALIMUMAB-FKJP PREFILLED SYRINGE KIT<br>40 MG/0.8ML       | 6627001535F820 | Brand |

| ADALIMUMAB-<br>ADAZ  | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40<br>MG/0.4ML               | 6627001504D515 | Brand |
|--|---|----------------|-------|
| ADALIMUMAB-<br>ADAZ  | ADALIMUMAB-ADAZ SOLN PREFILLED<br>SYRINGE 40 MG/0.4ML           | 6627001504E515 | Brand |
| HYRIMOZ  | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40 MG/0.4ML                  | 6627001504D515 | Brand |
| HYRIMOZ  | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40 MG/0.8ML                  | 6627001504D520 | Brand |
| HYRIMOZ<br>CROHN'S<br>DISEASE AND<br>ULCERATIVE<br>COLITIS STARTER<br>PACK | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80<br>MG/0.8ML               | 6627001504D540 | Brand |
| HYRIMOZ  | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML                  | 6627001504D540 | Brand |
| HYRIMOZ<br>PLAQUE<br>PSORIASIS<br>STARTER PACK                             | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80<br>MG/0.8ML & 40 MG/0.4ML | 6627001504D560 | Brand |
| HYRIMOZ  | ADALIMUMAB-ADAZ SOLN PREFILLED<br>SYRINGE 10 MG/0.1ML           | 6627001504E508 | Brand |
| HYRIMOZ  | ADALIMUMAB-ADAZ SOLN PREFILLED<br>SYRINGE 20 MG/0.2ML           | 6627001504E513 | Brand |
| HYRIMOZ  | ADALIMUMAB-ADAZ SOLN PREFILLED<br>SYRINGE 40 MG/0.4ML           | 6627001504E515 | Brand |
| HYRIMOZ  | ADALIMUMAB-ADAZ SOLN PREFILLED<br>SYRINGE 40 MG/0.8ML           | 6627001504E520 | Brand |
| HYRIMOZ<br>PEDIATRIC<br>CROHNS<br>DISEASE<br>STARTER PACK                  | ADALIMUMAB-ADAZ SOLN PREFILLED<br>SYRINGE 80 MG/0.8ML           | 6627001504E540 | Brand |
| HYRIMOZ<br>PEDIATRIC<br>CROHN'SDISEASE<br>STARTER PACK                     | ADALIMUMAB-ADAZ SOLN PREFILLED SYR 80<br>MG/0.8ML & 40 MG/0.4ML | 6627001504E560 | Brand |

- **1** One of the following:
- **1.1** All of the following:
- **1.1.1** Diagnosis of moderate to severe and/or refractory hidradenitis suppurativa (HS) (Hurley II; Hurley III stage)

#### **AND**

**1.1.2** Lesions are present despite treatment with topical antibiotics, systemic antibiotics, intralesional glucocorticoids, and/or surgical debridement

#### **AND**

1.1.3 Prescribed by or in consultation with a dermatologist

### **AND**

**1.1.4** Not used in combination with other biologic DMARDs (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

#### OR

| Product Name: Humira, Hadlima, Adalimumab-fkjp, Hyrimoz, Adalimumab-adaz |  |
|--|--|
| Diagnosis  | Hidradenitis Suppurativa (HS)                          |
| Approval Length  | 12/31/2039   |
| Guideline Type   | Prior Authorization – All Plans except IL and MN Plans |

| Product<br>Name                    | Generic Name                            | GPI            | Brand/Generic |
|------------------------------------|---|----------------|---------------|
| HUMIRA PEN                         | ADALIMUMAB PEN-INJECTOR KIT 40 MG/0.8ML | 6627001500F420 | Brand         |
| HUMIRA PEN-<br>CD/UC/HS<br>STARTER | ADALIMUMAB PEN-INJECTOR KIT 40 MG/0.8ML | 6627001500F420 | Brand         |
| HUMIRA PEN                         | ADALIMUMAB PEN-INJECTOR KIT 40 MG/0.4ML | 6627001500F430 | Brand         |
| HUMIRA PEN                         | ADALIMUMAB PEN-INJECTOR KIT 80 MG/0.8ML | 6627001500F440 | Brand         |
| HUMIRA PEN-<br>CD/UC/HS<br>STARTER | ADALIMUMAB PEN-INJECTOR KIT 80 MG/0.8ML | 6627001500F440 | Brand         |

| HUMIRA               | ADALIMUMAB PREFILLED SYRINGE KIT 10<br>MG/0.1ML       | 6627001500F804 | Brand |
|----------------------|---|----------------|-------|
| HUMIRA               | ADALIMUMAB PREFILLED SYRINGE KIT 20<br>MG/0.2ML       | 6627001500F809 | Brand |
| HUMIRA               | ADALIMUMAB PREFILLED SYRINGE KIT 40<br>MG/0.8ML       | 6627001500F820 | Brand |
| HUMIRA               | ADALIMUMAB PREFILLED SYRINGE KIT 40<br>MG/0.4ML       | 6627001500F830 | Brand |
| HADLIMA<br>PUSHTOUCH | ADALIMUMAB-BWWD SOLN AUTO-INJECTOR 40 MG/0.4ML        | 6627001520D510 | Brand |
| HADLIMA<br>PUSHTOUCH | ADALIMUMAB-BWWD SOLN AUTO-INJECTOR 40 MG/0.8ML        | 6627001520D520 | Brand |
| HADLIMA              | ADALIMUMAB-BWWD SOLN PREFILLED SYRINGE<br>40 MG/0.4ML | 6627001520E510 | Brand |
| HADLIMA              | ADALIMUMAB-BWWD SOLN PREFILLED SYRINGE<br>40 MG/0.8ML | 6627001520E520 | Brand |
| ADALIMUMAB-<br>FKJP  | ADALIMUMAB-FKJP AUTO-INJECTOR KIT 40<br>MG/0.8ML      | 6627001535F520 | Brand |
| ADALIMUMAB-<br>FKJP  | ADALIMUMAB-FKJP PREFILLED SYRINGE KIT 20<br>MG/0.4ML  | 6627001535F810 | Brand |
| ADALIMUMAB-<br>FKJP  | ADALIMUMAB-FKJP PREFILLED SYRINGE KIT 40<br>MG/0.8ML  | 6627001535F820 | Brand |
| ADALIMUMAB-<br>ADAZ  | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40<br>MG/0.4ML     | 6627001504D515 | Brand |
| ADALIMUMAB-<br>ADAZ  | ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 40 MG/0.4ML    | 6627001504E515 | Brand |
| HYRIMOZ              | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40<br>MG/0.4ML     | 6627001504D515 | Brand |
| HYRIMOZ              | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40<br>MG/0.8ML     | 6627001504D520 | Brand |
| HYRIMOZ              | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80<br>MG/0.8ML     | 6627001504D540 | Brand |
| HYRIMOZ              | ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 10 MG/0.1ML    | 6627001504E508 | Brand |
| HYRIMOZ              | ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 20 MG/0.2ML    | 6627001504E513 | Brand |
| HYRIMOZ              | ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 40 MG/0.4ML    | 6627001504E515 | Brand |
| HYRIMOZ              | ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 40 MG/0.8ML    | 6627001504E520 | Brand |

1 - One of the following:

- 1.1 All of the following:
- **1.1.1** Diagnosis of moderate to severe and/or refractory hidradenitis suppurativa (HS) (Hurley II; Hurley III stage)

#### **AND**

**1.1.2** Lesions are present despite treatment with topical antibiotics, systemic antibiotics, intralesional glucocorticoids, and/or surgical debridement

#### **AND**

1.1.3 Prescribed by or in consultation with a dermatologist

#### **AND**

**1.1.4** Not used in combination with other biologic DMARDs (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

#### OR

| Product Name: Humira, Hadlima, Adalimumab-fkjp, Hyrimoz, Adalimumab-adaz |                                       |
|--|---------------------------------------|
| Diagnosis  | Psoriatic Arthritis (PsA)             |
| Approval Length  | 12 month(s)                           |
| Therapy Stage  | Initial Authorization                 |
| Guideline Type   | Prior Authorization – IL and MN Plans |

| Product Name                 | Generic Name                            | GPI            | Brand/Generic |
|------------------------------|---|----------------|---------------|
| HUMIRA PEN-<br>PS/UV STARTER | ADALIMUMAB PEN-INJECTOR KIT 40 MG/0.8ML | 6627001500F420 | Brand         |
| HUMIRA PEN                   | ADALIMUMAB PEN-INJECTOR KIT 40 MG/0.8ML | 6627001500F420 | Brand         |

| HUMIRA PEN-<br>CD/UC/HS<br>STARTER           | ADALIMUMAB PEN-INJECTOR KIT 40 MG/0.8ML                    | 6627001500F420 | Brand |
|--|--|----------------|-------|
| HUMIRA PEN                                   | ADALIMUMAB PEN-INJECTOR KIT 40 MG/0.4ML                    | 6627001500F430 | Brand |
| HUMIRA PEN-<br>PEDIATRIC UC<br>STARTER PACK  | ADALIMUMAB PEN-INJECTOR KIT 80 MG/0.8ML                    | 6627001500F440 | Brand |
| HUMIRA PEN                                   | ADALIMUMAB PEN-INJECTOR KIT 80 MG/0.8ML                    | 6627001500F440 | Brand |
| HUMIRA PEN-<br>CD/UC/HS<br>STARTER           | ADALIMUMAB PEN-INJECTOR KIT 80 MG/0.8ML                    | 6627001500F440 | Brand |
| HUMIRA PEN-<br>PS/UV STARTER                 | ADALIMUMAB PEN-INJECTOR KIT 80 MG/0.8ML & 40 MG/0.4ML      | 6627001500F450 | Brand |
| HUMIRA                                       | ADALIMUMAB PREFILLED SYRINGE KIT 10 MG/0.1ML               | 6627001500F804 | Brand |
| HUMIRA                                       | ADALIMUMAB PREFILLED SYRINGE KIT 20<br>MG/0.2ML            | 6627001500F809 | Brand |
| HUMIRA                                       | ADALIMUMAB PREFILLED SYRINGE KIT 40<br>MG/0.8ML            | 6627001500F820 | Brand |
| HUMIRA                                       | ADALIMUMAB PREFILLED SYRINGE KIT 40<br>MG/0.4ML            | 6627001500F830 | Brand |
| HUMIRA PEDIATRIC CROHNS DISEASE STARTER PACK | ADALIMUMAB PREFILLED SYRINGE KIT 80<br>MG/0.8ML            | 6627001500F840 | Brand |
| HUMIRA PEDIATRIC CROHNS DISEASE STARTER PACK | ADALIMUMAB PREFILLED SYRINGE KIT 80 MG/0.8ML & 40 MG/0.4ML | 6627001500F880 | Brand |
| HADLIMA<br>PUSHTOUCH                         | ADALIMUMAB-BWWD SOLN AUTO-INJECTOR<br>40 MG/0.4ML          | 6627001520D510 | Brand |
| HADLIMA<br>PUSHTOUCH                         | ADALIMUMAB-BWWD SOLN AUTO-INJECTOR<br>40 MG/0.8ML          | 6627001520D520 | Brand |
| HADLIMA                                      | ADALIMUMAB-BWWD SOLN PREFILLED<br>SYRINGE 40 MG/0.4ML      | 6627001520E510 | Brand |
| HADLIMA                                      | ADALIMUMAB-BWWD SOLN PREFILLED<br>SYRINGE 40 MG/0.8ML      | 6627001520E520 | Brand |
| ADALIMUMAB-<br>FKJP                          | ADALIMUMAB-FKJP AUTO-INJECTOR KIT 40<br>MG/0.8ML           | 6627001535F520 | Brand |
| ADALIMUMAB-<br>FKJP                          | ADALIMUMAB-FKJP PREFILLED SYRINGE KIT<br>20 MG/0.4ML       | 6627001535F810 | Brand |
| ADALIMUMAB-<br>FKJP                          | ADALIMUMAB-FKJP PREFILLED SYRINGE KIT<br>40 MG/0.8ML       | 6627001535F820 | Brand |
| ADALIMUMAB-<br>ADAZ                          | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40 MG/0.4ML             | 6627001504D515 | Brand |

| ADALIMUMAB-<br>ADAZ  | ADALIMUMAB-ADAZ SOLN PREFILLED<br>SYRINGE 40 MG/0.4ML           | 6627001504E515 | Brand |
|--|---|----------------|-------|
| HYRIMOZ  | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40<br>MG/0.4ML               | 6627001504D515 | Brand |
| HYRIMOZ  | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40 MG/0.8ML                  | 6627001504D520 | Brand |
| HYRIMOZ<br>CROHN'S<br>DISEASE AND<br>ULCERATIVE<br>COLITIS STARTER<br>PACK | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80<br>MG/0.8ML               | 6627001504D540 | Brand |
| HYRIMOZ  | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80<br>MG/0.8ML               | 6627001504D540 | Brand |
| HYRIMOZ<br>PLAQUE<br>PSORIASIS<br>STARTER PACK                             | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80<br>MG/0.8ML & 40 MG/0.4ML | 6627001504D560 | Brand |
| HYRIMOZ  | ADALIMUMAB-ADAZ SOLN PREFILLED<br>SYRINGE 10 MG/0.1ML           | 6627001504E508 | Brand |
| HYRIMOZ  | ADALIMUMAB-ADAZ SOLN PREFILLED<br>SYRINGE 20 MG/0.2ML           | 6627001504E513 | Brand |
| HYRIMOZ  | ADALIMUMAB-ADAZ SOLN PREFILLED<br>SYRINGE 40 MG/0.4ML           | 6627001504E515 | Brand |
| HYRIMOZ  | ADALIMUMAB-ADAZ SOLN PREFILLED<br>SYRINGE 40 MG/0.8ML           | 6627001504E520 | Brand |
| HYRIMOZ<br>PEDIATRIC<br>CROHNS<br>DISEASE<br>STARTER PACK                  | ADALIMUMAB-ADAZ SOLN PREFILLED<br>SYRINGE 80 MG/0.8ML           | 6627001504E540 | Brand |
| HYRIMOZ<br>PEDIATRIC<br>CROHN'SDISEASE<br>STARTER PACK                     | ADALIMUMAB-ADAZ SOLN PREFILLED SYR 80<br>MG/0.8ML & 40 MG/0.4ML | 6627001504E560 | Brand |

- **1** One of the following:
- **1.1** All of the following:
- **1.1.1** Diagnosis of moderate to severely active psoriatic arthritis (PsA)

## AND

**1.1.2** Prescribed by or in consultation with a dermatologist or rheumatologist

#### **AND**

- **1.1.3** Submission of medical records (e.g., chart notes) documenting at least ONE of the following:
  - actively inflamed joints
  - axial disease
  - active skin, nail, or scalp psoriasis involvement
  - dactylitis
  - enthesitis

#### **AND**

**1.1.4** Not used in combination with other biologic DMARDs (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

#### OR

| Notes  | *Place authorization at a GPI 8 with an Ignore Drug Status of I    |
|--------|--|
| 110100 | , I lace administration at a Of 10 With an Ignore Brag etatae of 1 |

| Product Name: Humira, Hadlima, Adalimumab-fkjp, Hyrimoz, Adalimumab-adaz |  |
|--|--|
| Diagnosis  | Psoriatic Arthritis (PsA)                              |
| Approval Length  | 12/31/2039   |
| Guideline Type   | Prior Authorization – All Plans except IL and MN Plans |

| Product<br>Name | Generic Name                                    | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| HUMIRA PEN      | ADALIMUMAB PEN-INJECTOR KIT 40 MG/0.8ML         | 6627001500F420 | Brand         |
| HUMIRA PEN      | ADALIMUMAB PEN-INJECTOR KIT 40 MG/0.4ML         | 6627001500F430 | Brand         |
| HUMIRA PEN      | ADALIMUMAB PEN-INJECTOR KIT 80 MG/0.8ML         | 6627001500F440 | Brand         |
| HUMIRA          | ADALIMUMAB PREFILLED SYRINGE KIT 10 MG/0.1ML    | 6627001500F804 | Brand         |
| HUMIRA          | ADALIMUMAB PREFILLED SYRINGE KIT 20<br>MG/0.2ML | 6627001500F809 | Brand         |

| HUMIRA               | ADALIMUMAB PREFILLED SYRINGE KIT 40<br>MG/0.8ML       | 6627001500F820 | Brand |
|----------------------|---|----------------|-------|
| HUMIRA               | ADALIMUMAB PREFILLED SYRINGE KIT 40<br>MG/0.4ML       | 6627001500F830 | Brand |
| HADLIMA<br>PUSHTOUCH | ADALIMUMAB-BWWD SOLN AUTO-INJECTOR 40<br>MG/0.4ML     | 6627001520D510 | Brand |
| HADLIMA<br>PUSHTOUCH | ADALIMUMAB-BWWD SOLN AUTO-INJECTOR 40 MG/0.8ML        | 6627001520D520 | Brand |
| HADLIMA              | ADALIMUMAB-BWWD SOLN PREFILLED SYRINGE<br>40 MG/0.4ML | 6627001520E510 | Brand |
| HADLIMA              | ADALIMUMAB-BWWD SOLN PREFILLED SYRINGE<br>40 MG/0.8ML | 6627001520E520 | Brand |
| ADALIMUMAB-<br>FKJP  | ADALIMUMAB-FKJP AUTO-INJECTOR KIT 40<br>MG/0.8ML      | 6627001535F520 | Brand |
| ADALIMUMAB-<br>FKJP  | ADALIMUMAB-FKJP PREFILLED SYRINGE KIT 20<br>MG/0.4ML  | 6627001535F810 | Brand |
| ADALIMUMAB-<br>FKJP  | ADALIMUMAB-FKJP PREFILLED SYRINGE KIT 40<br>MG/0.8ML  | 6627001535F820 | Brand |
| ADALIMUMAB-<br>ADAZ  | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40<br>MG/0.4ML     | 6627001504D515 | Brand |
| ADALIMUMAB-<br>ADAZ  | ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 40 MG/0.4ML    | 6627001504E515 | Brand |
| HYRIMOZ              | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40<br>MG/0.4ML     | 6627001504D515 | Brand |
| HYRIMOZ              | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40<br>MG/0.8ML     | 6627001504D520 | Brand |
| HYRIMOZ              | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80<br>MG/0.8ML     | 6627001504D540 | Brand |
| HYRIMOZ              | ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 10 MG/0.1ML    | 6627001504E508 | Brand |
| HYRIMOZ              | ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 20 MG/0.2ML    | 6627001504E513 | Brand |
| HYRIMOZ              | ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 40 MG/0.4ML    | 6627001504E515 | Brand |
| HYRIMOZ              | ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 40 MG/0.8ML    | 6627001504E520 | Brand |
|                      |   |                |       |

- **1** One of the following:
- **1.1** All of the following:
- 1.1.1 Diagnosis of moderate to severely active psoriatic arthritis (PsA)

#### **AND**

**1.1.2** Prescribed by or in consultation with a dermatologist or rheumatologist

#### **AND**

- **1.1.3** Submission of medical records (e.g., chart notes) documenting at least ONE of the following:
  - actively inflamed joints
  - axial disease
  - active skin, nail, or scalp psoriasis involvement
  - dactylitis
  - enthesitis

#### AND

**1.1.4** Not used in combination with other biologic DMARDs (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

### OR

| Notes  | *Place authorization at a GPI 8 with an Ignore Drug Status of I |
|--------|---|
| 110162 | Flace authorization at a GFT o with an ignore Drug Status of t  |

| Product Name: Humira, Hadlima, Adalimumab-fkjp, Hyrimoz, Adalimumab-adaz   |                                       |  |
|--|---------------------------------------|--|
| Diagnosis  Polyarticular Juvenile Idiopathic Arthritis (PJIA), Moderate to Severely Active Rheumatoid Arthritis (RA) |                                       |  |
| Approval Length  | 12 month(s)                           |  |
| Therapy Stage  | Initial Authorization                 |  |
| Guideline Type   | Prior Authorization – IL and MN Plans |  |

| Product Name                 | Generic Name                            | GPI            | Brand/Generic |
|------------------------------|---|----------------|---------------|
| HUMIRA PEN-<br>PS/UV STARTER | ADALIMUMAB PEN-INJECTOR KIT 40 MG/0.8ML | 6627001500F420 | Brand         |

| HUMIRA PEN   | ADALIMUMAB PEN-INJECTOR KIT 40 MG/0.8ML                    | 6627001500F420 | Brand |
|--|--|----------------|-------|
| HUMIRA PEN-<br>CD/UC/HS<br>STARTER                       | ADALIMUMAB PEN-INJECTOR KIT 40 MG/0.8ML                    | 6627001500F420 | Brand |
| HUMIRA PEN   | ADALIMUMAB PEN-INJECTOR KIT 40 MG/0.4ML                    | 6627001500F430 | Brand |
| HUMIRA PEN-<br>PEDIATRIC UC<br>STARTER PACK              | ADALIMUMAB PEN-INJECTOR KIT 80 MG/0.8ML                    | 6627001500F440 | Brand |
| HUMIRA PEN   | ADALIMUMAB PEN-INJECTOR KIT 80 MG/0.8ML                    | 6627001500F440 | Brand |
| HUMIRA PEN-<br>CD/UC/HS<br>STARTER                       | ADALIMUMAB PEN-INJECTOR KIT 80 MG/0.8ML                    | 6627001500F440 | Brand |
| HUMIRA PEN-<br>PS/UV STARTER                             | ADALIMUMAB PEN-INJECTOR KIT 80 MG/0.8ML & 40 MG/0.4ML      | 6627001500F450 | Brand |
| HUMIRA   | ADALIMUMAB PREFILLED SYRINGE KIT 10 MG/0.1ML               | 6627001500F804 | Brand |
| HUMIRA   | ADALIMUMAB PREFILLED SYRINGE KIT 20 MG/0.2ML               | 6627001500F809 | Brand |
| HUMIRA   | ADALIMUMAB PREFILLED SYRINGE KIT 40 MG/0.8ML               | 6627001500F820 | Brand |
| HUMIRA   | ADALIMUMAB PREFILLED SYRINGE KIT 40 MG/0.4ML               | 6627001500F830 | Brand |
| HUMIRA<br>PEDIATRIC<br>CROHNS<br>DISEASE<br>STARTER PACK | ADALIMUMAB PREFILLED SYRINGE KIT 80 MG/0.8ML               | 6627001500F840 | Brand |
| HUMIRA PEDIATRIC CROHNS DISEASE STARTER PACK             | ADALIMUMAB PREFILLED SYRINGE KIT 80 MG/0.8ML & 40 MG/0.4ML | 6627001500F880 | Brand |
| HADLIMA<br>PUSHTOUCH                                     | ADALIMUMAB-BWWD SOLN AUTO-INJECTOR<br>40 MG/0.4ML          | 6627001520D510 | Brand |
| HADLIMA<br>PUSHTOUCH                                     | ADALIMUMAB-BWWD SOLN AUTO-INJECTOR<br>40 MG/0.8ML          | 6627001520D520 | Brand |
| HADLIMA  | ADALIMUMAB-BWWD SOLN PREFILLED<br>SYRINGE 40 MG/0.4ML      | 6627001520E510 | Brand |
| HADLIMA  | ADALIMUMAB-BWWD SOLN PREFILLED<br>SYRINGE 40 MG/0.8ML      | 6627001520E520 | Brand |
| ADALIMUMAB-<br>FKJP                                      | ADALIMUMAB-FKJP AUTO-INJECTOR KIT 40 MG/0.8ML              | 6627001535F520 | Brand |
| ADALIMUMAB-<br>FKJP                                      | ADALIMUMAB-FKJP PREFILLED SYRINGE KIT 20 MG/0.4ML          | 6627001535F810 | Brand |
| ADALIMUMAB-<br>FKJP                                      | ADALIMUMAB-FKJP PREFILLED SYRINGE KIT<br>40 MG/0.8ML       | 6627001535F820 | Brand |

| ADALIMUMAB-<br>ADAZ  | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40<br>MG/0.4ML               | 6627001504D515 | Brand |
|--|---|----------------|-------|
| ADALIMUMAB-<br>ADAZ  | ADALIMUMAB-ADAZ SOLN PREFILLED<br>SYRINGE 40 MG/0.4ML           | 6627001504E515 | Brand |
| HYRIMOZ  | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40 MG/0.4ML                  | 6627001504D515 | Brand |
| HYRIMOZ  | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40 MG/0.8ML                  | 6627001504D520 | Brand |
| HYRIMOZ<br>CROHN'S<br>DISEASE AND<br>ULCERATIVE<br>COLITIS STARTER<br>PACK | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80<br>MG/0.8ML               | 6627001504D540 | Brand |
| HYRIMOZ  | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML                  | 6627001504D540 | Brand |
| HYRIMOZ<br>PLAQUE<br>PSORIASIS<br>STARTER PACK                             | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80<br>MG/0.8ML & 40 MG/0.4ML | 6627001504D560 | Brand |
| HYRIMOZ  | ADALIMUMAB-ADAZ SOLN PREFILLED<br>SYRINGE 10 MG/0.1ML           | 6627001504E508 | Brand |
| HYRIMOZ  | ADALIMUMAB-ADAZ SOLN PREFILLED<br>SYRINGE 20 MG/0.2ML           | 6627001504E513 | Brand |
| HYRIMOZ  | ADALIMUMAB-ADAZ SOLN PREFILLED<br>SYRINGE 40 MG/0.4ML           | 6627001504E515 | Brand |
| HYRIMOZ  | ADALIMUMAB-ADAZ SOLN PREFILLED<br>SYRINGE 40 MG/0.8ML           | 6627001504E520 | Brand |
| HYRIMOZ<br>PEDIATRIC<br>CROHNS<br>DISEASE<br>STARTER PACK                  | ADALIMUMAB-ADAZ SOLN PREFILLED<br>SYRINGE 80 MG/0.8ML           | 6627001504E540 | Brand |
| HYRIMOZ<br>PEDIATRIC<br>CROHN'SDISEASE<br>STARTER PACK                     | ADALIMUMAB-ADAZ SOLN PREFILLED SYR 80<br>MG/0.8ML & 40 MG/0.4ML | 6627001504E560 | Brand |

- **1** One of the following:
- **1.1** All of the following:
- **1.1.1** Diagnosis of one of the following:
  - Moderate to severely active rheumatoid arthritis (RA) Polyarticular juvenile idiopathic arthritis (PJIA)

#### **AND**

**1.1.2** Prescribed by or in consultation with a rheumatologist

#### **AND**

- **1.1.3** Submission of medical records (e.g., chart notes) documenting a 3-month trial and failure, intolerance, or contraindication to ONE of the following:
  - methotrexate (MTX)\*\*
  - leflunomide
  - hydroxychloroquine
  - sulfasalazine

#### **AND**

**1.1.4** Not used in combination with other biologic DMARDs (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

#### OR

| *Place authorization at a GPI 8 with an Ignore Drug Status of I. **Absol ute contraindications to methotrexate are pregnancy, nursing, alcoholis m, alcoholic liver disease or other chronic liver disease, immunodeficie |
|---|
| ncy syndromes, bone marrow hyperplasia, leukopenia, thrombocytope nia or significant anemia, or hypersensitivity to methotrexate.   |

| Product Name    | Product Name: Humira, Hadlima, Adalimumab-fkjp, Hyrimoz, Adalimumab-adaz |   |                   |               |
|-----------------|--|---|-------------------|---------------|
| Diagnosis       |  | Polyarticular Juvenile Idiopathic Arthritis (PJIA), Moderate to Severely Active Rheumatoid Arthritis (RA) |                   |               |
| Approval Length |  | 12/31/2039  |                   |               |
| Guideline Type  |  | Prior Authorization – All Plans excep   | t IL and MN Plans |               |
| Product<br>Name | Generic  | Name  | GPI               | Brand/Generic |

| HUMIRA PEN           | ADALIMUMAB PEN-INJECTOR KIT 40 MG/0.8ML               | 6627001500F420                   | Brand |
|----------------------|---|----------------------------------|-------|
| HUMIRA PEN           | ADALIMUMAB PEN-INJECTOR KIT 40 MG/0.4ML               | 6627001500F420<br>6627001500F430 | Brand |
| HUMIRA PEN           | ADALIMUMAB PEN-INJECTOR KIT 80 MG/0.8ML               |                                  | Brand |
| HUMIRA               | ADALIMUMAB PREFILLED SYRINGE KIT 10                   | 6627001500F440                   | Brand |
| TIOWINA              | MG/0.1ML  | 6627001500F804                   | Біапц |
| HUMIRA               | ADALIMUMAB PREFILLED SYRINGE KIT 20<br>MG/0.2ML       | 6627001500F809                   | Brand |
| HUMIRA               | ADALIMUMAB PREFILLED SYRINGE KIT 40<br>MG/0.8ML       | 6627001500F820                   | Brand |
| HUMIRA               | ADALIMUMAB PREFILLED SYRINGE KIT 40 MG/0.4ML          | 6627001500F830                   | Brand |
| HADLIMA<br>PUSHTOUCH | ADALIMUMAB-BWWD SOLN AUTO-INJECTOR 40<br>MG/0.4ML     | 6627001520D510                   | Brand |
| HADLIMA<br>PUSHTOUCH | ADALIMUMAB-BWWD SOLN AUTO-INJECTOR 40 MG/0.8ML        | 6627001520D520                   | Brand |
| HADLIMA              | ADALIMUMAB-BWWD SOLN PREFILLED SYRINGE<br>40 MG/0.4ML | 6627001520E510                   | Brand |
| HADLIMA              | ADALIMUMAB-BWWD SOLN PREFILLED SYRINGE<br>40 MG/0.8ML | 6627001520E520                   | Brand |
| ADALIMUMAB-<br>FKJP  | ADALIMUMAB-FKJP AUTO-INJECTOR KIT 40<br>MG/0.8ML      | 6627001535F520                   | Brand |
| ADALIMUMAB-<br>FKJP  | ADALIMUMAB-FKJP PREFILLED SYRINGE KIT 20<br>MG/0.4ML  | 6627001535F810                   | Brand |
| ADALIMUMAB-<br>FKJP  | ADALIMUMAB-FKJP PREFILLED SYRINGE KIT 40<br>MG/0.8ML  | 6627001535F820                   | Brand |
| ADALIMUMAB-<br>ADAZ  | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40<br>MG/0.4ML     | 6627001504D515                   | Brand |
| ADALIMUMAB-<br>ADAZ  | ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 40 MG/0.4ML    | 6627001504E515                   | Brand |
| HYRIMOZ              | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40<br>MG/0.4ML     | 6627001504D515                   | Brand |
| HYRIMOZ              | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40<br>MG/0.8ML     | 6627001504D520                   | Brand |
| HYRIMOZ              | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80<br>MG/0.8ML     | 6627001504D540                   | Brand |
| HYRIMOZ              | ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 10 MG/0.1ML    | 6627001504E508                   | Brand |
| HYRIMOZ              | ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 20 MG/0.2ML    | 6627001504E513                   | Brand |
| HYRIMOZ              | ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 40 MG/0.4ML    | 6627001504E515                   | Brand |
| HYRIMOZ              | ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 40 MG/0.8ML    | 6627001504E520                   | Brand |

- 1 One of the following:
- **1.1** All of the following:
- **1.1.1** Diagnosis of one of the following:
  - Moderate to severely active rheumatoid arthritis (RA)
  - Polyarticular juvenile idiopathic arthritis (PJIA)

#### **AND**

**1.1.2** Prescribed by or in consultation with a rheumatologist

#### AND

- **1.1.3** Submission of medical records (e.g., chart notes) documenting a 3-month trial and failure, intolerance, or contraindication to ONE of the following:
  - methotrexate (MTX)\*\*
  - leflunomide
  - hydroxychloroquine
  - sulfasalazine

#### **AND**

**1.1.4** Not used in combination with other biologic DMARDs (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

#### OR

| *Place authorization at a GPI 8 with an Ignore Drug Status of I. **Absol |
|--|
| ute contraindications to methotrexate are pregnancy, nursing, alcoholis  |
| m, alcoholic liver disease or other chronic liver disease, immunodeficie |
| ncy syndromes, bone marrow hyperplasia, leukopenia, thrombocytope        |
| nia or significant anemia, or hypersensitivity to methotrexate.          |

| Product Name: Humira, Hadlima, Adalimumab-fkjp, Hyrimoz, Adalimumab-adaz |                                       |  |
|--|---------------------------------------|--|
| Diagnosis  | Ankylosing Spondylitis (AS)           |  |
| Approval Length  | 12 month(s)                           |  |
| Therapy Stage  | Initial Authorization                 |  |
| Guideline Type   | Prior Authorization – IL and MN Plans |  |

| Product<br>Name      | Generic Name  | GPI            | Brand/Generic |
|----------------------|---|----------------|---------------|
| HUMIRA PEN           | ADALIMUMAB PEN-INJECTOR KIT 40 MG/0.8ML               | 6627001500F420 | Brand         |
| HUMIRA PEN           | ADALIMUMAB PEN-INJECTOR KIT 40 MG/0.4ML               | 6627001500F430 | Brand         |
| HUMIRA PEN           | ADALIMUMAB PEN-INJECTOR KIT 80 MG/0.8ML               | 6627001500F440 | Brand         |
| HUMIRA               | ADALIMUMAB PREFILLED SYRINGE KIT 10 MG/0.1ML          | 6627001500F804 | Brand         |
| HUMIRA               | ADALIMUMAB PREFILLED SYRINGE KIT 20<br>MG/0.2ML       | 6627001500F809 | Brand         |
| HUMIRA               | ADALIMUMAB PREFILLED SYRINGE KIT 40<br>MG/0.8ML       | 6627001500F820 | Brand         |
| HUMIRA               | ADALIMUMAB PREFILLED SYRINGE KIT 40<br>MG/0.4ML       | 6627001500F830 | Brand         |
| HADLIMA<br>PUSHTOUCH | ADALIMUMAB-BWWD SOLN AUTO-INJECTOR 40 MG/0.4ML        | 6627001520D510 | Brand         |
| HADLIMA<br>PUSHTOUCH | ADALIMUMAB-BWWD SOLN AUTO-INJECTOR 40 MG/0.8ML        | 6627001520D520 | Brand         |
| HADLIMA              | ADALIMUMAB-BWWD SOLN PREFILLED SYRINGE<br>40 MG/0.4ML | 6627001520E510 | Brand         |
| HADLIMA              | ADALIMUMAB-BWWD SOLN PREFILLED SYRINGE<br>40 MG/0.8ML | 6627001520E520 | Brand         |
| ADALIMUMAB-<br>FKJP  | ADALIMUMAB-FKJP AUTO-INJECTOR KIT 40<br>MG/0.8ML      | 6627001535F520 | Brand         |
| ADALIMUMAB-<br>FKJP  | ADALIMUMAB-FKJP PREFILLED SYRINGE KIT 20<br>MG/0.4ML  | 6627001535F810 | Brand         |
| ADALIMUMAB-<br>FKJP  | ADALIMUMAB-FKJP PREFILLED SYRINGE KIT 40 MG/0.8ML     | 6627001535F820 | Brand         |
| ADALIMUMAB-<br>ADAZ  | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40<br>MG/0.4ML     | 6627001504D515 | Brand         |
| ADALIMUMAB-<br>ADAZ  | ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 40 MG/0.4ML    | 6627001504E515 | Brand         |
| HYRIMOZ              | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40<br>MG/0.4ML     | 6627001504D515 | Brand         |
| HYRIMOZ              | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40<br>MG/0.8ML     | 6627001504D520 | Brand         |

| HYRIMOZ | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80<br>MG/0.8ML  | 6627001504D540 | Brand |
|---------|--|----------------|-------|
| HYRIMOZ | ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 10 MG/0.1ML | 6627001504E508 | Brand |
| HYRIMOZ | ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 20 MG/0.2ML | 6627001504E513 | Brand |
| HYRIMOZ | ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 40 MG/0.4ML | 6627001504E515 | Brand |
| HYRIMOZ | ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 40 MG/0.8ML | 6627001504E520 | Brand |

- 1 One of the following:
- **1.1** All of the following:
- **1.1.1** Diagnosis of ankylosing spondylitis (AS)

### **AND**

**1.1.2** Prescribed by or in consultation with a rheumatologist

#### **AND**

**1.1.3** Minimum duration of a 1-month trial and failure, contraindication, or intolerance of scheduled prescription doses of TWO different NSAIDs (e.g., naproxen, nabumetone, diclofenac)

### **AND**

**1.1.4** Not used in combination with other biologic DMARDs (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

#### OR

| Notes | *Place authorization at a GPI 8 with an Ignore Drug Status of I |
|-------|---|
|-------|---|

| Product Name: Humira, Hadlima, Adalimumab-fkjp, Hyrimoz, Adalimumab-adaz |  |  |
|--|--|--|
| Diagnosis  | Ankylosing Spondylitis (AS)                            |  |
| Approval Length  | 12/31/2039   |  |
| Guideline Type   | Prior Authorization – All Plans Except IL and MN Plans |  |

| Product Name                                 | Generic Name  | GPI            | Brand/Generic |
|--|---|----------------|---------------|
| HUMIRA PEN-<br>PS/UV STARTER                 | ADALIMUMAB PEN-INJECTOR KIT 40 MG/0.8ML                       | 6627001500F420 | Brand         |
| HUMIRA PEN                                   | ADALIMUMAB PEN-INJECTOR KIT 40 MG/0.8ML                       | 6627001500F420 | Brand         |
| HUMIRA PEN-<br>CD/UC/HS<br>STARTER           | ADALIMUMAB PEN-INJECTOR KIT 40 MG/0.8ML                       | 6627001500F420 | Brand         |
| HUMIRA PEN                                   | ADALIMUMAB PEN-INJECTOR KIT 40 MG/0.4ML                       | 6627001500F430 | Brand         |
| HUMIRA PEN-<br>PEDIATRIC UC<br>STARTER PACK  | ADALIMUMAB PEN-INJECTOR KIT 80 MG/0.8ML                       | 6627001500F440 | Brand         |
| HUMIRA PEN                                   | ADALIMUMAB PEN-INJECTOR KIT 80 MG/0.8ML                       | 6627001500F440 | Brand         |
| HUMIRA PEN-<br>CD/UC/HS<br>STARTER           | ADALIMUMAB PEN-INJECTOR KIT 80 MG/0.8ML                       | 6627001500F440 | Brand         |
| HUMIRA PEN-<br>PS/UV STARTER                 | ADALIMUMAB PEN-INJECTOR KIT 80 MG/0.8ML & 40 MG/0.4ML         | 6627001500F450 | Brand         |
| HUMIRA                                       | ADALIMUMAB PREFILLED SYRINGE KIT 10<br>MG/0.1ML               | 6627001500F804 | Brand         |
| HUMIRA                                       | ADALIMUMAB PREFILLED SYRINGE KIT 20<br>MG/0.2ML               | 6627001500F809 | Brand         |
| HUMIRA                                       | ADALIMUMAB PREFILLED SYRINGE KIT 40<br>MG/0.8ML               | 6627001500F820 | Brand         |
| HUMIRA                                       | ADALIMUMAB PREFILLED SYRINGE KIT 40<br>MG/0.4ML               | 6627001500F830 | Brand         |
| HUMIRA PEDIATRIC CROHNS DISEASE STARTER PACK | ADALIMUMAB PREFILLED SYRINGE KIT 80<br>MG/0.8ML               | 6627001500F840 | Brand         |
| HUMIRA PEDIATRIC CROHNS DISEASE STARTER PACK | ADALIMUMAB PREFILLED SYRINGE KIT 80<br>MG/0.8ML & 40 MG/0.4ML | 6627001500F880 | Brand         |
| HADLIMA<br>PUSHTOUCH                         | ADALIMUMAB-BWWD SOLN AUTO-INJECTOR<br>40 MG/0.4ML             | 6627001520D510 | Brand         |

| HADLIMA<br>PUSHTOUCH   | ADALIMUMAB-BWWD SOLN AUTO-INJECTOR<br>40 MG/0.8ML               | 6627001520D520 | Brand |
|--|---|----------------|-------|
| HADLIMA  | ADALIMUMAB-BWWD SOLN PREFILLED<br>SYRINGE 40 MG/0.4ML           | 6627001520E510 | Brand |
| HADLIMA  | ADALIMUMAB-BWWD SOLN PREFILLED<br>SYRINGE 40 MG/0.8ML           | 6627001520E520 | Brand |
| ADALIMUMAB-<br>FKJP  | ADALIMUMAB-FKJP AUTO-INJECTOR KIT 40<br>MG/0.8ML                | 6627001535F520 | Brand |
| ADALIMUMAB-<br>FKJP  | ADALIMUMAB-FKJP PREFILLED SYRINGE KIT<br>20 MG/0.4ML            | 6627001535F810 | Brand |
| ADALIMUMAB-<br>FKJP  | ADALIMUMAB-FKJP PREFILLED SYRINGE KIT<br>40 MG/0.8ML            | 6627001535F820 | Brand |
| ADALIMUMAB-<br>ADAZ  | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40 MG/0.4ML                  | 6627001504D515 | Brand |
| ADALIMUMAB-<br>ADAZ  | ADALIMUMAB-ADAZ SOLN PREFILLED<br>SYRINGE 40 MG/0.4ML           | 6627001504E515 | Brand |
| HYRIMOZ  | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40 MG/0.4ML                  | 6627001504D515 | Brand |
| HYRIMOZ  | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40 MG/0.8ML                  | 6627001504D520 | Brand |
| HYRIMOZ<br>CROHN'S<br>DISEASE AND<br>ULCERATIVE<br>COLITIS STARTER<br>PACK | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML                  | 6627001504D540 | Brand |
| HYRIMOZ  | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML                  | 6627001504D540 | Brand |
| HYRIMOZ<br>PLAQUE<br>PSORIASIS<br>STARTER PACK                             | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80<br>MG/0.8ML & 40 MG/0.4ML | 6627001504D560 | Brand |
| HYRIMOZ  | ADALIMUMAB-ADAZ SOLN PREFILLED<br>SYRINGE 10 MG/0.1ML           | 6627001504E508 | Brand |
| HYRIMOZ  | ADALIMUMAB-ADAZ SOLN PREFILLED<br>SYRINGE 20 MG/0.2ML           | 6627001504E513 | Brand |
| HYRIMOZ  | ADALIMUMAB-ADAZ SOLN PREFILLED<br>SYRINGE 40 MG/0.4ML           | 6627001504E515 | Brand |
| HYRIMOZ  | ADALIMUMAB-ADAZ SOLN PREFILLED<br>SYRINGE 40 MG/0.8ML           | 6627001504E520 | Brand |
| HYRIMOZ<br>PEDIATRIC<br>CROHNS<br>DISEASE<br>STARTER PACK                  | ADALIMUMAB-ADAZ SOLN PREFILLED<br>SYRINGE 80 MG/0.8ML           | 6627001504E540 | Brand |
| HYRIMOZ<br>PEDIATRIC<br>CROHN'SDISEASE                                     | ADALIMUMAB-ADAZ SOLN PREFILLED SYR 80 MG/0.8ML & 40 MG/0.4ML    | 6627001504E560 | Brand |

| STARTER PACK |  |  |
|--------------|--|--|

- 1 One of the following:
- **1.1** All of the following:
- **1.1.1** Diagnosis of ankylosing spondylitis (AS)

#### **AND**

**1.1.2** Prescribed by or in consultation with a rheumatologist

#### **AND**

**1.1.3** Minimum duration of a 1-month trial and failure, contraindication, or intolerance of scheduled prescription doses of TWO different NSAIDs (e.g., naproxen, nabumetone, diclofenac)

#### **AND**

**1.1.4** Not used in combination with other biologic DMARDs (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

#### OR

**1.2** Continuation of previous therapy with Humira or an Adalimumab biosimilar, confirmed by paid claims, medical records (e.g. chart notes), or provider attestation

| Notes  | *Place authorization at a GPI 8 with an Ignore Drug Status of I      |
|--------|--|
| 140100 | , I lado dali lonzalion di a or i o willi an ignoro brag olalao or i |

| Product Name: Humira, Hadlima, Adalimumab-fkjp, Hyrimoz, Adalimumab-adaz |                       |  |
|--|-----------------------|--|
| Diagnosis Non-infectious Uveitis   |                       |  |
| Approval Length  | 12 month(s)           |  |
| Therapy Stage  | Initial Authorization |  |

| Guideline Type Prior Authorization – IL and MN Plans     |   |                |               |
|--|---|----------------|---------------|
| Product Name   | Generic Name  | GPI            | Brand/Generic |
| HUMIRA PEN-<br>PS/UV STARTER                             | ADALIMUMAB PEN-INJECTOR KIT 40 MG/0.8ML                       | 6627001500F420 | Brand         |
| HUMIRA PEN   | ADALIMUMAB PEN-INJECTOR KIT 40 MG/0.8ML                       | 6627001500F420 | Brand         |
| HUMIRA PEN-<br>CD/UC/HS<br>STARTER                       | ADALIMUMAB PEN-INJECTOR KIT 40 MG/0.8ML                       | 6627001500F420 | Brand         |
| HUMIRA PEN   | ADALIMUMAB PEN-INJECTOR KIT 40 MG/0.4ML                       | 6627001500F430 | Brand         |
| HUMIRA PEN-<br>PEDIATRIC UC<br>STARTER PACK              | ADALIMUMAB PEN-INJECTOR KIT 80 MG/0.8ML                       | 6627001500F440 | Brand         |
| HUMIRA PEN   | ADALIMUMAB PEN-INJECTOR KIT 80 MG/0.8ML                       | 6627001500F440 | Brand         |
| HUMIRA PEN-<br>CD/UC/HS<br>STARTER                       | ADALIMUMAB PEN-INJECTOR KIT 80 MG/0.8ML                       | 6627001500F440 | Brand         |
| HUMIRA PEN-<br>PS/UV STARTER                             | ADALIMUMAB PEN-INJECTOR KIT 80 MG/0.8ML & 40 MG/0.4ML         | 6627001500F450 | Brand         |
| HUMIRA   | ADALIMUMAB PREFILLED SYRINGE KIT 10<br>MG/0.1ML               | 6627001500F804 | Brand         |
| HUMIRA   | ADALIMUMAB PREFILLED SYRINGE KIT 20<br>MG/0.2ML               | 6627001500F809 | Brand         |
| HUMIRA   | ADALIMUMAB PREFILLED SYRINGE KIT 40 MG/0.8ML                  | 6627001500F820 | Brand         |
| HUMIRA   | ADALIMUMAB PREFILLED SYRINGE KIT 40 MG/0.4ML                  | 6627001500F830 | Brand         |
| HUMIRA<br>PEDIATRIC<br>CROHNS<br>DISEASE<br>STARTER PACK | ADALIMUMAB PREFILLED SYRINGE KIT 80<br>MG/0.8ML               | 6627001500F840 | Brand         |
| HUMIRA PEDIATRIC CROHNS DISEASE STARTER PACK             | ADALIMUMAB PREFILLED SYRINGE KIT 80<br>MG/0.8ML & 40 MG/0.4ML | 6627001500F880 | Brand         |
| HADLIMA<br>PUSHTOUCH                                     | ADALIMUMAB-BWWD SOLN AUTO-INJECTOR<br>40 MG/0.4ML             | 6627001520D510 | Brand         |
| HADLIMA<br>PUSHTOUCH                                     | ADALIMUMAB-BWWD SOLN AUTO-INJECTOR<br>40 MG/0.8ML             | 6627001520D520 | Brand         |
| HADLIMA  | ADALIMUMAB-BWWD SOLN PREFILLED<br>SYRINGE 40 MG/0.4ML         | 6627001520E510 | Brand         |
| HADLIMA  | ADALIMUMAB-BWWD SOLN PREFILLED<br>SYRINGE 40 MG/0.8ML         | 6627001520E520 | Brand         |
| ADALIMUMAB-<br>FKJP                                      | ADALIMUMAB-FKJP AUTO-INJECTOR KIT 40<br>MG/0.8ML              | 6627001535F520 | Brand         |

| ADALIMUMAB-<br>FKJP  | ADALIMUMAB-FKJP PREFILLED SYRINGE KIT<br>20 MG/0.4ML         | 6627001535F810 | Brand |
|--|--|----------------|-------|
| ADALIMUMAB-<br>FKJP  | ADALIMUMAB-FKJP PREFILLED SYRINGE KIT<br>40 MG/0.8ML         | 6627001535F820 | Brand |
| ADALIMUMAB-<br>ADAZ  | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40 MG/0.4ML               | 6627001504D515 | Brand |
| ADALIMUMAB-<br>ADAZ  | ADALIMUMAB-ADAZ SOLN PREFILLED<br>SYRINGE 40 MG/0.4ML        | 6627001504E515 | Brand |
| HYRIMOZ  | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40 MG/0.4ML               | 6627001504D515 | Brand |
| HYRIMOZ  | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40 MG/0.8ML               | 6627001504D520 | Brand |
| HYRIMOZ<br>CROHN'S<br>DISEASE AND<br>ULCERATIVE<br>COLITIS STARTER<br>PACK | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80<br>MG/0.8ML            | 6627001504D540 | Brand |
| HYRIMOZ  | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML               | 6627001504D540 | Brand |
| HYRIMOZ<br>PLAQUE<br>PSORIASIS<br>STARTER PACK                             | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML & 40 MG/0.4ML | 6627001504D560 | Brand |
| HYRIMOZ  | ADALIMUMAB-ADAZ SOLN PREFILLED<br>SYRINGE 10 MG/0.1ML        | 6627001504E508 | Brand |
| HYRIMOZ  | ADALIMUMAB-ADAZ SOLN PREFILLED<br>SYRINGE 20 MG/0.2ML        | 6627001504E513 | Brand |
| HYRIMOZ  | ADALIMUMAB-ADAZ SOLN PREFILLED<br>SYRINGE 40 MG/0.4ML        | 6627001504E515 | Brand |
| HYRIMOZ  | ADALIMUMAB-ADAZ SOLN PREFILLED<br>SYRINGE 40 MG/0.8ML        | 6627001504E520 | Brand |
| HYRIMOZ<br>PEDIATRIC<br>CROHNS<br>DISEASE<br>STARTER PACK                  | ADALIMUMAB-ADAZ SOLN PREFILLED<br>SYRINGE 80 MG/0.8ML        | 6627001504E540 | Brand |
| HYRIMOZ<br>PEDIATRIC<br>CROHN'SDISEASE<br>STARTER PACK                     | ADALIMUMAB-ADAZ SOLN PREFILLED SYR 80 MG/0.8ML & 40 MG/0.4ML | 6627001504E560 | Brand |

- **1** One of the following:
- **1.1** All of the following:

1.1.1 Diagnosis of non-infectious uveitis

#### **AND**

**1.1.2** Prescribed by or in consultation with a rheumatologist and verified by an ophthalmologist or other eye specialist

#### **AND**

**1.1.3** Condition classified as intermediate, posterior or panuveitis

#### AND

**1.1.4** Not used in combination with other biologic DMARDs (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

#### OR

**1.2** Continuation of previous therapy with Humira or an Adalimumab biosimilar, confirmed by paid claims, medical records (e.g. chart notes), or provider attestation.

| Notes | *Place authorization at a GPI 8 with an Ignore Drug Status of I |
|-------|---|
|-------|---|

| Product Name: Humira, Hadlima, Adalimumab-fkjp, Hyrimoz, Adalimumab-adaz |  |  |
|--|--|--|
| Diagnosis  | Non-infectious Uveitis                                 |  |
| Approval Length  | 12/31/2039   |  |
| Guideline Type   | Prior Authorization – All Plans except IL and MN Plans |  |

| Product<br>Name                 | Generic Name                            | GPI            | Brand/Generic |
|---------------------------------|---|----------------|---------------|
| HUMIRA PEN-<br>PS/UV<br>STARTER | ADALIMUMAB PEN-INJECTOR KIT 40 MG/0.8ML | 6627001500F420 | Brand         |
| HUMIRA PEN                      | ADALIMUMAB PEN-INJECTOR KIT 40 MG/0.8ML | 6627001500F420 | Brand         |
| HUMIRA PEN                      | ADALIMUMAB PEN-INJECTOR KIT 40 MG/0.4ML | 6627001500F430 | Brand         |
| HUMIRA PEN                      | ADALIMUMAB PEN-INJECTOR KIT 80 MG/0.8ML | 6627001500F440 | Brand         |

| HUMIRA PEN-<br>PS/UV<br>STARTER | ADALIMUMAB PEN-INJECTOR KIT 80 MG/0.8ML & 40 MG/0.4ML | 6627001500F450 | Brand |
|---------------------------------|---|----------------|-------|
| HUMIRA                          | ADALIMUMAB PREFILLED SYRINGE KIT 10<br>MG/0.1ML       | 6627001500F804 | Brand |
| HUMIRA                          | ADALIMUMAB PREFILLED SYRINGE KIT 20<br>MG/0.2ML       | 6627001500F809 | Brand |
| HUMIRA                          | ADALIMUMAB PREFILLED SYRINGE KIT 40<br>MG/0.8ML       | 6627001500F820 | Brand |
| HUMIRA                          | ADALIMUMAB PREFILLED SYRINGE KIT 40<br>MG/0.4ML       | 6627001500F830 | Brand |
| HADLIMA<br>PUSHTOUCH            | ADALIMUMAB-BWWD SOLN AUTO-INJECTOR 40 MG/0.4ML        | 6627001520D510 | Brand |
| HADLIMA<br>PUSHTOUCH            | ADALIMUMAB-BWWD SOLN AUTO-INJECTOR 40 MG/0.8ML        | 6627001520D520 | Brand |
| HADLIMA                         | ADALIMUMAB-BWWD SOLN PREFILLED SYRINGE<br>40 MG/0.4ML | 6627001520E510 | Brand |
| HADLIMA                         | ADALIMUMAB-BWWD SOLN PREFILLED SYRINGE<br>40 MG/0.8ML | 6627001520E520 | Brand |
| ADALIMUMAB-<br>FKJP             | ADALIMUMAB-FKJP AUTO-INJECTOR KIT 40<br>MG/0.8ML      | 6627001535F520 | Brand |
| ADALIMUMAB-<br>FKJP             | ADALIMUMAB-FKJP PREFILLED SYRINGE KIT 20<br>MG/0.4ML  | 6627001535F810 | Brand |
| ADALIMUMAB-<br>FKJP             | ADALIMUMAB-FKJP PREFILLED SYRINGE KIT 40<br>MG/0.8ML  | 6627001535F820 | Brand |
| ADALIMUMAB-<br>ADAZ             | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40<br>MG/0.4ML     | 6627001504D515 | Brand |
| ADALIMUMAB-<br>ADAZ             | ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 40 MG/0.4ML    | 6627001504E515 | Brand |
| HYRIMOZ                         | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40<br>MG/0.4ML     | 6627001504D515 | Brand |
| HYRIMOZ                         | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40<br>MG/0.8ML     | 6627001504D520 | Brand |
| HYRIMOZ                         | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80<br>MG/0.8ML     | 6627001504D540 | Brand |
| HYRIMOZ                         | ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 10 MG/0.1ML    | 6627001504E508 | Brand |
| HYRIMOZ                         | ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 20 MG/0.2ML    | 6627001504E513 | Brand |
| HYRIMOZ                         | ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 40 MG/0.4ML    | 6627001504E515 | Brand |
| HYRIMOZ                         | ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 40 MG/0.8ML    | 6627001504E520 | Brand |

- 1 One of the following:
- **1.1** All of the following:
- 1.1.1 Diagnosis of non-infectious uveitis

#### **AND**

**1.1.2** Prescribed by or in consultation with a rheumatologist and verified by an ophthalmologist or other eye specialist

#### **AND**

**1.1.3** Condition classified as intermediate, posterior or panuveitis

#### **AND**

**1.1.4** Not used in combination with other biologic DMARDs (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

#### OR

**1.2** Continuation of previous therapy with Humira or an Adalimumab biosimilar, confirmed by paid claims, medical records (e.g. chart notes), or provider attestation.

| L     | 1+D   |
|-------|---|
| Notes | *Place authorization at a GPI 8 with an Ignore Drug Status of I |

| Product Name: Humira, Hadlima, Adalimumab-fkjp, Hyrimoz, Adalimumab-adaz |  |  |
|--|--|--|
| Diagnosis  | Moderate to Severely Active Crohn's Disease (CD) |  |
| Approval Length  | 12 month(s)                                      |  |
| Therapy Stage  | Initial Authorization                            |  |
| Guideline Type   | Prior Authorization – IL and MN Plans            |  |

| Product Name                 | Generic Name                            | GPI            | Brand/Generic |
|------------------------------|---|----------------|---------------|
| HUMIRA PEN-<br>PS/UV STARTER | ADALIMUMAB PEN-INJECTOR KIT 40 MG/0.8ML | 6627001500F420 | Brand         |

| HUMIRA PEN   | ADALIMUMAB PEN-INJECTOR KIT 40 MG/0.8ML                    | 6627001500F420 | Brand |
|--|--|----------------|-------|
| HUMIRA PEN-<br>CD/UC/HS<br>STARTER                       | ADALIMUMAB PEN-INJECTOR KIT 40 MG/0.8ML                    | 6627001500F420 | Brand |
| HUMIRA PEN   | ADALIMUMAB PEN-INJECTOR KIT 40 MG/0.4ML                    | 6627001500F430 | Brand |
| HUMIRA PEN-<br>PEDIATRIC UC<br>STARTER PACK              | ADALIMUMAB PEN-INJECTOR KIT 80 MG/0.8ML                    | 6627001500F440 | Brand |
| HUMIRA PEN   | ADALIMUMAB PEN-INJECTOR KIT 80 MG/0.8ML                    | 6627001500F440 | Brand |
| HUMIRA PEN-<br>CD/UC/HS<br>STARTER                       | ADALIMUMAB PEN-INJECTOR KIT 80 MG/0.8ML                    | 6627001500F440 | Brand |
| HUMIRA PEN-<br>PS/UV STARTER                             | ADALIMUMAB PEN-INJECTOR KIT 80 MG/0.8ML & 40 MG/0.4ML      | 6627001500F450 | Brand |
| HUMIRA   | ADALIMUMAB PREFILLED SYRINGE KIT 10 MG/0.1ML               | 6627001500F804 | Brand |
| HUMIRA   | ADALIMUMAB PREFILLED SYRINGE KIT 20 MG/0.2ML               | 6627001500F809 | Brand |
| HUMIRA   | ADALIMUMAB PREFILLED SYRINGE KIT 40 MG/0.8ML               | 6627001500F820 | Brand |
| HUMIRA   | ADALIMUMAB PREFILLED SYRINGE KIT 40 MG/0.4ML               | 6627001500F830 | Brand |
| HUMIRA<br>PEDIATRIC<br>CROHNS<br>DISEASE<br>STARTER PACK | ADALIMUMAB PREFILLED SYRINGE KIT 80 MG/0.8ML               | 6627001500F840 | Brand |
| HUMIRA PEDIATRIC CROHNS DISEASE STARTER PACK             | ADALIMUMAB PREFILLED SYRINGE KIT 80 MG/0.8ML & 40 MG/0.4ML | 6627001500F880 | Brand |
| HADLIMA<br>PUSHTOUCH                                     | ADALIMUMAB-BWWD SOLN AUTO-INJECTOR<br>40 MG/0.4ML          | 6627001520D510 | Brand |
| HADLIMA<br>PUSHTOUCH                                     | ADALIMUMAB-BWWD SOLN AUTO-INJECTOR<br>40 MG/0.8ML          | 6627001520D520 | Brand |
| HADLIMA  | ADALIMUMAB-BWWD SOLN PREFILLED<br>SYRINGE 40 MG/0.4ML      | 6627001520E510 | Brand |
| HADLIMA  | ADALIMUMAB-BWWD SOLN PREFILLED<br>SYRINGE 40 MG/0.8ML      | 6627001520E520 | Brand |
| ADALIMUMAB-<br>FKJP                                      | ADALIMUMAB-FKJP AUTO-INJECTOR KIT 40 MG/0.8ML              | 6627001535F520 | Brand |
| ADALIMUMAB-<br>FKJP                                      | ADALIMUMAB-FKJP PREFILLED SYRINGE KIT 20 MG/0.4ML          | 6627001535F810 | Brand |
| ADALIMUMAB-<br>FKJP                                      | ADALIMUMAB-FKJP PREFILLED SYRINGE KIT<br>40 MG/0.8ML       | 6627001535F820 | Brand |

| ADALIMUMAB-<br>ADAZ  | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40<br>MG/0.4ML               | 6627001504D515 | Brand |
|--|---|----------------|-------|
| ADALIMUMAB-<br>ADAZ  | ADALIMUMAB-ADAZ SOLN PREFILLED<br>SYRINGE 40 MG/0.4ML           | 6627001504E515 | Brand |
| HYRIMOZ  | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40 MG/0.4ML                  | 6627001504D515 | Brand |
| HYRIMOZ  | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40 MG/0.8ML                  | 6627001504D520 | Brand |
| HYRIMOZ<br>CROHN'S<br>DISEASE AND<br>ULCERATIVE<br>COLITIS STARTER<br>PACK | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80<br>MG/0.8ML               | 6627001504D540 | Brand |
| HYRIMOZ  | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80<br>MG/0.8ML               | 6627001504D540 | Brand |
| HYRIMOZ<br>PLAQUE<br>PSORIASIS<br>STARTER PACK                             | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80<br>MG/0.8ML & 40 MG/0.4ML | 6627001504D560 | Brand |
| HYRIMOZ  | ADALIMUMAB-ADAZ SOLN PREFILLED<br>SYRINGE 10 MG/0.1ML           | 6627001504E508 | Brand |
| HYRIMOZ  | ADALIMUMAB-ADAZ SOLN PREFILLED<br>SYRINGE 20 MG/0.2ML           | 6627001504E513 | Brand |
| HYRIMOZ  | ADALIMUMAB-ADAZ SOLN PREFILLED<br>SYRINGE 40 MG/0.4ML           | 6627001504E515 | Brand |
| HYRIMOZ  | ADALIMUMAB-ADAZ SOLN PREFILLED<br>SYRINGE 40 MG/0.8ML           | 6627001504E520 | Brand |
| HYRIMOZ<br>PEDIATRIC<br>CROHNS<br>DISEASE<br>STARTER PACK                  | ADALIMUMAB-ADAZ SOLN PREFILLED<br>SYRINGE 80 MG/0.8ML           | 6627001504E540 | Brand |
| HYRIMOZ<br>PEDIATRIC<br>CROHN'SDISEASE<br>STARTER PACK                     | ADALIMUMAB-ADAZ SOLN PREFILLED SYR 80<br>MG/0.8ML & 40 MG/0.4ML | 6627001504E560 | Brand |

- **1** One of the following:
- **1.1** All of the following:
- **1.1.1** Diagnosis of moderate to severely active Crohn's disease (CD)

AND

**1.1.2** Prescribed by or in consultation with a gastroenterologist

#### **AND**

- **1.1.3** One of the following:
- **1.1.3.1** Member is considered high-risk based on ONE of the following characteristics:
  - Age less than 30 years at diagnosis
  - Extensive anatomic involvement
  - Perianal and/or severe rectal disease
  - Deep ulcers
  - Prior surgical resection
  - Stricturing and/or penetrating behavior
  - Fistulizing disease
  - Extraintestinal manifestations of inflammation (e.g., uveitis, erythema nodosum, pyoderma gangrenosum, spondyloarthropathy)

OR

- **1.1.3.2** Both of the following:
- **1.1.3.2.1** Member is considered low-risk

#### **AND**

- **1.1.3.2.2** One of the following:
- Trial and failure, contraindication, or intolerance to one conventional therapy (e.g., azathioprine, balsalazide, corticosteroids, mesalamine, mercaptopurine, methotrexate, sulfasalazine)
- Inadequate disease control or inability to achieve remission after an adequate trial of 3 months with one conventional therapy
- Demonstrated steroid dependence
- Conventional therapy clinically inappropriate based on location of disease

#### **AND**

**1.1.4** Not used in combination with other biologic DMARDs (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

# OR

**1.2** Continuation of previous therapy with Humira or an Adalimumab biosimilar, confirmed by paid claims, medical records (e.g. chart notes), or provider attestation.

| Product Name: Humira, Hadlima, Adalimumab-fkjp, Hyrimoz, Adalimumab-adaz |  |  |  |
|--|--|--|--|
| Diagnosis  | Moderate to Severely Active Crohn's Disease (CD)       |  |  |
| Approval Length  | 12/31/2039   |  |  |
| Guideline Type   | Prior Authorization – All Plans except IL and MN Plans |  |  |

| Product Name                                 | Generic Name  | GPI            | Brand/Generic |
|--|---|----------------|---------------|
| HUMIRA PEN                                   | ADALIMUMAB PEN-INJECTOR KIT 40 MG/0.8ML                       | 6627001500F420 | Brand         |
| HUMIRA PEN-<br>CD/UC/HS<br>STARTER           | ADALIMUMAB PEN-INJECTOR KIT 40 MG/0.8ML                       | 6627001500F420 | Brand         |
| HUMIRA PEN                                   | ADALIMUMAB PEN-INJECTOR KIT 40 MG/0.4ML                       | 6627001500F430 | Brand         |
| HUMIRA PEN                                   | ADALIMUMAB PEN-INJECTOR KIT 80 MG/0.8ML                       | 6627001500F440 | Brand         |
| HUMIRA PEN-<br>CD/UC/HS<br>STARTER           | ADALIMUMAB PEN-INJECTOR KIT 80 MG/0.8ML                       | 6627001500F440 | Brand         |
| HUMIRA                                       | ADALIMUMAB PREFILLED SYRINGE KIT 10<br>MG/0.1ML               | 6627001500F804 | Brand         |
| HUMIRA                                       | ADALIMUMAB PREFILLED SYRINGE KIT 20<br>MG/0.2ML               | 6627001500F809 | Brand         |
| HUMIRA                                       | ADALIMUMAB PREFILLED SYRINGE KIT 40<br>MG/0.8ML               | 6627001500F820 | Brand         |
| HUMIRA                                       | ADALIMUMAB PREFILLED SYRINGE KIT 40<br>MG/0.4ML               | 6627001500F830 | Brand         |
| HUMIRA PEDIATRIC CROHNS DISEASE STARTER PACK | ADALIMUMAB PREFILLED SYRINGE KIT 80<br>MG/0.8ML               | 6627001500F840 | Brand         |
| HUMIRA PEDIATRIC CROHNS DISEASE STARTER PACK | ADALIMUMAB PREFILLED SYRINGE KIT 80<br>MG/0.8ML & 40 MG/0.4ML | 6627001500F880 | Brand         |
| HADLIMA<br>PUSHTOUCH                         | ADALIMUMAB-BWWD SOLN AUTO-INJECTOR<br>40 MG/0.4ML             | 6627001520D510 | Brand         |

| HADLIMA<br>PUSHTOUCH   | ADALIMUMAB-BWWD SOLN AUTO-INJECTOR<br>40 MG/0.8ML               | 6627001520D520 | Brand |
|--|---|----------------|-------|
| HADLIMA  | ADALIMUMAB-BWWD SOLN PREFILLED<br>SYRINGE 40 MG/0.4ML           | 6627001520E510 | Brand |
| HADLIMA  | ADALIMUMAB-BWWD SOLN PREFILLED<br>SYRINGE 40 MG/0.8ML           | 6627001520E520 | Brand |
| ADALIMUMAB-<br>FKJP  | ADALIMUMAB-FKJP AUTO-INJECTOR KIT 40 MG/0.8ML                   | 6627001535F520 | Brand |
| ADALIMUMAB-<br>FKJP  | ADALIMUMAB-FKJP PREFILLED SYRINGE KIT<br>20 MG/0.4ML            | 6627001535F810 | Brand |
| ADALIMUMAB-<br>FKJP  | ADALIMUMAB-FKJP PREFILLED SYRINGE KIT<br>40 MG/0.8ML            | 6627001535F820 | Brand |
| ADALIMUMAB-<br>ADAZ  | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40 MG/0.4ML                  | 6627001504D515 | Brand |
| ADALIMUMAB-<br>ADAZ  | ADALIMUMAB-ADAZ SOLN PREFILLED<br>SYRINGE 40 MG/0.4ML           | 6627001504E515 | Brand |
| HYRIMOZ  | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40 MG/0.4ML                  | 6627001504D515 | Brand |
| HYRIMOZ  | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40 MG/0.8ML                  | 6627001504D520 | Brand |
| HYRIMOZ<br>CROHN'S<br>DISEASE AND<br>ULCERATIVE<br>COLITIS STARTER<br>PACK | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML                  | 6627001504D540 | Brand |
| HYRIMOZ  | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML                  | 6627001504D540 | Brand |
| HYRIMOZ  | ADALIMUMAB-ADAZ SOLN PREFILLED<br>SYRINGE 10 MG/0.1ML           | 6627001504E508 | Brand |
| HYRIMOZ  | ADALIMUMAB-ADAZ SOLN PREFILLED<br>SYRINGE 20 MG/0.2ML           | 6627001504E513 | Brand |
| HYRIMOZ  | ADALIMUMAB-ADAZ SOLN PREFILLED<br>SYRINGE 40 MG/0.4ML           | 6627001504E515 | Brand |
| HYRIMOZ  | ADALIMUMAB-ADAZ SOLN PREFILLED<br>SYRINGE 40 MG/0.8ML           | 6627001504E520 | Brand |
| HYRIMOZ<br>PEDIATRIC<br>CROHNS<br>DISEASE<br>STARTER PACK                  | ADALIMUMAB-ADAZ SOLN PREFILLED<br>SYRINGE 80 MG/0.8ML           | 6627001504E540 | Brand |
| HYRIMOZ<br>PEDIATRIC<br>CROHN'SDISEASE<br>STARTER PACK                     | ADALIMUMAB-ADAZ SOLN PREFILLED SYR 80<br>MG/0.8ML & 40 MG/0.4ML | 6627001504E560 | Brand |

| Approval Criteria  |
|--|
| 1 - One of the following:  |
| 1.1 All of the following:  |
| 1.1.1 Diagnosis of moderate to severely active Crohn's disease (CD)  |
| AND  |
| 1.1.2 Prescribed by or in consultation with a gastroenterologist   |
| AND  |
| 1.1.3 One of the following:  |
| 1.1.3.1 Member is considered high-risk based on ONE of the following characteristics:  |
| <ul> <li>Age less than 30 years at diagnosis</li> <li>Extensive anatomic involvement</li> <li>Perianal and/or severe rectal disease</li> <li>Deep ulcers</li> <li>Prior surgical resection</li> <li>Stricturing and/or penetrating behavior</li> <li>Fistulizing disease</li> <li>Extraintestinal manifestations of inflammation (e.g., uveitis, erythema nodosum, pyoderma gangrenosum, spondyloarthropathy)</li> </ul> |
| OR   |
| 1.1.3.2 Both of the following:   |
| 1.1.3.2.1 Member is considered low-risk  |
| AND  |

**1.1.3.2.2** One of the following:

# Trial and failure, contraindication, or intolerance to one conventional therapy (e.g., azathioprine, balsalazide, corticosteroids, mesalamine, mercaptopurine, methotrexate, sulfasalazine)

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- Inadequate disease control or inability to achieve remission after an adequate trial of 3 months with one conventional therapy
- Demonstrated steroid dependence
- Conventional therapy clinically inappropriate based on location of disease

#### **AND**

**1.1.4** Not used in combination with other biologic DMARDs (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

#### OR

**1.2** Continuation of previous therapy with Humira or an Adalimumab biosimilar, confirmed by paid claims, medical records (e.g. chart notes), or provider attestation.

| Product Name: Humira, Hadlima, Adalimumab-fkjp, Hyrimoz, Adalimumab-adaz |   |  |
|--|---|--|
| Diagnosis  | Moderate to Severely Active Ulcerative Colitis (UC) |  |
| Approval Length  | 12 month(s)   |  |
| Therapy Stage  | Initial Authorization                               |  |
| Guideline Type   | Prior Authorization – IL and MN Plans               |  |

| Product Name                                | Generic Name  | GPI            | Brand/Generic |
|---|---|----------------|---------------|
| HUMIRA PEN-<br>PS/UV STARTER                | ADALIMUMAB PEN-INJECTOR KIT 40 MG/0.8ML               | 6627001500F420 | Brand         |
| HUMIRA PEN                                  | ADALIMUMAB PEN-INJECTOR KIT 40 MG/0.8ML               | 6627001500F420 | Brand         |
| HUMIRA PEN-<br>CD/UC/HS<br>STARTER          | ADALIMUMAB PEN-INJECTOR KIT 40 MG/0.8ML               | 6627001500F420 | Brand         |
| HUMIRA PEN                                  | ADALIMUMAB PEN-INJECTOR KIT 40 MG/0.4ML               | 6627001500F430 | Brand         |
| HUMIRA PEN-<br>PEDIATRIC UC<br>STARTER PACK | ADALIMUMAB PEN-INJECTOR KIT 80 MG/0.8ML               | 6627001500F440 | Brand         |
| HUMIRA PEN                                  | ADALIMUMAB PEN-INJECTOR KIT 80 MG/0.8ML               | 6627001500F440 | Brand         |
| HUMIRA PEN-<br>CD/UC/HS<br>STARTER          | ADALIMUMAB PEN-INJECTOR KIT 80 MG/0.8ML               | 6627001500F440 | Brand         |
| HUMIRA PEN-<br>PS/UV STARTER                | ADALIMUMAB PEN-INJECTOR KIT 80 MG/0.8ML & 40 MG/0.4ML | 6627001500F450 | Brand         |

| HUMIRA   | ADALIMUMAB PREFILLED SYRINGE KIT 10                           | 6627001500F804 | Brand |
|--|---|----------------|-------|
| HUMIRA   | MG/0.1ML  ADALIMUMAB PREFILLED SYRINGE KIT 20 MG/0.2ML        | 6627001500F809 | Brand |
| HUMIRA   | ADALIMUMAB PREFILLED SYRINGE KIT 40 MG/0.8ML                  | 6627001500F820 | Brand |
| HUMIRA   | ADALIMUMAB PREFILLED SYRINGE KIT 40<br>MG/0.4ML               | 6627001500F830 | Brand |
| HUMIRA PEDIATRIC CROHNS DISEASE STARTER PACK                               | ADALIMUMAB PREFILLED SYRINGE KIT 80<br>MG/0.8ML               | 6627001500F840 | Brand |
| HUMIRA PEDIATRIC CROHNS DISEASE STARTER PACK                               | ADALIMUMAB PREFILLED SYRINGE KIT 80<br>MG/0.8ML & 40 MG/0.4ML | 6627001500F880 | Brand |
| HADLIMA<br>PUSHTOUCH   | ADALIMUMAB-BWWD SOLN AUTO-INJECTOR<br>40 MG/0.4ML             | 6627001520D510 | Brand |
| HADLIMA<br>PUSHTOUCH   | ADALIMUMAB-BWWD SOLN AUTO-INJECTOR<br>40 MG/0.8ML             | 6627001520D520 | Brand |
| HADLIMA  | ADALIMUMAB-BWWD SOLN PREFILLED<br>SYRINGE 40 MG/0.4ML         | 6627001520E510 | Brand |
| HADLIMA  | ADALIMUMAB-BWWD SOLN PREFILLED<br>SYRINGE 40 MG/0.8ML         | 6627001520E520 | Brand |
| ADALIMUMAB-<br>FKJP  | ADALIMUMAB-FKJP AUTO-INJECTOR KIT 40<br>MG/0.8ML              | 6627001535F520 | Brand |
| ADALIMUMAB-<br>FKJP  | ADALIMUMAB-FKJP PREFILLED SYRINGE KIT<br>20 MG/0.4ML          | 6627001535F810 | Brand |
| ADALIMUMAB-<br>FKJP  | ADALIMUMAB-FKJP PREFILLED SYRINGE KIT<br>40 MG/0.8ML          | 6627001535F820 | Brand |
| ADALIMUMAB-<br>ADAZ  | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40 MG/0.4ML                | 6627001504D515 | Brand |
| ADALIMUMAB-<br>ADAZ  | ADALIMUMAB-ADAZ SOLN PREFILLED<br>SYRINGE 40 MG/0.4ML         | 6627001504E515 | Brand |
| HYRIMOZ  | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40 MG/0.4ML                | 6627001504D515 | Brand |
| HYRIMOZ  | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40 MG/0.8ML                | 6627001504D520 | Brand |
| HYRIMOZ<br>CROHN'S<br>DISEASE AND<br>ULCERATIVE<br>COLITIS STARTER<br>PACK | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80<br>MG/0.8ML             | 6627001504D540 | Brand |
| HYRIMOZ  | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80<br>MG/0.8ML             | 6627001504D540 | Brand |

| HYRIMOZ<br>PLAQUE<br>PSORIASIS<br>STARTER PACK            | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80<br>MG/0.8ML & 40 MG/0.4ML | 6627001504D560 | Brand |
|---|---|----------------|-------|
| HYRIMOZ   | ADALIMUMAB-ADAZ SOLN PREFILLED<br>SYRINGE 10 MG/0.1ML           | 6627001504E508 | Brand |
| HYRIMOZ   | ADALIMUMAB-ADAZ SOLN PREFILLED<br>SYRINGE 20 MG/0.2ML           | 6627001504E513 | Brand |
| HYRIMOZ   | ADALIMUMAB-ADAZ SOLN PREFILLED<br>SYRINGE 40 MG/0.4ML           | 6627001504E515 | Brand |
| HYRIMOZ   | ADALIMUMAB-ADAZ SOLN PREFILLED<br>SYRINGE 40 MG/0.8ML           | 6627001504E520 | Brand |
| HYRIMOZ<br>PEDIATRIC<br>CROHNS<br>DISEASE<br>STARTER PACK | ADALIMUMAB-ADAZ SOLN PREFILLED<br>SYRINGE 80 MG/0.8ML           | 6627001504E540 | Brand |
| HYRIMOZ<br>PEDIATRIC<br>CROHN'SDISEASE<br>STARTER PACK    | ADALIMUMAB-ADAZ SOLN PREFILLED SYR 80<br>MG/0.8ML & 40 MG/0.4ML | 6627001504E560 | Brand |

- 1 One of the following:
  - **1.1** All of the following:
  - **1.1.1** Diagnosis of moderate to severely active ulcerative colitis (UC)

#### AND

**1.1.2** Prescribed by or in consultation with a gastroenterologist

#### AND

- **1.1.3** Member is considered high-risk based on at least one of the following characteristics:
  - Extensive colitis
  - Deep ulcers
  - Age less than 40 yearsHigh CRP and ESR

  - Steroid-requiring disease
  - History of hospitalization

- C. difficile infection
- CMV infection

## AND

**1.1.4** Trial and failure, contraindication, or intolerance to a short course (2 to 4 weeks) of oral corticosteroids

#### **AND**

**1.1.5** Not used in combination with other biologic DMARDs (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

#### OR

**1.2** Continuation of previous therapy with Humira or an Adalimumab biosimilar, confirmed by paid claims, medical records (e.g. chart notes), or provider attestation

| Notes | *Place authorization at a GPI 8 with an Ignore Drug Status of I |
|-------|---|
|-------|---|

| Product Name: Humira, Hadlima, Adalimumab-fkjp, Hyrimoz, Adalimumab-adaz |  |  |
|--|--|--|
| Diagnosis Moderate to Severely Active Ulcerative Colitis (UC)            |  |  |
| Approval Length 12/31/2039   |  |  |
| Guideline Type Prior Authorization – All Plans except IL and MN Plans    |  |  |

| Product<br>Name                                | Generic Name                            | GPI            | Brand/Generic |
|--|---|----------------|---------------|
| HUMIRA PEN                                     | ADALIMUMAB PEN-INJECTOR KIT 40 MG/0.8ML | 6627001500F420 | Brand         |
| HUMIRA PEN-<br>CD/UC/HS<br>STARTER             | ADALIMUMAB PEN-INJECTOR KIT 40 MG/0.8ML | 6627001500F420 | Brand         |
| HUMIRA PEN                                     | ADALIMUMAB PEN-INJECTOR KIT 40 MG/0.4ML | 6627001500F430 | Brand         |
| HUMIRA PEN-<br>PEDIATRIC<br>UC STARTER<br>PACK | ADALIMUMAB PEN-INJECTOR KIT 80 MG/0.8ML | 6627001500F440 | Brand         |
| HUMIRA PEN                                     | ADALIMUMAB PEN-INJECTOR KIT 80 MG/0.8ML | 6627001500F440 | Brand         |
| HUMIRA PEN-<br>CD/UC/HS                        | ADALIMUMAB PEN-INJECTOR KIT 80 MG/0.8ML | 6627001500F440 | Brand         |

| STARTER   |   |                |       |
|---|---|----------------|-------|
| HUMIRA  | ADALIMUMAB PREFILLED SYRINGE KIT 10<br>MG/0.1ML       | 6627001500F804 | Brand |
| HUMIRA  | ADALIMUMAB PREFILLED SYRINGE KIT 20<br>MG/0.2ML       | 6627001500F809 | Brand |
| HUMIRA  | ADALIMUMAB PREFILLED SYRINGE KIT 40<br>MG/0.8ML       | 6627001500F820 | Brand |
| HUMIRA  | ADALIMUMAB PREFILLED SYRINGE KIT 40<br>MG/0.4ML       | 6627001500F830 | Brand |
| HADLIMA<br>PUSHTOUCH  | ADALIMUMAB-BWWD SOLN AUTO-INJECTOR 40 MG/0.4ML        | 6627001520D510 | Brand |
| HADLIMA<br>PUSHTOUCH  | ADALIMUMAB-BWWD SOLN AUTO-INJECTOR 40 MG/0.8ML        | 6627001520D520 | Brand |
| HADLIMA   | ADALIMUMAB-BWWD SOLN PREFILLED SYRINGE<br>40 MG/0.4ML | 6627001520E510 | Brand |
| HADLIMA   | ADALIMUMAB-BWWD SOLN PREFILLED SYRINGE<br>40 MG/0.8ML | 6627001520E520 | Brand |
| ADALIMUMAB-<br>FKJP   | ADALIMUMAB-FKJP AUTO-INJECTOR KIT 40<br>MG/0.8ML      | 6627001535F520 | Brand |
| ADALIMUMAB-<br>FKJP   | ADALIMUMAB-FKJP PREFILLED SYRINGE KIT 20<br>MG/0.4ML  | 6627001535F810 | Brand |
| ADALIMUMAB-<br>FKJP   | ADALIMUMAB-FKJP PREFILLED SYRINGE KIT 40<br>MG/0.8ML  | 6627001535F820 | Brand |
| ADALIMUMAB-<br>ADAZ   | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40<br>MG/0.4ML     | 6627001504D515 | Brand |
| ADALIMUMAB-<br>ADAZ   | ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 40 MG/0.4ML    | 6627001504E515 | Brand |
| HYRIMOZ   | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40<br>MG/0.4ML     | 6627001504D515 | Brand |
| HYRIMOZ   | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40<br>MG/0.8ML     | 6627001504D520 | Brand |
| HYRIMOZ<br>CROHN'S<br>DISEASE AND<br>ULCERATIVE<br>COLITIS<br>STARTER<br>PACK | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80<br>MG/0.8ML     | 6627001504D540 | Brand |
| HYRIMOZ   | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80<br>MG/0.8ML     | 6627001504D540 | Brand |
| HYRIMOZ   | ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 10 MG/0.1ML    | 6627001504E508 | Brand |
| HYRIMOZ   | ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 20 MG/0.2ML    | 6627001504E513 | Brand |
| HYRIMOZ   | ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 40 MG/0.4ML    | 6627001504E515 | Brand |

| HYRIMOZ | ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 40 MG/0.8ML | 6627001504E520 | Brand |
|---------|--|----------------|-------|
|---------|--|----------------|-------|

- 1 One of the following:
- **1.1** All of the following:
- **1.1.1** Diagnosis of moderate to severely active ulcerative colitis (UC)

#### **AND**

**1.1.2** Prescribed by or in consultation with a gastroenterologist

#### **AND**

- **1.1.3** Member is considered high-risk based on at least one of the following characteristics:
  - Extensive colitis
  - Deep ulcers
  - Age less than 40 years
  - High CRP and ESR
  - Steroid-requiring disease
  - History of hospitalization
  - C. difficile infection
  - CMV infection

#### AND

**1.1.4** Trial and failure, contraindication, or intolerance to a short course (2 to 4 weeks) of oral corticosteroids

#### **AND**

**1.1.5** Not used in combination with other biologic DMARDs (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

## OR

**1.2** Continuation of previous therapy with Humira or an Adalimumab biosimilar, confirmed by paid claims, medical records (e.g. chart notes), or provider attestation

Notes \*Place authorization at a GPI 8 with an Ignore Drug Status of I

| Product Name: Humira, Hadlima, Adalimumab-fkjp, Hyrimoz, Adalimumab-adaz |                 |  |
|--|-----------------|--|
| Diagnosis  | All Indications |  |
| Approval Length  | 12 month(s)     |  |
| Therapy Stage  | Reauthorization |  |
| Guideline Type Prior Authorization - IL and MN Plans                     |                 |  |

| Product Name   | Generic Name  | GPI            | Brand/Generic |
|--|---|----------------|---------------|
| HUMIRA PEN-<br>PS/UV STARTER                             | ADALIMUMAB PEN-INJECTOR KIT 40 MG/0.8ML               | 6627001500F420 | Brand         |
| HUMIRA PEN   | ADALIMUMAB PEN-INJECTOR KIT 40 MG/0.8ML               | 6627001500F420 | Brand         |
| HUMIRA PEN-<br>CD/UC/HS<br>STARTER                       | ADALIMUMAB PEN-INJECTOR KIT 40 MG/0.8ML               | 6627001500F420 | Brand         |
| HUMIRA PEN   | ADALIMUMAB PEN-INJECTOR KIT 40 MG/0.4ML               | 6627001500F430 | Brand         |
| HUMIRA PEN-<br>PEDIATRIC UC<br>STARTER PACK              | ADALIMUMAB PEN-INJECTOR KIT 80 MG/0.8ML               | 6627001500F440 | Brand         |
| HUMIRA PEN   | ADALIMUMAB PEN-INJECTOR KIT 80 MG/0.8ML               | 6627001500F440 | Brand         |
| HUMIRA PEN-<br>CD/UC/HS<br>STARTER                       | ADALIMUMAB PEN-INJECTOR KIT 80 MG/0.8ML               | 6627001500F440 | Brand         |
| HUMIRA PEN-<br>PS/UV STARTER                             | ADALIMUMAB PEN-INJECTOR KIT 80 MG/0.8ML & 40 MG/0.4ML | 6627001500F450 | Brand         |
| HUMIRA   | ADALIMUMAB PREFILLED SYRINGE KIT 10<br>MG/0.1ML       | 6627001500F804 | Brand         |
| HUMIRA   | ADALIMUMAB PREFILLED SYRINGE KIT 20<br>MG/0.2ML       | 6627001500F809 | Brand         |
| HUMIRA   | ADALIMUMAB PREFILLED SYRINGE KIT 40<br>MG/0.8ML       | 6627001500F820 | Brand         |
| HUMIRA   | ADALIMUMAB PREFILLED SYRINGE KIT 40<br>MG/0.4ML       | 6627001500F830 | Brand         |
| HUMIRA<br>PEDIATRIC<br>CROHNS<br>DISEASE<br>STARTER PACK | ADALIMUMAB PREFILLED SYRINGE KIT 80<br>MG/0.8ML       | 6627001500F840 | Brand         |

| HUMIRA<br>PEDIATRIC<br>CROHNS<br>DISEASE<br>STARTER PACK                   | ADALIMUMAB PREFILLED SYRINGE KIT 80<br>MG/0.8ML & 40 MG/0.4ML   | 6627001500F880 | Brand |
|--|---|----------------|-------|
| HADLIMA<br>PUSHTOUCH   | ADALIMUMAB-BWWD SOLN AUTO-INJECTOR<br>40 MG/0.4ML               | 6627001520D510 | Brand |
| HADLIMA<br>PUSHTOUCH   | ADALIMUMAB-BWWD SOLN AUTO-INJECTOR<br>40 MG/0.8ML               | 6627001520D520 | Brand |
| HADLIMA  | ADALIMUMAB-BWWD SOLN PREFILLED<br>SYRINGE 40 MG/0.4ML           | 6627001520E510 | Brand |
| HADLIMA  | ADALIMUMAB-BWWD SOLN PREFILLED<br>SYRINGE 40 MG/0.8ML           | 6627001520E520 | Brand |
| ADALIMUMAB-<br>FKJP  | ADALIMUMAB-FKJP AUTO-INJECTOR KIT 40<br>MG/0.8ML                | 6627001535F520 | Brand |
| ADALIMUMAB-<br>FKJP  | ADALIMUMAB-FKJP PREFILLED SYRINGE KIT<br>20 MG/0.4ML            | 6627001535F810 | Brand |
| ADALIMUMAB-<br>FKJP  | ADALIMUMAB-FKJP PREFILLED SYRINGE KIT<br>40 MG/0.8ML            | 6627001535F820 | Brand |
| ADALIMUMAB-<br>ADAZ  | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40 MG/0.4ML                  | 6627001504D515 | Brand |
| ADALIMUMAB-<br>ADAZ  | ADALIMUMAB-ADAZ SOLN PREFILLED<br>SYRINGE 40 MG/0.4ML           | 6627001504E515 | Brand |
| HYRIMOZ  | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40 MG/0.4ML                  | 6627001504D515 | Brand |
| HYRIMOZ  | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40 MG/0.8ML                  | 6627001504D520 | Brand |
| HYRIMOZ<br>CROHN'S<br>DISEASE AND<br>ULCERATIVE<br>COLITIS STARTER<br>PACK | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML                  | 6627001504D540 | Brand |
| HYRIMOZ  | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML                  | 6627001504D540 | Brand |
| HYRIMOZ<br>PLAQUE<br>PSORIASIS<br>STARTER PACK                             | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80<br>MG/0.8ML & 40 MG/0.4ML | 6627001504D560 | Brand |
| HYRIMOZ  | ADALIMUMAB-ADAZ SOLN PREFILLED<br>SYRINGE 10 MG/0.1ML           | 6627001504E508 | Brand |
| HYRIMOZ  | ADALIMUMAB-ADAZ SOLN PREFILLED<br>SYRINGE 20 MG/0.2ML           | 6627001504E513 | Brand |
| HYRIMOZ  | ADALIMUMAB-ADAZ SOLN PREFILLED<br>SYRINGE 40 MG/0.4ML           | 6627001504E515 | Brand |
| HYRIMOZ  | ADALIMUMAB-ADAZ SOLN PREFILLED<br>SYRINGE 40 MG/0.8ML           | 6627001504E520 | Brand |

| HYRIMOZ<br>PEDIATRIC<br>CROHNS<br>DISEASE<br>STARTER PACK | ADALIMUMAB-ADAZ SOLN PREFILLED<br>SYRINGE 80 MG/0.8ML        | 6627001504E540 | Brand |
|---|--|----------------|-------|
| HYRIMOZ<br>PEDIATRIC<br>CROHN'SDISEASE<br>STARTER PACK    | ADALIMUMAB-ADAZ SOLN PREFILLED SYR 80 MG/0.8ML & 40 MG/0.4ML | 6627001504E560 | Brand |

**1** - Prescriber provides clinical documentation from the previous 12 months of the member's response to therapy including individual improvements in functional status related to therapeutic response

| Notes | *If clinical documentation or claims history indicate ongoing treatment with an increased quantity, the reauthorization approval should include the quantity limit exception. |
|-------|---|
|       | Place authorization at a GPI 8 with an Ignore Drug Status of I  |

| Product Name: Humira, Hadlima, Adalimumab-fkjp, Hyrimoz, Adalimumab-adaz |  |  |
|--|--|--|
| Diagnosis  | Moderate to Severely Active Rheumatoid Arthritis, JIA, PSA, AS, plaque psoriasis |  |
| Approval Length  | 12/31/2039   |  |
| Guideline Type   | Quantity Exception – All Plans except IL and MN Plans                            |  |

| Product<br>Name                    | Generic Name  | GPI            | Brand/Generic |
|------------------------------------|---|----------------|---------------|
| HUMIRA PEN-<br>PS/UV<br>STARTER    | ADALIMUMAB PEN-INJECTOR KIT 40 MG/0.8ML               | 6627001500F420 | Brand         |
| HUMIRA PEN                         | ADALIMUMAB PEN-INJECTOR KIT 40 MG/0.8ML               | 6627001500F420 | Brand         |
| HUMIRA PEN-<br>CD/UC/HS<br>STARTER | ADALIMUMAB PEN-INJECTOR KIT 40 MG/0.8ML               | 6627001500F420 | Brand         |
| HUMIRA PEN                         | ADALIMUMAB PEN-INJECTOR KIT 40 MG/0.4ML               | 6627001500F430 | Brand         |
| HUMIRA PEN                         | ADALIMUMAB PEN-INJECTOR KIT 80 MG/0.8ML               | 6627001500F440 | Brand         |
| HUMIRA PEN-<br>CD/UC/HS<br>STARTER | ADALIMUMAB PEN-INJECTOR KIT 80 MG/0.8ML               | 6627001500F440 | Brand         |
| HUMIRA PEN-<br>PS/UV               | ADALIMUMAB PEN-INJECTOR KIT 80 MG/0.8ML & 40 MG/0.4ML | 6627001500F450 | Brand         |

| STARTER   |   |                |       |
|---|---|----------------|-------|
| HUMIRA  | ADALIMUMAB PREFILLED SYRINGE KIT 10<br>MG/0.1ML                 | 6627001500F804 | Brand |
| HUMIRA  | ADALIMUMAB PREFILLED SYRINGE KIT 20<br>MG/0.2ML                 | 6627001500F809 | Brand |
| HUMIRA  | ADALIMUMAB PREFILLED SYRINGE KIT 40<br>MG/0.8ML                 | 6627001500F820 | Brand |
| HUMIRA  | ADALIMUMAB PREFILLED SYRINGE KIT 40<br>MG/0.4ML                 | 6627001500F830 | Brand |
| HADLIMA<br>PUSHTOUCH                              | ADALIMUMAB-BWWD SOLN AUTO-INJECTOR 40 MG/0.4ML                  | 6627001520D510 | Brand |
| HADLIMA<br>PUSHTOUCH                              | ADALIMUMAB-BWWD SOLN AUTO-INJECTOR 40 MG/0.8ML                  | 6627001520D520 | Brand |
| HADLIMA   | ADALIMUMAB-BWWD SOLN PREFILLED SYRINGE<br>40 MG/0.4ML           | 6627001520E510 | Brand |
| HADLIMA   | ADALIMUMAB-BWWD SOLN PREFILLED SYRINGE<br>40 MG/0.8ML           | 6627001520E520 | Brand |
| ADALIMUMAB-<br>FKJP                               | ADALIMUMAB-FKJP AUTO-INJECTOR KIT 40<br>MG/0.8ML                | 6627001535F520 | Brand |
| ADALIMUMAB-<br>FKJP                               | ADALIMUMAB-FKJP PREFILLED SYRINGE KIT 20<br>MG/0.4ML            | 6627001535F810 | Brand |
| ADALIMUMAB-<br>FKJP                               | ADALIMUMAB-FKJP PREFILLED SYRINGE KIT 40<br>MG/0.8ML            | 6627001535F820 | Brand |
| ADALIMUMAB-<br>ADAZ                               | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40<br>MG/0.4ML               | 6627001504D515 | Brand |
| ADALIMUMAB-<br>ADAZ                               | ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 40 MG/0.4ML              | 6627001504E515 | Brand |
| HYRIMOZ   | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40<br>MG/0.4ML               | 6627001504D515 | Brand |
| HYRIMOZ   | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40<br>MG/0.8ML               | 6627001504D520 | Brand |
| HYRIMOZ   | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80<br>MG/0.8ML               | 6627001504D540 | Brand |
| HYRIMOZ<br>PLAQUE<br>PSORIASIS<br>STARTER<br>PACK | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80<br>MG/0.8ML & 40 MG/0.4ML | 6627001504D560 | Brand |
| HYRIMOZ   | ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 10 MG/0.1ML              | 6627001504E508 | Brand |
| HYRIMOZ   | ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 20 MG/0.2ML              | 6627001504E513 | Brand |
| HYRIMOZ   | ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 40 MG/0.4ML              | 6627001504E515 | Brand |
| HYRIMOZ   | ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 40 MG/0.8ML              | 6627001504E520 | Brand |

**1** - Failure of an adherent 3-month trial of standard maintenance dosing with concomitant methotrexate (unless contraindicated or not appropriate for indication being requested)

#### OR

- **2** There is a confirmed history of an approved quantity limit exception (via prior authorization or historical authorization on file) for any of the following:
  - Humira
  - Adalimumab biosimilar

| _ |       |   |
|---|-------|---|
| Ν | lotes | *Place authorization at a GPI 8 with an Ignore Drug Status of I |

| Product Name: Humira, Hadlima, Adalimumab-fkjp, Hyrimoz, Adalimumab-adaz                   |             |  |  |
|--|-------------|--|--|
| Diagnosis Moderate to Severely Active Rheumatoid Arthritis, JIA, PSA, AS, plaque psoriasis |             |  |  |
| Approval Length  | 12 month(s) |  |  |
| Guideline Type Quantity Exception – IL and MN Plans  |             |  |  |

| Product<br>Name                    | Generic Name  | GPI            | Brand/Generic |
|------------------------------------|---|----------------|---------------|
| HUMIRA PEN-<br>PS/UV<br>STARTER    | ADALIMUMAB PEN-INJECTOR KIT 40 MG/0.8ML               | 6627001500F420 | Brand         |
| HUMIRA PEN                         | ADALIMUMAB PEN-INJECTOR KIT 40 MG/0.8ML               | 6627001500F420 | Brand         |
| HUMIRA PEN-<br>CD/UC/HS<br>STARTER | ADALIMUMAB PEN-INJECTOR KIT 40 MG/0.8ML               | 6627001500F420 | Brand         |
| HUMIRA PEN                         | ADALIMUMAB PEN-INJECTOR KIT 40 MG/0.4ML               | 6627001500F430 | Brand         |
| HUMIRA PEN                         | ADALIMUMAB PEN-INJECTOR KIT 80 MG/0.8ML               | 6627001500F440 | Brand         |
| HUMIRA PEN-<br>CD/UC/HS<br>STARTER | ADALIMUMAB PEN-INJECTOR KIT 80 MG/0.8ML               | 6627001500F440 | Brand         |
| HUMIRA PEN-<br>PS/UV<br>STARTER    | ADALIMUMAB PEN-INJECTOR KIT 80 MG/0.8ML & 40 MG/0.4ML | 6627001500F450 | Brand         |
| HUMIRA                             | ADALIMUMAB PREFILLED SYRINGE KIT 10                   | 6627001500F804 | Brand         |

|   | MG/0.1ML  |                |       |
|---|---|----------------|-------|
| HUMIRA  | ADALIMUMAB PREFILLED SYRINGE KIT 20<br>MG/0.2ML                 | 6627001500F809 | Brand |
| HUMIRA  | ADALIMUMAB PREFILLED SYRINGE KIT 40 MG/0.8ML                    | 6627001500F820 | Brand |
| HUMIRA  | ADALIMUMAB PREFILLED SYRINGE KIT 40<br>MG/0.4ML                 | 6627001500F830 | Brand |
| HADLIMA<br>PUSHTOUCH                              | ADALIMUMAB-BWWD SOLN AUTO-INJECTOR 40 MG/0.4ML                  | 6627001520D510 | Brand |
| HADLIMA<br>PUSHTOUCH                              | ADALIMUMAB-BWWD SOLN AUTO-INJECTOR 40 MG/0.8ML                  | 6627001520D520 | Brand |
| HADLIMA   | ADALIMUMAB-BWWD SOLN PREFILLED SYRINGE<br>40 MG/0.4ML           | 6627001520E510 | Brand |
| HADLIMA   | ADALIMUMAB-BWWD SOLN PREFILLED SYRINGE<br>40 MG/0.8ML           | 6627001520E520 | Brand |
| ADALIMUMAB-<br>FKJP                               | ADALIMUMAB-FKJP AUTO-INJECTOR KIT 40<br>MG/0.8ML                | 6627001535F520 | Brand |
| ADALIMUMAB-<br>FKJP                               | ADALIMUMAB-FKJP PREFILLED SYRINGE KIT 20<br>MG/0.4ML            | 6627001535F810 | Brand |
| ADALIMUMAB-<br>FKJP                               | ADALIMUMAB-FKJP PREFILLED SYRINGE KIT 40<br>MG/0.8ML            | 6627001535F820 | Brand |
| ADALIMUMAB-<br>ADAZ                               | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40<br>MG/0.4ML               | 6627001504D515 | Brand |
| ADALIMUMAB-<br>ADAZ                               | ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 40 MG/0.4ML              | 6627001504E515 | Brand |
| HYRIMOZ   | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40 MG/0.4ML                  | 6627001504D515 | Brand |
| HYRIMOZ   | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40 MG/0.8ML                  | 6627001504D520 | Brand |
| HYRIMOZ   | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80<br>MG/0.8ML               | 6627001504D540 | Brand |
| HYRIMOZ<br>PLAQUE<br>PSORIASIS<br>STARTER<br>PACK | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80<br>MG/0.8ML & 40 MG/0.4ML | 6627001504D560 | Brand |
| HYRIMOZ   | ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 10 MG/0.1ML              | 6627001504E508 | Brand |
| HYRIMOZ   | ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 20 MG/0.2ML              | 6627001504E513 | Brand |
| HYRIMOZ   | ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 40 MG/0.4ML              | 6627001504E515 | Brand |
| HYRIMOZ   | ADALIMUMAB-ADAZ SOLN PREFILLED SYRINGE 40 MG/0.8ML              | 6627001504E520 | Brand |

**1** - Failure of an adherent 3-month trial of standard maintenance dosing with concomitant methotrexate (unless contraindicated or not appropriate for indication being requested)

#### OR

- **2** There is a confirmed history of an approved quantity limit exception (via prior authorization or historical authorization on file) for any of the following:
  - Humira
  - Adalimumab biosimilar

| Notes | *Place authorization at a GPI 8 with an Ignore Drug Status of I |
|-------|---|
| Notes | *Place authorization at a GPI 8 with an Ignore Drug Status of I |

| Product Name: Humira, Hadlima, Adalimumab-fkjp, Hyrimoz, Adalimumab-adaz |  |  |  |
|--|--|--|--|
| Diagnosis Crohn's disease, ulcerative colitis                            |  |  |  |
| Approval Length 12 month(s)  |  |  |  |
| Guideline Type Quantity Exception – IL and MN Plans                      |  |  |  |

| Product Name                                | Generic Name                                    | GPI            | Brand/Generic |
|---|---|----------------|---------------|
| HUMIRA PEN                                  | ADALIMUMAB PEN-INJECTOR KIT 40 MG/0.8ML         | 6627001500F420 | Brand         |
| HUMIRA PEN-<br>CD/UC/HS<br>STARTER          | ADALIMUMAB PEN-INJECTOR KIT 40 MG/0.8ML         | 6627001500F420 | Brand         |
| HUMIRA PEN                                  | ADALIMUMAB PEN-INJECTOR KIT 40 MG/0.4ML         | 6627001500F430 | Brand         |
| HUMIRA PEN-<br>PEDIATRIC UC<br>STARTER PACK | ADALIMUMAB PEN-INJECTOR KIT 80 MG/0.8ML         | 6627001500F440 | Brand         |
| HUMIRA PEN                                  | ADALIMUMAB PEN-INJECTOR KIT 80 MG/0.8ML         | 6627001500F440 | Brand         |
| HUMIRA PEN-<br>CD/UC/HS<br>STARTER          | ADALIMUMAB PEN-INJECTOR KIT 80 MG/0.8ML         | 6627001500F440 | Brand         |
| HUMIRA                                      | ADALIMUMAB PREFILLED SYRINGE KIT 10<br>MG/0.1ML | 6627001500F804 | Brand         |
| HUMIRA                                      | ADALIMUMAB PREFILLED SYRINGE KIT 20<br>MG/0.2ML | 6627001500F809 | Brand         |
| HUMIRA                                      | ADALIMUMAB PREFILLED SYRINGE KIT 40 MG/0.8ML    | 6627001500F820 | Brand         |
| HUMIRA                                      | ADALIMUMAB PREFILLED SYRINGE KIT 40<br>MG/0.4ML | 6627001500F830 | Brand         |

| HUMIRA   | ADALIMUMAB PREFILLED SYRINGE KIT 80                           | 00070045005040 | Brand |
|--|---|----------------|-------|
| PEDIATRIC<br>CROHNS<br>DISEASE<br>STARTER PACK                             | MG/0.8ML  | 6627001500F840 | Brand |
| HUMIRA PEDIATRIC CROHNS DISEASE STARTER PACK                               | ADALIMUMAB PREFILLED SYRINGE KIT 80<br>MG/0.8ML & 40 MG/0.4ML | 6627001500F880 | Brand |
| HADLIMA<br>PUSHTOUCH   | ADALIMUMAB-BWWD SOLN AUTO-INJECTOR<br>40 MG/0.4ML             | 6627001520D510 | Brand |
| HADLIMA<br>PUSHTOUCH   | ADALIMUMAB-BWWD SOLN AUTO-INJECTOR<br>40 MG/0.8ML             | 6627001520D520 | Brand |
| HADLIMA  | ADALIMUMAB-BWWD SOLN PREFILLED<br>SYRINGE 40 MG/0.4ML         | 6627001520E510 | Brand |
| HADLIMA  | ADALIMUMAB-BWWD SOLN PREFILLED<br>SYRINGE 40 MG/0.8ML         | 6627001520E520 | Brand |
| ADALIMUMAB-<br>FKJP  | ADALIMUMAB-FKJP AUTO-INJECTOR KIT 40<br>MG/0.8ML              | 6627001535F520 | Brand |
| ADALIMUMAB-<br>FKJP  | ADALIMUMAB-FKJP PREFILLED SYRINGE KIT<br>20 MG/0.4ML          | 6627001535F810 | Brand |
| ADALIMUMAB-<br>FKJP  | ADALIMUMAB-FKJP PREFILLED SYRINGE KIT<br>40 MG/0.8ML          | 6627001535F820 | Brand |
| ADALIMUMAB-<br>ADAZ  | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40 MG/0.4ML                | 6627001504D515 | Brand |
| ADALIMUMAB-<br>ADAZ  | ADALIMUMAB-ADAZ SOLN PREFILLED<br>SYRINGE 40 MG/0.4ML         | 6627001504E515 | Brand |
| HYRIMOZ  | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40 MG/0.4ML                | 6627001504D515 | Brand |
| HYRIMOZ  | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40 MG/0.8ML                | 6627001504D520 | Brand |
| HYRIMOZ<br>CROHN'S<br>DISEASE AND<br>ULCERATIVE<br>COLITIS STARTER<br>PACK | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML                | 6627001504D540 | Brand |
| HYRIMOZ  | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML                | 6627001504D540 | Brand |
| HYRIMOZ  | ADALIMUMAB-ADAZ SOLN PREFILLED<br>SYRINGE 10 MG/0.1ML         | 6627001504E508 | Brand |
| HYRIMOZ  | ADALIMUMAB-ADAZ SOLN PREFILLED<br>SYRINGE 20 MG/0.2ML         | 6627001504E513 | Brand |
| HYRIMOZ  | ADALIMUMAB-ADAZ SOLN PREFILLED<br>SYRINGE 40 MG/0.4ML         | 6627001504E515 | Brand |
| HYRIMOZ  | ADALIMUMAB-ADAZ SOLN PREFILLED<br>SYRINGE 40 MG/0.8ML         | 6627001504E520 | Brand |

| HYRIMOZ<br>PEDIATRIC<br>CROHNS<br>DISEASE<br>STARTER PACK | ADALIMUMAB-ADAZ SOLN PREFILLED<br>SYRINGE 80 MG/0.8ML           | 6627001504E540 | Brand |
|---|---|----------------|-------|
| HYRIMOZ<br>PEDIATRIC<br>CROHN'SDISEASE<br>STARTER PACK    | ADALIMUMAB-ADAZ SOLN PREFILLED SYR 80<br>MG/0.8ML & 40 MG/0.4ML | 6627001504E560 | Brand |

- 1 One of the following:
- **1.1** Both of the following:
- **1.1.1** Failure of a two-month trial of monthly therapy after completion of induction dosing regimen

#### **AND**

**1.1.2** Based on subtherapeutic drug concentrations and absence (or low levels) of drug antibodies

#### OR

- **1.2** There is a confirmed history of an approved quantity limit exception (via prior authorization or historical authorization on file) for any of the following:
  - Humira
  - Adalimumab biosimilar

| Notes | *Place authorization at a GPI 8 with an Ignore Drug Status of I |
|-------|---|
|       | ]   |

| Product Name: Humira, Hadlima, Adalimumab-fkjp, Hyrimoz, Adalimumab-adaz |  |  |  |
|--|--|--|--|
| Diagnosis  | Crohn's disease, ulcerative colitis                                  |  |  |
| Approval Length  | 12 month(s)  |  |  |
| Guideline Type   | Guideline Type Quantity Exception – All plans except IL and MN Plans |  |  |
| Product Name Generic Name GPI Brand/Generic                              |  |  |  |

| HUMIRA PEN-<br>PS/UV STARTER                             | ADALIMUMAB PEN-INJECTOR KIT 40 MG/0.8ML                       | 6627001500F420 | Brand |
|--|---|----------------|-------|
| HUMIRA PEN   | ADALIMUMAB PEN-INJECTOR KIT 40 MG/0.8ML                       | 6627001500F420 | Brand |
| HUMIRA PEN-<br>CD/UC/HS<br>STARTER                       | ADALIMUMAB PEN-INJECTOR KIT 40 MG/0.8ML                       | 6627001500F420 | Brand |
| HUMIRA PEN   | ADALIMUMAB PEN-INJECTOR KIT 40 MG/0.4ML                       | 6627001500F430 | Brand |
| HUMIRA PEN-<br>PEDIATRIC UC<br>STARTER PACK              | ADALIMUMAB PEN-INJECTOR KIT 80 MG/0.8ML                       | 6627001500F440 | Brand |
| HUMIRA PEN   | ADALIMUMAB PEN-INJECTOR KIT 80 MG/0.8ML                       | 6627001500F440 | Brand |
| HUMIRA PEN-<br>CD/UC/HS<br>STARTER                       | ADALIMUMAB PEN-INJECTOR KIT 80 MG/0.8ML                       | 6627001500F440 | Brand |
| HUMIRA PEN-<br>PS/UV STARTER                             | ADALIMUMAB PEN-INJECTOR KIT 80 MG/0.8ML & 40 MG/0.4ML         | 6627001500F450 | Brand |
| HUMIRA   | ADALIMUMAB PREFILLED SYRINGE KIT 10 MG/0.1ML                  | 6627001500F804 | Brand |
| HUMIRA   | ADALIMUMAB PREFILLED SYRINGE KIT 20 MG/0.2ML                  | 6627001500F809 | Brand |
| HUMIRA   | ADALIMUMAB PREFILLED SYRINGE KIT 40 MG/0.8ML                  | 6627001500F820 | Brand |
| HUMIRA   | ADALIMUMAB PREFILLED SYRINGE KIT 40 MG/0.4ML                  | 6627001500F830 | Brand |
| HUMIRA<br>PEDIATRIC<br>CROHNS<br>DISEASE<br>STARTER PACK | ADALIMUMAB PREFILLED SYRINGE KIT 80<br>MG/0.8ML               | 6627001500F840 | Brand |
| HUMIRA<br>PEDIATRIC<br>CROHNS<br>DISEASE<br>STARTER PACK | ADALIMUMAB PREFILLED SYRINGE KIT 80<br>MG/0.8ML & 40 MG/0.4ML | 6627001500F880 | Brand |
| HADLIMA<br>PUSHTOUCH                                     | ADALIMUMAB-BWWD SOLN AUTO-INJECTOR<br>40 MG/0.4ML             | 6627001520D510 | Brand |
| HADLIMA<br>PUSHTOUCH                                     | ADALIMUMAB-BWWD SOLN AUTO-INJECTOR<br>40 MG/0.8ML             | 6627001520D520 | Brand |
| HADLIMA  | ADALIMUMAB-BWWD SOLN PREFILLED<br>SYRINGE 40 MG/0.4ML         | 6627001520E510 | Brand |
| HADLIMA  | ADALIMUMAB-BWWD SOLN PREFILLED<br>SYRINGE 40 MG/0.8ML         | 6627001520E520 | Brand |
| ADALIMUMAB-<br>FKJP                                      | ADALIMUMAB-FKJP AUTO-INJECTOR KIT 40<br>MG/0.8ML              | 6627001535F520 | Brand |
| ADALIMUMAB-<br>FKJP                                      | ADALIMUMAB-FKJP PREFILLED SYRINGE KIT<br>20 MG/0.4ML          | 6627001535F810 | Brand |

| ADALIMUMAB-<br>FKJP  | ADALIMUMAB-FKJP PREFILLED SYRINGE KIT<br>40 MG/0.8ML            | 6627001535F820 | Brand |
|--|---|----------------|-------|
| ADALIMUMAB-<br>ADAZ  | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40<br>MG/0.4ML               | 6627001504D515 | Brand |
| ADALIMUMAB-<br>ADAZ  | ADALIMUMAB-ADAZ SOLN PREFILLED<br>SYRINGE 40 MG/0.4ML           | 6627001504E515 | Brand |
| HYRIMOZ  | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40<br>MG/0.4ML               | 6627001504D515 | Brand |
| HYRIMOZ  | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 40 MG/0.8ML                  | 6627001504D520 | Brand |
| HYRIMOZ<br>CROHN'S<br>DISEASE AND<br>ULCERATIVE<br>COLITIS STARTER<br>PACK | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80<br>MG/0.8ML               | 6627001504D540 | Brand |
| HYRIMOZ  | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80 MG/0.8ML                  | 6627001504D540 | Brand |
| HYRIMOZ<br>PLAQUE<br>PSORIASIS<br>STARTER PACK                             | ADALIMUMAB-ADAZ SOLN AUTO-INJECTOR 80<br>MG/0.8ML & 40 MG/0.4ML | 6627001504D560 | Brand |
| HYRIMOZ  | ADALIMUMAB-ADAZ SOLN PREFILLED<br>SYRINGE 10 MG/0.1ML           | 6627001504E508 | Brand |
| HYRIMOZ  | ADALIMUMAB-ADAZ SOLN PREFILLED<br>SYRINGE 20 MG/0.2ML           | 6627001504E513 | Brand |
| HYRIMOZ  | ADALIMUMAB-ADAZ SOLN PREFILLED<br>SYRINGE 40 MG/0.4ML           | 6627001504E515 | Brand |
| HYRIMOZ  | ADALIMUMAB-ADAZ SOLN PREFILLED<br>SYRINGE 40 MG/0.8ML           | 6627001504E520 | Brand |
| HYRIMOZ<br>PEDIATRIC<br>CROHNS<br>DISEASE<br>STARTER PACK                  | ADALIMUMAB-ADAZ SOLN PREFILLED<br>SYRINGE 80 MG/0.8ML           | 6627001504E540 | Brand |
| HYRIMOZ<br>PEDIATRIC<br>CROHN'SDISEASE<br>STARTER PACK                     | ADALIMUMAB-ADAZ SOLN PREFILLED SYR 80<br>MG/0.8ML & 40 MG/0.4ML | 6627001504E560 | Brand |

- 1 One of the following:
- **1.1** Both of the following:
- 1.1.1 Failure of a two-month trial of monthly therapy after completion of induction dosing

regimen

#### **AND**

**1.1.2** Based on subtherapeutic drug concentrations and absence (or low levels) of drug antibodies

OR

- **1.2** There is a confirmed history of an approved quantity limit exception (via prior authorization or historical authorization on file) for any of the following:
  - Humira
  - Adalimumab biosimilar

Notes \*Place authorization at a GPI 8 with an Ignore Drug Status of I

# 2. Background

# Benefit/Coverage/Program Information

#### **Quantity Limits**

| Drug Name                               | Drug Status             | Quantity Limits<br>(maintenance/28<br>days) based on<br>indication | Approval<br>Limits |
|---|-------------------------|--|--------------------|
| Adalimumab-bwwd<br>(Hadlima)            | Preferred<br>Restricted | #2<br>#4 for HS indication   | None*              |
| Adalimumab-fkjp<br>(unbranded)          | Preferred<br>Restricted | #2<br>#4 for HS indication   | None*              |
| Adalimumab-adaz (Hyrimoz)               | Preferred<br>Restricted | #2<br>#4 for HS indication   | None*              |
| Adalimumab-adaz-<br>(unbranded Hyrimoz) | Preferred<br>Restricted | #2   | None*              |

|   | #4 for HS indication |  |
|---|----------------------|--|
| *Initial and renewal approvals limited to 12 months for IL and MN plans |                      |  |

# 3. Revision History

| Date      | Notes            |
|-----------|------------------|
| 3/21/2024 | Update guideline |

| Adlarity (donepezil)   |  |  |  |
|--|--|--|--|
| The State Annual and Confidence To Mark State Control of Association (Association) and Associati |  |  |  |
|  |  |  |  |

# **Prior Authorization Guideline**

| Guideline ID          | GL-129155            |  |
|-----------------------|----------------------|--|
| <b>Guideline Name</b> | Adlarity (donepezil) |  |
| Formulary             | Quartz               |  |

# **Guideline Note:**

| Effective Date: |
|-----------------|
|-----------------|

# 1. Criteria

| Product Name: Adlarity     |   |  |
|----------------------------|---|--|
| Approval Length 12/31/2039 |   |  |
| Guideline Type             | Prior Authorization- All plans except IL and MN Plans |  |

| Product<br>Name | Generic Name   | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| ADLARITY        | DONEPEZIL HYDROCHLORIDE TD PATCH WEEKLY 5<br>MG/DAY  | 62051025108820 | Brand         |
| ADLARITY        | DONEPEZIL HYDROCHLORIDE TD PATCH WEEKLY 10<br>MG/DAY | 62051025108830 | Brand         |

# **Approval Criteria**

1 - Diagnosis of dementia associated with Alzheimer's disease

#### **AND**

**2** - Trial and failure, intolerance, or contraindication to two oral acetylcholinesterase inhibitors (eg donepezil, galantamine), one of which must be donepezil

#### **AND**

**3** - Trial and failure, intolerance, or contraindication to an acetylcholinesterase inhibitor patch (eg rivastigmine patch)

| Product Name: Adlarity |                                     |  |
|------------------------|-------------------------------------|--|
| Approval Length        | 12 month(s)                         |  |
| Therapy Stage          | Initial Authorization               |  |
| Guideline Type         | Prior Authorization-IL and MN plans |  |

| Product<br>Name | Generic Name   | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| ADLARITY        | DONEPEZIL HYDROCHLORIDE TD PATCH WEEKLY 5<br>MG/DAY  | 62051025108820 | Brand         |
| ADLARITY        | DONEPEZIL HYDROCHLORIDE TD PATCH WEEKLY 10<br>MG/DAY | 62051025108830 | Brand         |

#### **Approval Criteria**

1 - Diagnosis of dementia associated with Alzheimer's disease

#### **AND**

**2** - Trial and failure, intolerance, or contraindication to two oral acetylcholinesterase inhibitors (eg donepezil, galantamine), one of which must be donepezil

#### **AND**

**3** - Trial and failure, intolerance, or contraindication to an acetylcholinesterase inhibitor patch (eg rivastigmine patch)

| Product Name: Adlarity |                                     |  |
|------------------------|-------------------------------------|--|
| Approval Length        | 12 month(s)                         |  |
| Therapy Stage          | Reauthorization                     |  |
| Guideline Type         | Prior Authorization-IL and MN plans |  |

| Product<br>Name | Generic Name   | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| ADLARITY        | DONEPEZIL HYDROCHLORIDE TD PATCH WEEKLY 5<br>MG/DAY  | 62051025108820 | Brand         |
| ADLARITY        | DONEPEZIL HYDROCHLORIDE TD PATCH WEEKLY 10<br>MG/DAY | 62051025108830 | Brand         |

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug

# 2. Revision History

| Date      | Notes       |
|-----------|-------------|
| 9/20/2023 | New Program |

| 1 | Afrezza (Insulin Regular, Human)   |  |  |  |  |  |
|---|--|--|--|--|--|--|
|   | Deliverage were higher to the treatment of some left with the particle would derive to |  |  |  |  |  |

# **Prior Authorization Guideline**

| Guideline ID          | GL-129628                        |  |
|-----------------------|----------------------------------|--|
| <b>Guideline Name</b> | Afrezza (Insulin Regular, Human) |  |
| Formulary             | Quartz                           |  |

# **Guideline Note:**

| Effective Date: |
|-----------------|
|-----------------|

# 1. Criteria

| Product Name: Afrezza                                |                       |  |
|--|-----------------------|--|
| Approval Length                                      | 12 month(s)           |  |
| Therapy Stage  | Initial Authorization |  |
| Guideline Type Prior Authorization - IL and MN Plans |                       |  |

| Product<br>Name   | Generic Name  | GPI            | Brand/Generic |
|---|---|----------------|---------------|
| AFREZZA INSULIN REGULAR (HUMAN) INHALATION POWDER 4 27104010002940 Brand UNIT/CARTRIDGE |   | Brand          |               |
| AFREZZA   | INSULIN REGULAR (HUMAN) INHALATION POWDER 8 UNIT/CARTRIDGE  | 27104010002950 | Brand         |
| AFREZZA   | INSULIN REGULAR (HUMAN) INHALATION POWDER 12 UNIT/CARTRIDGE | 27104010002955 | Brand         |
| AFREZZA INSULIN REGULAR (HUMAN) INHAL POWD 90 X 4 UNIT 2710401000293                    |   | 27104010002978 | Brand         |

| AFREZZA | INSULIN REGULAR (HUMAN) INH POWD 90 X 8 UNIT & 90 X 12 UNIT  | 27104010002988 | Brand |
|---------|--|----------------|-------|
| AFREZZA | INSULIN REGULAR (HUMAN) INH POWD 60X4 & 60X8 & 60X12 UT/CART | 27104010002990 | Brand |

1 - Diagnosis of diabetes mellitus

#### **AND**

2 - Prescription is initiated by, or in consultation with, an Endocrinologist

#### **AND**

**3** - Documented disability that does not physically allow the administration of insulin from conventional vials or pens

#### **AND**

4 - Does not have a documented chronic lung disease (asthma, COPD, etc.)

#### **AND**

5 - Is a nonsmoker

| Product Name: Afrezza             |  |   |                |               |
|-----------------------------------|--|---|----------------|---------------|
| Approval Length                   |  | 12 month(s)                               |                |               |
| Therapy Stage                     |  | Reauthorization                           |                |               |
| Guideline Type                    |  | Prior Authorization - IL and MN Plans     |                |               |
| Product Generic Na<br>Name        |  | ime                                       | GPI            | Brand/Generic |
| AFREZZA INSULIN REG<br>UNIT/CARTR |  | GULAR (HUMAN) INHALATION POWDER 4<br>IDGE | 27104010002940 | Brand         |

| AFREZZA | INSULIN REGULAR (HUMAN) INHALATION POWDER 8 UNIT/CARTRIDGE   | 27104010002950 | Brand |
|---------|--|----------------|-------|
| AFREZZA | INSULIN REGULAR (HUMAN) INHALATION POWDER 12 UNIT/CARTRIDGE  | 27104010002955 | Brand |
| AFREZZA | INSULIN REGULAR (HUMAN) INHAL POWD 90 X 4 UNIT & 90 X 8 UNIT | 27104010002978 | Brand |
| AFREZZA | INSULIN REGULAR (HUMAN) INH POWD 90 X 8 UNIT & 90 X 12 UNIT  | 27104010002988 | Brand |
| AFREZZA | INSULIN REGULAR (HUMAN) INH POWD 60X4 & 60X8 & 60X12 UT/CART | 27104010002990 | Brand |

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug.

| Product Name: Afrezza |  |  |
|-----------------------|--|--|
| Approval Length       | 12/31/2039                                       |  |
| Guideline Type        | Prior Authorization - All plans except IL and MN |  |

| Product<br>Name | Generic Name   | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| AFREZZA         | INSULIN REGULAR (HUMAN) INHALATION POWDER 4 UNIT/CARTRIDGE   | 27104010002940 | Brand         |
| AFREZZA         | INSULIN REGULAR (HUMAN) INHALATION POWDER 8 UNIT/CARTRIDGE   | 27104010002950 | Brand         |
| AFREZZA         | INSULIN REGULAR (HUMAN) INHALATION POWDER 12 UNIT/CARTRIDGE  | 27104010002955 | Brand         |
| AFREZZA         | INSULIN REGULAR (HUMAN) INHAL POWD 90 X 4 UNIT & 90 X 8 UNIT | 27104010002978 | Brand         |
| AFREZZA         | INSULIN REGULAR (HUMAN) INH POWD 90 X 8 UNIT & 90 X 12 UNIT  | 27104010002988 | Brand         |
| AFREZZA         | INSULIN REGULAR (HUMAN) INH POWD 60X4 & 60X8 & 60X12 UT/CART | 27104010002990 | Brand         |

### **Approval Criteria**

1 - Diagnosis of diabetes mellitus

### **AND**

2 - Prescription is initiated by, or in consultation with, an Endocrinologist

#### AND

**3** - Documented disability that does not physically allow the administration of insulin from conventional vials or pens

#### **AND**

4 - Does not have a documented chronic lung disease (asthma, COPD, etc.)

#### **AND**

5 - Is a nonsmoker

| Date      | Notes       |
|-----------|-------------|
| 10/6/2023 | New Program |

| Alosetron  |
|--|
| The best and required to be being the boundary to come a select to the property of the security of the securit |
|  |
|  |

| Guideline ID          | GL-136350 |
|-----------------------|-----------|
| <b>Guideline Name</b> | Alosetron |
| Formulary             | Quartz    |

### **Guideline Note:**

| Effective Date: |
|-----------------|
|-----------------|

### 1. Criteria

| Product Name: Generic Alosetron |                                       |
|---------------------------------|---------------------------------------|
| Approval Length                 | 12 month(s)                           |
| Therapy Stage                   | Initial Authorization                 |
| Guideline Type                  | Prior Authorization - IL and MN Plans |

| Product Name               | Generic Name                          | GPI            | Brand/Generic |
|----------------------------|---------------------------------------|----------------|---------------|
| ALOSETRON<br>HYDROCHLORIDE | ALOSETRON HCL TAB 0.5 MG (BASE EQUIV) | 52554015100310 | Generic       |
| ALOSETRON<br>HYDROCHLORIDE | ALOSETRON HCL TAB 1 MG (BASE EQUIV)   | 52554015100320 | Generic       |

### **Approval Criteria**

1 - Diagnosis of diarrhea- predominant irritable bowel syndrome (IBS)

#### AND

2 - Member is female

#### AND

**3** - Trial and failure of one-month trial of conventional therapy (such as loperamide or diphenoxylate/atropine)

| Product Name: Generic Alosetron |                                       |  |
|---------------------------------|---------------------------------------|--|
| Approval Length                 | 12 month(s)                           |  |
| Therapy Stage                   | Reauthorization                       |  |
| Guideline Type                  | Prior Authorization - IL and MN Plans |  |

| Product Name               | Generic Name                          | GPI            | Brand/Generic |
|----------------------------|---------------------------------------|----------------|---------------|
| ALOSETRON<br>HYDROCHLORIDE | ALOSETRON HCL TAB 0.5 MG (BASE EQUIV) | 52554015100310 | Generic       |
| ALOSETRON<br>HYDROCHLORIDE | ALOSETRON HCL TAB 1 MG (BASE EQUIV)   | 52554015100320 | Generic       |

### **Approval Criteria**

 ${f 1}$  - Submission of medical notes (e.g., chart notes) from the past 12 months that the person is continuing therapy with the requested medication

| Product Name: Generic Alosetron |  |
|---------------------------------|--|
| Approval Length                 | 12/31/2039                                       |
| Guideline Type                  | Prior Authorization - All Plans except IL and MN |

| Product Name               | Generic Name                          | GPI            | Brand/Generic |
|----------------------------|---------------------------------------|----------------|---------------|
| ALOSETRON<br>HYDROCHLORIDE | ALOSETRON HCL TAB 0.5 MG (BASE EQUIV) | 52554015100310 | Generic       |
| ALOSETRON<br>HYDROCHLORIDE | ALOSETRON HCL TAB 1 MG (BASE EQUIV)   | 52554015100320 | Generic       |

- **1** One of the following:
- **1.1** All of the following:
- **1.1.1** Diagnosis of diarrhea- predominant irritable bowel syndrome (IBS)

**AND** 

1.1.2 Member is female

AND

**1.1.3** Trial and failure of one-month trial of conventional therapy (such as loperamide or diphenoxylate/atropine)

OR

**1.2** Member is new to the plan (within the past 90 days) and submission of medical notes (e.g., chart notes) from the past 12 months that the person is continuing therapy with the requested medication

| Date       | Notes       |
|------------|-------------|
| 11/15/2023 | New Program |

| Ampyra (Dalfampridine)                                |  |  |  |  |
|---|--|--|--|--|
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| Guideline ID   | GL-129138              |
|----------------|------------------------|
| Guideline Name | Ampyra (Dalfampridine) |
| Formulary      | Quartz                 |

## **Guideline Note:**

| Effective Date: |
|-----------------|
|-----------------|

### 1. Criteria

| Product Name: Generic Dalfampridine |                       |
|-------------------------------------|-----------------------|
| Approval Length                     | 12 month(s)           |
| Therapy Stage                       | Initial Authorization |
| Guideline Type                      | Prior Authorization   |

| Product Name        | Generic Name                    | GPI            | Brand/Generic |
|---------------------|---------------------------------|----------------|---------------|
| DALFAMPRIDINE<br>ER | DALFAMPRIDINE TAB ER 12HR 10 MG | 62406030007420 | Generic       |

### **Approval Criteria**

1 - Diagnosis of multiple sclerosis

#### **AND**

2 - Person is ambulatory with or without assistance

#### AND

**3** - Baseline assessment (ex: timed 25-foot walk) or supporting documentation indicating difficulty ambulating (ex: gait contributing to falls, etc.)

| Product Name: Generic Dalfampridine |                     |
|-------------------------------------|---------------------|
| Approval Length                     | 12 month(s)         |
| Therapy Stage                       | Reauthorization     |
| Guideline Type                      | Prior Authorization |

| Product Name        | Generic Name                    | GPI            | Brand/Generic |
|---------------------|---------------------------------|----------------|---------------|
| DALFAMPRIDINE<br>ER | DALFAMPRIDINE TAB ER 12HR 10 MG | 62406030007420 | Generic       |

### **Approval Criteria**

**1** - Prescriber provides clinical documentation from the previous 12 months that the person has a diagnosis of multiple sclerosis and remains ambulatory (with or without assistance).

| Date      | Notes       |
|-----------|-------------|
| 9/20/2023 | New Program |

| Antifibrotic Agents  |  |
|--|--|
| The Marketing are an integral to be the marketin man of most of the first thing provides considerations. |  |

| Guideline ID          | GL-129091           |
|-----------------------|---------------------|
| <b>Guideline Name</b> | Antifibrotic Agents |
| Formulary             | Quartz              |

### **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

### 1. Criteria

| Product Name: Generic pirfenidone                                     |  |  |
|---|--|--|
| Approval Length 12/31/2039  |  |  |
| Guideline Type Prior Authorization - All plans except IL and MN Plans |  |  |

| Product<br>Name | Generic Name           | GPI            | Brand/Generic |
|-----------------|------------------------|----------------|---------------|
| PIRFENIDONE     | PIRFENIDONE CAP 267 MG | 45550060000120 | Generic       |
| PIRFENIDONE     | PIRFENIDONE TAB 267 MG | 45550060000325 | Generic       |
| PIRFENIDONE     | PIRFENIDONE TAB 801 MG | 45550060000345 | Generic       |

### **Approval Criteria**

1 - Diagnosis of idiopathic pulmonary fibrosis (IPF) confirmed by high-resolution computed

| tomography    |
|---------------|
|               |
|               |
| torriograpity |

#### **AND**

2 - Member is 18 years of age or older

#### **AND**

3 - Prescribed by or in consultation with a pulmonologist

| Product Name: Generic pirfenidone |                                       |  |
|-----------------------------------|---------------------------------------|--|
| Approval Length                   | 12 month(s)                           |  |
| Therapy Stage                     | Initial Authorization                 |  |
| Guideline Type                    | Prior Authorization - IL and MN Plans |  |

| Product<br>Name | Generic Name           | GPI            | Brand/Generic |
|-----------------|------------------------|----------------|---------------|
| PIRFENIDONE     | PIRFENIDONE CAP 267 MG | 45550060000120 | Generic       |
| PIRFENIDONE     | PIRFENIDONE TAB 267 MG | 45550060000325 | Generic       |
| PIRFENIDONE     | PIRFENIDONE TAB 801 MG | 45550060000345 | Generic       |

### **Approval Criteria**

 ${\bf 1}$  - Diagnosis of idiopathic pulmonary fibrosis (IPF) confirmed by high-resolution computed tomography

#### **AND**

2 - Member is 18 years of age or older

#### **AND**

**3** - Prescribed by or in consultation with a pulmonologist

| Product Name: Ofev  |  |  |
|---|--|--|
| Approval Length 12/31/2039  |  |  |
| Guideline Type Prior Authorization - All plans except IL and MN Plans |  |  |

| Product<br>Name | Generic Name                                    | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| OFEV            | NINTEDANIB ESYLATE CAP 100 MG (BASE EQUIVALENT) | 45554050200120 | Brand         |
| OFEV            | NINTEDANIB ESYLATE CAP 150 MG (BASE EQUIVALENT) | 45554050200130 | Brand         |

- **1** ONE of the following:
- **1.1** Diagnosis of idiopathic pulmonary fibrosis (IPF) confirmed by high-resolution computed tomography

OR

1.2 Chronic Fibrosing Interstitial Lung Diseases with a Progressive Phenotype

OR

- **1.3** Both of the following:
  - Diagnosis of systemic sclerosis associated lung disease (SSc-ILD)
  - Trial and failure, contraindication or intolerance to cyclophosphamide

**AND** 

2 - Member is 18 years of age or older

**AND** 

3 - Prescribed by or in consultation with a pulmonologist

| Product Name: Ofev |                                       |  |
|--------------------|---------------------------------------|--|
| Approval Length    | 12 month(s)                           |  |
| Therapy Stage      | Initial Authorization                 |  |
| Guideline Type     | Prior Authorization - IL and MN Plans |  |

| Product<br>Name | Generic Name                                    | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| OFEV            | NINTEDANIB ESYLATE CAP 100 MG (BASE EQUIVALENT) | 45554050200120 | Brand         |
| OFEV            | NINTEDANIB ESYLATE CAP 150 MG (BASE EQUIVALENT) | 45554050200130 | Brand         |

- 1 ONE of the following:
- **1.1** Diagnosis of idiopathic pulmonary fibrosis (IPF) confirmed by high-resolution computed tomography

OR

1.2 Chronic Fibrosing Interstitial Lung Diseases with a Progressive Phenotype

OR

- **1.3** Both of the following:
  - Diagnosis of systemic sclerosis associated lung disease (SSc-ILD)
  - Trial and failure, contraindication or intolerance to cyclophosphamide

**AND** 

2 - Member is 18 years of age or older

**AND** 

3 - Prescribed by or in consultation with a pulmonologist

| Product Name: Generic pirfenidone, Ofev |                                       |  |
|---|---------------------------------------|--|
| Approval Length 12 month(s)             |                                       |  |
| Therapy Stage Reauthorization           |                                       |  |
| Guideline Type                          | Prior Authorization - IL and MN Plans |  |

| Product<br>Name | Generic Name                                    | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| PIRFENIDONE     | PIRFENIDONE CAP 267 MG                          | 45550060000120 | Generic       |
| PIRFENIDONE     | PIRFENIDONE TAB 267 MG                          | 45550060000325 | Generic       |
| PIRFENIDONE     | PIRFENIDONE TAB 801 MG                          | 45550060000345 | Generic       |
| OFEV            | NINTEDANIB ESYLATE CAP 100 MG (BASE EQUIVALENT) | 45554050200120 | Brand         |
| OFEV            | NINTEDANIB ESYLATE CAP 150 MG (BASE EQUIVALENT) | 45554050200130 | Brand         |

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug

| Date      | Notes                   |
|-----------|-------------------------|
| 9/19/2023 | 2024 New Implementation |

| Arikayce (amikacin inhaled)  |  |  |  |
|--|--|--|--|
| (2) Substituting and subsigns for the sequence of substituting and substitution and substit |  |  |  |

| Guideline ID          | GL-128153                   |  |
|-----------------------|-----------------------------|--|
| <b>Guideline Name</b> | Arikayce (amikacin inhaled) |  |
| Formulary             | Quartz                      |  |

### **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

### 1. Criteria

| Product Name: Arikayce*                                   |  |  |
|---|--|--|
| Approval Length 12 month(s)                               |  |  |
| Therapy Stage Initial Authorization                       |  |  |
| Guideline Type Prior Authorization - IL and MN Plans Only |  |  |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| ARIKAYCE        | AMIKACIN SULFATE LIPOSOME INHAL SUSP 590 MG/8.4ML (BASE EQ) | 07000010121830 | Brand         |

### **Approval Criteria**

1 - Diagnosis of Mycobacterium avium complex (MAC) lung disease

#### **AND**

2 - Prescribed by, or in consultation with, an Infectious Disease expert

#### **AND**

**3** - Submission of medical records (e.g., chart notes) of positive sputum cultures despite at least 6 months of multidrug background therapy

| *Member new to the plan (as evidenced by coverage effective date of I ess than or equal to 90 days) who initiated therapy using a manufactur er-sponsored free drug program, provider samples, and/or vouchers wil I go through initial criteria, otherwise for continuation of therapy for new |
|---|
| to plan, reauthorization criteria applies   |

| Product Name: Arikayce*             |  |  |
|-------------------------------------|--|--|
| Approval Length 6 month(s)          |  |  |
| Therapy Stage Initial Authorization |  |  |
| Guideline Type                      | Prior Authorization - All Plans except IL and MN |  |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| ARIKAYCE        | AMIKACIN SULFATE LIPOSOME INHAL SUSP 590 MG/8.4ML (BASE EQ) | 07000010121830 | Brand         |

#### **Approval Criteria**

1 - Diagnosis of Mycobacterium avium complex (MAC) lung disease

#### **AND**

2 - Prescribed by, or in consultation with, an Infectious Disease expert

#### **AND**

| <b>3</b> - Submission of medical records (e.g., chart notes) of positive sputum cultures despite at least 6 months of multidrug background therapy |   |  |
|--|---|--|
| Notes  | *Member new to the plan (as evidenced by coverage effective date of I ess than or equal to 90 days) who initiated therapy using a manufactur er-sponsored free drug program, provider samples, and/or vouchers wil I go through initial criteria, otherwise for continuation of therapy for new to plan, reauthorization criteria applies |  |

| Product Name: Arikayce*       |                     |  |
|-------------------------------|---------------------|--|
| Approval Length 12 month(s)   |                     |  |
| Therapy Stage Reauthorization |                     |  |
| Guideline Type                | Prior Authorization |  |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| ARIKAYCE        | AMIKACIN SULFATE LIPOSOME INHAL SUSP 590 MG/8.4ML (BASE EQ) | 07000010121830 | Brand         |

1 - Diagnosis of Mycobacterium avium complex (MAC) lung disease

#### **AND**

2 - Prescribed by, or in consultation with, an Infectious Disease expert

#### **AND**

3 - Person achieves and/or maintains negative sputum culture status by 6 months

| Notes | *Member new to the plan (as evidenced by coverage effective date of I ess than or equal to 90 days) who initiated therapy using a manufactur er-sponsored free drug program, provider samples, and/or vouchers wil I go through initial criteria, otherwise for continuation of therapy for new |
|-------|---|
|       | to plan, reauthorization criteria applies   |

| Date      | Notes       |
|-----------|-------------|
| 11/3/2023 | New Program |

| Atac                            | and (c  | andes   | artan)              |  |  |
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|                                 |   |   |                     |  |  |

| Guideline ID          | GL-128902             |
|-----------------------|-----------------------|
| <b>Guideline Name</b> | Atacand (candesartan) |
| Formulary             | Quartz                |

# **Guideline Note:**

| Effective Date: |
|-----------------|
|-----------------|

## 1. Criteria

| Product Name: Generic Candesartan            |            |   |                |               |
|--|------------|---|----------------|---------------|
| Approval Length                              | 12/31/203  | 12/31/2039  |                |               |
| Guideline Type                               | Prior Auth | Prior Authorization - All plans except IL and MN                |                |               |
| Product Name                                 |            | Generic Name  | GPI            | Brand/Generic |
| CANDESARTAN CILEXETIL                        |            | CANDESARTAN CILEXETIL<br>TAB 4 MG                               | 36150020100310 | Generic       |
| CANDESARTAN CILEXETIL                        |            | CANDESARTAN CILEXETIL<br>TAB 8 MG                               | 36150020100320 | Generic       |
| CANDESARTAN CILEXETIL                        |            | CANDESARTAN CILEXETIL<br>TAB 16 MG                              | 36150020100330 | Generic       |
| CANDESARTAN CILEXETIL                        |            | CANDESARTAN CILEXETIL<br>TAB 32 MG                              | 36150020100340 | Generic       |
| CANDESARTAN<br>CILEXETIL/HYDROCHLOROTHIAZIDE |            | CANDESARTAN CILEXETIL-<br>HYDROCHLOROTHIAZIDE<br>TAB 16-12.5 MG | 36994002200320 | Generic       |

| CANDESARTAN<br>CILEXETIL/HYDROCHLOROTHIAZIDE | CANDESARTAN CILEXETIL-<br>HYDROCHLOROTHIAZIDE<br>TAB 32-12.5 MG | 36994002200340 | Generic |
|--|---|----------------|---------|
| CANDESARTAN<br>CILEXETIL/HYDROCHLOROTHIAZIDE | CANDESARTAN CILEXETIL-<br>HYDROCHLOROTHIAZIDE<br>TAB 32-25 MG   | 36994002200350 | Generic |

1 - Diagnosis of heart failure

| Product Name: Generic Candesartan |                       |
|-----------------------------------|-----------------------|
| Approval Length                   | 12 month(s)           |
| Therapy Stage                     | Initial Authorization |
| Guideline Type                    | IL and MN Plans Only  |

| Product Name                                 | Generic Name  | GPI            | Brand/Generic |
|--|---|----------------|---------------|
| CANDESARTAN CILEXETIL                        | CANDESARTAN CILEXETIL<br>TAB 4 MG                               | 36150020100310 | Generic       |
| CANDESARTAN CILEXETIL                        | CANDESARTAN CILEXETIL<br>TAB 8 MG                               | 36150020100320 | Generic       |
| CANDESARTAN CILEXETIL                        | CANDESARTAN CILEXETIL<br>TAB 16 MG                              | 36150020100330 | Generic       |
| CANDESARTAN CILEXETIL                        | CANDESARTAN CILEXETIL<br>TAB 32 MG                              | 36150020100340 | Generic       |
| CANDESARTAN<br>CILEXETIL/HYDROCHLOROTHIAZIDE | CANDESARTAN CILEXETIL-<br>HYDROCHLOROTHIAZIDE<br>TAB 16-12.5 MG | 36994002200320 | Generic       |
| CANDESARTAN<br>CILEXETIL/HYDROCHLOROTHIAZIDE | CANDESARTAN CILEXETIL-<br>HYDROCHLOROTHIAZIDE<br>TAB 32-12.5 MG | 36994002200340 | Generic       |
| CANDESARTAN<br>CILEXETIL/HYDROCHLOROTHIAZIDE | CANDESARTAN CILEXETIL-<br>HYDROCHLOROTHIAZIDE<br>TAB 32-25 MG   | 36994002200350 | Generic       |

## **Approval Criteria**

1 - Diagnosis of heart failure

Product Name: Generic Candesartan

| Approval Length | 12 month(s)                           |
|-----------------|---------------------------------------|
| Therapy Stage   | Reauthorization                       |
| Guideline Type  | Prior Authorization - IL and MN Plans |

| Product Name                                 | Generic Name  | GPI            | Brand/Generic |
|--|---|----------------|---------------|
| CANDESARTAN CILEXETIL                        | CANDESARTAN CILEXETIL<br>TAB 4 MG                               | 36150020100310 | Generic       |
| CANDESARTAN CILEXETIL                        | CANDESARTAN CILEXETIL<br>TAB 8 MG                               | 36150020100320 | Generic       |
| CANDESARTAN CILEXETIL                        | CANDESARTAN CILEXETIL<br>TAB 16 MG                              | 36150020100330 | Generic       |
| CANDESARTAN CILEXETIL                        | CANDESARTAN CILEXETIL<br>TAB 32 MG                              | 36150020100340 | Generic       |
| CANDESARTAN<br>CILEXETIL/HYDROCHLOROTHIAZIDE | CANDESARTAN CILEXETIL-<br>HYDROCHLOROTHIAZIDE<br>TAB 16-12.5 MG | 36994002200320 | Generic       |
| CANDESARTAN<br>CILEXETIL/HYDROCHLOROTHIAZIDE | CANDESARTAN CILEXETIL-<br>HYDROCHLOROTHIAZIDE<br>TAB 32-12.5 MG | 36994002200340 | Generic       |
| CANDESARTAN<br>CILEXETIL/HYDROCHLOROTHIAZIDE | CANDESARTAN CILEXETIL-<br>HYDROCHLOROTHIAZIDE<br>TAB 32-25 MG   | 36994002200350 | Generic       |

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug.

| Date      | Notes       |
|-----------|-------------|
| 9/26/2023 | New Program |

| Auryxia (Ferric Citrate)   |  |  |  |
|--|--|--|--|
| The State Stranger commission for the State State Council, council, a state like State Sta |  |  |  |
|  |  |  |  |

| Guideline ID          | GL-129081                |
|-----------------------|--------------------------|
| <b>Guideline Name</b> | Auryxia (Ferric Citrate) |
| Formulary             | Quartz                   |

### **Guideline Note:**

| Effective Date: |
|-----------------|
|-----------------|

### 1. Criteria

| Product Name: Auryxia |  |                 |               |
|-----------------------|--|-----------------|---------------|
| Approval Length       | 12/31/2039                             |                 |               |
| Guideline Type        | Prior Authorization - All Plans Except | IL and MN Plans |               |
| Product Generic Na    | ame                                    | GPI             | Brand/Generic |

| Product<br>Name | Generic Name                                 | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| AURYXIA         | FERRIC CITRATE TAB 1 GM (210 MG FERRIC IRON) | 52800030100320 | Brand         |

### **Approval Criteria**

- 1 One of the following:
- **1.1** All of the following:
- 1.1.1 Diagnosis of chronic kidney disease (CKD)

| AND   |
|---|
| 1.1.2 Member has hyperphosphatemia requiring dialysis   |
| AND   |
| 1.1.3 Trial and failure or intolerance (e.g. side effects) from Both of the following:  |
| <ul><li>Sevelamer product (i.e., Renagel, Renvela)</li><li>Fosrenol (lanthanum)</li></ul>   |
| OR  |
| 1.2 All of the following:   |
| 1.2.1 Diagnosis of iron deficiency anemia   |
| AND   |
| 1.2.2 Member has chronic kidney disease (CKD)   |
| AND   |
| 1.2.3 Memebr is not on dialysis   |
| AND   |
| <b>1.2.4</b> Trial and failure, or intolerance (e.g. side effects) to at least 2 forms of oral iron products (i.e., ferrous sulfate, polysaccharide complex, ferrous fumarate, ferrous gluconate) |

| Product Name: Auryxia |                       |
|-----------------------|-----------------------|
| Approval Length       | 12 month(s)           |
| Therapy Stage         | Initial Authorization |

| Guideline Type      |                | Prior Authorization - IL and MN Plans* |                |               |
|---------------------|----------------|--|----------------|---------------|
| Product<br>Name     | d Generic Name |  | GPI            | Brand/Generic |
| AURYXIA FERRIC CITE |                | RATE TAB 1 GM (210 MG FERRIC IRON)     | 52800030100320 | Brand         |
|                     |                |  |                |               |

- 1 One of the following:
- **1.1** All of the following:
- **1.1.1** Diagnosis of chronic kidney disease (CKD)

AND

1.1.2 Member has hyperphosphatemia requiring dialysis

#### **AND**

- **1.1.3** Trial and failure or intolerance (e.g. side effects) from Both of the following:
  - Sevelamer product (i.e., Renagel, Renvela)
  - Fosrenol (lanthanum)

OR

- **1.2** All of the following:
- **1.2.1** Diagnosis of iron deficiency anemia

**AND** 

**1.2.2** Member has chronic kidney disease (CKD)

**AND** 

### 1.2.3 Member is not on dialysis

#### **AND**

**1.2.4** Trial and failure, or intolerance (e.g. side effects) to at least 2 forms of oral iron products (i.e., ferrous sulfate, polysaccharide complex, ferrous fumarate, ferrous gluconate)

| Notes | *Members new to the plan (as evidenced by coverage effective date of   |
|-------|--|
|       | less than or equal to 90 days) must meet the initial criteria coverage |

| Product Name: Auryxia |  |
|-----------------------|--|
| Approval Length       | 12 month(s)                            |
| Therapy Stage         | Reauthorization                        |
| Guideline Type        | Prior Authorization - IL and MN Plans* |

| Product<br>Name | Generic Name                                 | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| AURYXIA         | FERRIC CITRATE TAB 1 GM (210 MG FERRIC IRON) | 52800030100320 | Brand         |

#### **Approval Criteria**

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug

| Notes | *Members new to the plan (as evidenced by coverage effective date of   |
|-------|--|
|       | less than or equal to 90 days) must meet the initial criteria coverage |

| Date      | Notes                   |
|-----------|-------------------------|
| 8/23/2023 | 2024 New Implementation |

| Austedo (deutetrabenazine)   |  |  |
|--|--|--|
| The behavior and the behavior of the section of the sec |  |  |

| Guideline ID          | GL-129069                  |
|-----------------------|----------------------------|
| <b>Guideline Name</b> | Austedo (deutetrabenazine) |
| Formulary             | Quartz                     |

# **Guideline Note:**

| Effective Date: |
|-----------------|
|-----------------|

## 1. Criteria

| Product Name: Austedo, Austedo XR |  |  |
|-----------------------------------|--|--|
| Approval Length                   | 12/31/2039   |  |
| Guideline Type                    | Prior Authorization - All Plans Except IL and MN Plans |  |

| Product<br>Name                              | Generic Name   | GPI            | Brand/Generic |
|--|--|----------------|---------------|
| AUSTEDO<br>PATIENT<br>TITRATION<br>KIT       | DEUTETRABENAZINE TAB TITRATION PACK 6 MG & 9 MG & 12 MG        | 6238003000B720 | Brand         |
| AUSTEDO<br>XR<br>PATIENT<br>TITRATION<br>KIT | DEUTETRABENAZINE TAB ER TITRATION PACK 6 MG<br>& 12 MG & 24 MG | 6238003000C120 | Brand         |
| AUSTEDO                                      | DEUTETRABENAZINE TAB 6 MG                                      | 62380030000310 | Brand         |

| AUSTEDO       | DEUTETRABENAZINE TAB 9 MG          | 62380030000320 | Brand |
|---------------|------------------------------------|----------------|-------|
| AUSTEDO       | DEUTETRABENAZINE TAB 12 MG         | 62380030000330 | Brand |
| AUSTEDO<br>XR | DEUTETRABENAZINE TAB ER 24HR 6 MG  | 62380030007510 | Brand |
| AUSTEDO<br>XR | DEUTETRABENAZINE TAB ER 24HR 12 MG | 62380030007520 | Brand |
| AUSTEDO<br>XR | DEUTETRABENAZINE TAB ER 24HR 24 MG | 62380030007530 | Brand |

- 1 One of the following:
- **1.1** All of the following:
- 1.1.1 Diagnosis of chorea associated with Huntington's disease

#### **AND**

**1.1.2** Prescribed by or in consultation with a neurologist or other expert in the treatment of Huntington's disease

OR

- **1.2** All of the following:
- 1.2.1 Diagnosis of tardive dyskinesia

**AND** 

- **1.2.2** One of the following:
  - Symptoms persist despite discontinuation of the offending dopamine receptor blocking drug
  - Submission of medical records (e.g. chart notes) why discontinuation of the drug is not a treatment option for the person based on their diagnosis and previous treatment history

**AND** 

**1.2.3** Trial and inadequate response to clonazepam (e.g., did not control symptoms, caused significant side effects)

#### **AND**

**1.2.4** Trial and failure, contraindication or intolerance to an adequate trial of trihexyphenidyl with documentation of tardive dystonia

#### **AND**

**1.2.5** Prescribed by or in consultation with a neurologist or other expert in the treatment of tardive dyskinesia/movement disorders

| Product Name: Austedo, Austedo XR |  |
|-----------------------------------|--|
| Approval Length                   | 12 month(s)                            |
| Therapy Stage                     | Initial Authorization                  |
| Guideline Type                    | Prior Authorization - IL and MN Plans* |

| Product<br>Name                              | Generic Name   | GPI            | Brand/Generic |
|--|--|----------------|---------------|
| AUSTEDO<br>PATIENT<br>TITRATION<br>KIT       | DEUTETRABENAZINE TAB TITRATION PACK 6 MG & 9 MG & 12 MG        | 6238003000B720 | Brand         |
| AUSTEDO<br>XR<br>PATIENT<br>TITRATION<br>KIT | DEUTETRABENAZINE TAB ER TITRATION PACK 6 MG<br>& 12 MG & 24 MG | 6238003000C120 | Brand         |
| AUSTEDO                                      | DEUTETRABENAZINE TAB 6 MG                                      | 62380030000310 | Brand         |
| AUSTEDO                                      | DEUTETRABENAZINE TAB 9 MG                                      | 62380030000320 | Brand         |
| AUSTEDO                                      | DEUTETRABENAZINE TAB 12 MG                                     | 62380030000330 | Brand         |
| AUSTEDO<br>XR                                | DEUTETRABENAZINE TAB ER 24HR 6 MG                              | 62380030007510 | Brand         |
| AUSTEDO<br>XR                                | DEUTETRABENAZINE TAB ER 24HR 12 MG                             | 62380030007520 | Brand         |
| AUSTEDO<br>XR                                | DEUTETRABENAZINE TAB ER 24HR 24 MG                             | 62380030007530 | Brand         |

| Approval Criteria   |
|---|
| 1 - One of the following:   |
| 1.1 All of the following:   |
| 1.1.1 Diagnosis of chorea associated with Huntington's disease  |
| AND   |
| <b>1.1.2</b> Prescribed by or in consultation with a neurologist or other expert in the treatment of Huntington's disease   |
| OR  |
| 1.2 All of the following:   |
| 1.2.1 Diagnosis of tardive dyskinesia   |
| AND   |
| 1.2.2 One of the following:   |
| Symptoms persist despite discontinuation of the offending dopamine receptor blocking  |
| <ul> <li>Submission of medical records (e.g. chart notes) why discontinuation of the drug is not a treatment option for the person based on their diagnosis and previous treatment history</li> </ul> |
| AND   |
| <b>1.2.3</b> Trial and inadequate response to clonazepam (e.g., did not control symptoms, caused significant side effects)  |
| AND   |
| <b>1.2.4</b> Trial and failure, contraindication or intolerance to an adequate trial of trihexyphenidyl   |

with documentation of tardive dystonia

#### **AND**

**1.2.5** Prescribed by or in consultation with a neurologist or other expert in the treatment of tardive dyskinesia/movement disorders

| Notes | *Members new to the plan (as evidenced by coverage effective date of   |
|-------|--|
|       | less than or equal to 90 days) must meet initial criteria for coverage |

| Product Name: Austedo, Austedo XR |  |
|-----------------------------------|--|
| Approval Length                   | 12 month(s)                            |
| Therapy Stage                     | Reauthorization                        |
| Guideline Type                    | Prior Authorization - IL and MN Plans* |

| Product<br>Name                              | Generic Name   | GPI            | Brand/Generic |
|--|--|----------------|---------------|
| AUSTEDO<br>PATIENT<br>TITRATION<br>KIT       | DEUTETRABENAZINE TAB TITRATION PACK 6 MG & 9 MG & 12 MG        | 6238003000B720 | Brand         |
| AUSTEDO<br>XR<br>PATIENT<br>TITRATION<br>KIT | DEUTETRABENAZINE TAB ER TITRATION PACK 6 MG<br>& 12 MG & 24 MG | 6238003000C120 | Brand         |
| AUSTEDO                                      | DEUTETRABENAZINE TAB 6 MG                                      | 62380030000310 | Brand         |
| AUSTEDO                                      | DEUTETRABENAZINE TAB 9 MG                                      | 62380030000320 | Brand         |
| AUSTEDO                                      | DEUTETRABENAZINE TAB 12 MG                                     | 62380030000330 | Brand         |
| AUSTEDO<br>XR                                | DEUTETRABENAZINE TAB ER 24HR 6 MG                              | 62380030007510 | Brand         |
| AUSTEDO<br>XR                                | DEUTETRABENAZINE TAB ER 24HR 12 MG                             | 62380030007520 | Brand         |
| AUSTEDO<br>XR                                | DEUTETRABENAZINE TAB ER 24HR 24 MG                             | 62380030007530 | Brand         |

### **Approval Criteria**

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug

| Notes | *Members new to the plan (as evidenced by coverage effective date of |
|-------|--|
|-------|--|

less than or equal to 90 days) must meet initial criteria for coverage

| Date      | Notes                   |
|-----------|-------------------------|
| 9/20/2023 | 2024 New Implementation |

| Auvelity (dextromethorphan-buprop |   |                 |  |
|-----------------------------------|---|-----------------|--|
| The bit of image connect the or   | eliphyst. Tur fir my taes taen moust, vocamel, or diddel, litely that is its points in the execu- | with an indice. |  |
|                                   |   |                 |  |

| Guideline ID          | GL-128137                             |
|-----------------------|---------------------------------------|
| <b>Guideline Name</b> | Auvelity (dextromethorphan-bupropion) |
| Formulary             | Quartz                                |

### **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

### 1. Criteria

| Product Name: Auvelity |                                |  |
|------------------------|--------------------------------|--|
| Approval Length        | 12 month(s)                    |  |
| Therapy Stage          | Initial Authorization          |  |
| Guideline Type         | Step Therapy - IL and MN Plans |  |

| Product<br>Name | Generic Name   | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| AUVELITY        | DEXTROMETHORPHAN HBR-BUPROPION HCL TAB<br>ER 45-105 MG | 58999902300420 | Brand         |

### **Approval Criteria**

**1** - Trial and failure, contraindication, or intolerance of at least two preferred antidepressants within the Selective Serotonin Reuptake inhibitor (SSRI) or Serotonin Norepinephrine Reuptake

### inhibitor (SNRI) drug classes

- citalopram
- escitalopram
- sertraline
- paroxetine
- fluoxetine
- venlafaxine
- duloxetine

| Product Name: Auvelity      |                                |  |
|-----------------------------|--------------------------------|--|
| Approval Length 12 month(s) |                                |  |
| Therapy Stage               | Reauthorization                |  |
| Guideline Type              | Step Therapy - IL and MN Plans |  |

| Product<br>Name | Generic Name   | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| AUVELITY        | DEXTROMETHORPHAN HBR-BUPROPION HCL TAB<br>ER 45-105 MG | 58999902300420 | Brand         |

#### **Approval Criteria**

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug

| Product Name: Auvelity   |  |  |
|--|--|--|
| Approval Length 12/31/2039                                     |  |  |
| Guideline Type Step Therapy - All plans except IL and MN Plans |  |  |

| Product<br>Name | Generic Name   | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| AUVELITY        | DEXTROMETHORPHAN HBR-BUPROPION HCL TAB<br>ER 45-105 MG | 58999902300420 | Brand         |

### **Approval Criteria**

**1** - Trial and failure, contraindication, or intolerance of at least two preferred antidepressants within the Selective Serotonin Reuptake inhibitor (SSRI) or Serotonin Norepinephrine Reuptake inhibitor (SNRI) drug classes

- citalopram escitalopram sertraline
- paroxetine
- fluoxetine
- venlafaxine
- duloxetine

| Date      | Notes       |
|-----------|-------------|
| 8/21/2023 | New Program |

| Azelex, Finacea (Azelaic   | : Acid) |
|--|---------|
| (2) Instituting contribution. Both my factors and, complex sides such platforty periods accountly account. |         |

| Guideline ID          | GL-127879                      |
|-----------------------|--------------------------------|
| <b>Guideline Name</b> | Azelex, Finacea (Azelaic Acid) |
| Formulary             | Quartz                         |

## **Guideline Note:**

| Effective Date: |
|-----------------|
|-----------------|

### 1. Criteria

| Product Name: Brand Finacea, Generic Azelaic Acid, Brand Azelex |                                |
|---|--------------------------------|
| Approval Length   | 12 month(s)                    |
| Therapy Stage   | Initial Authorization          |
| Guideline Type  | Step Therapy - IL and MN Plans |

| Product<br>Name | Generic Name           | GPI            | Brand/Generic |
|-----------------|------------------------|----------------|---------------|
| AZELEX          | AZELAIC ACID CREAM 20% | 90050005103720 | Brand         |
| FINACEA         | AZELAIC ACID FOAM 15%  | 90060010003920 | Brand         |
| AZELAIC<br>ACID | AZELAIC ACID GEL 15%   | 90060010004020 | Generic       |

### **Approval Criteria**

- 1 Both of the following:
- **1.1** Trial and failure of one topical tretinoin
  - tretinoin 0.01% gel
  - tretinoin 0.025% gel/cream
  - tretinoin 0.05% gel/cream
  - tretinoin 0.1% cream

#### AND

**1.2** Trial of topical adapalene (0.1% gel/cream, 0.3% gel)

#### OR

2 - For Generic Azelaic acid 15% or Brand Finacea 15% Foam: Diagnosis of rosacea

| Product Name: Brand Finacea, Generic Azelaic Acid, Brand Azelex |                                |
|---|--------------------------------|
| Approval Length   | 12 month(s)                    |
| Therapy Stage   | Reauthorization                |
| Guideline Type  | Step Therapy - IL and MN Plans |

| Product<br>Name | Generic Name           | GPI            | Brand/Generic |
|-----------------|------------------------|----------------|---------------|
| AZELEX          | AZELAIC ACID CREAM 20% | 90050005103720 | Brand         |
| FINACEA         | AZELAIC ACID FOAM 15%  | 90060010003920 | Brand         |
| AZELAIC<br>ACID | AZELAIC ACID GEL 15%   | 90060010004020 | Generic       |

#### **Approval Criteria**

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug

| Product Name: Brand Finacea, Generic Azelaic Acid, Brand Azelex |            |
|---|------------|
| Approval Length   | 12/31/2039 |

| Guideline Type  |                        | Step Therapy - All Plans except IL and MN Plans |                |               |
|-----------------|------------------------|---|----------------|---------------|
| Product<br>Name | Generic Name           |   | GPI            | Brand/Generic |
| AZELEX          | AZELAIC ACID CREAM 20% |   | 90050005103720 | Brand         |
| FINACEA         | AZELAIC ACID FOAM 15%  |   | 90060010003920 | Brand         |
| AZELAIC<br>ACID | AZELAIC ACI            | D GEL 15%                                       | 90060010004020 | Generic       |

- 1 Both of the following:
- 1.1 Trial and failure of one topical tretinoin
  - tretinoin 0.01% gel
  - tretinoin 0.025% gel/cream tretinoin 0.05% gel/cream

  - tretinoin 0.1% cream

**AND** 

**1.2** Trial of topical adapalene (0.1% gel/cream, 0.3% gel)

OR

2 - For Generic Azelaic acid 15% or Brand Finacea 15% Foam: Diagnosis of rosacea

| Date      | Notes        |
|-----------|--------------|
| 8/25/2023 | New Programs |

| Baxdela (Delafloxacin)  |
|---|
| The State of large control to Populage on "The District resp. Sea from record, or added to State I district the District of the Control State I State |
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|   |

| Guideline ID          | GL-136393              |  |  |
|-----------------------|------------------------|--|--|
| <b>Guideline Name</b> | Baxdela (Delafloxacin) |  |  |
| Formulary             | Quartz                 |  |  |

## **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

### 1. Criteria

| Product Name: Baxdel |  |  |
|----------------------|--|--|
| Approval Length      | See Note*  |  |
| Guideline Type       | Prior Authorization - All Plans except IL and MN Plans |  |

| Product<br>Name | Generic Name   | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| BAXDELA         | DELAFLOXACIN MEGLUMINE TAB 450 MG (BASE EQUIV)         | 05000025100320 | Brand         |
| BAXDELA         | DELAFLOXACIN MEGLUMINE FOR IV SOLN 300 MG (BASE EQUIV) | 05000025102120 | Brand         |

## **Approval Criteria**

1 - One of the following:

**1.1** Person has been receiving drug during hospitalization and needs to complete the course of therapy as an outpatient.

OR

- **1.2** Both of the following:
- **1.2.1** Outpatient treatment of bacterial resistant strains as ordered by, or in documented consultation with an Infectious Disease Specialist

#### **AND**

**1.2.2** Report of cultures and susceptibilities documenting resistance to preferred alternatives needs to be provided for approval

| Product Name: Baxdela                                |  |
|--|--|
| Approval Length 12 month(s)                          |  |
| Guideline Type Prior Authorization - IL and MN Plans |  |

| Product<br>Name | Generic Name   | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| BAXDELA         | DELAFLOXACIN MEGLUMINE TAB 450 MG (BASE EQUIV)         | 05000025100320 | Brand         |
| BAXDELA         | DELAFLOXACIN MEGLUMINE FOR IV SOLN 300 MG (BASE EQUIV) | 05000025102120 | Brand         |

#### **Approval Criteria**

**1** - Person has been receiving drug during hospitalization and needs to complete the course of therapy as an outpatient.

OR

- 2 Both of the following
- **2.1** Outpatient treatment of bacterial resistant strains as ordered by, or in documented consultation with an Infectious Disease Specialist.

#### AND

**2.2** Report of cultures and susceptibilities documenting resistance to preferred alternatives needs to be provided for approval

OR

**3** - For Illinois Plans Only - the requested drug is being used for the long-term treatment of tick-borne disease

| Date       | Notes            |
|------------|------------------|
| 11/17/2023 | Update guideline |

| Belsomra (suvorexant) |   |   |  |  |  |
|-----------------------|---|---|--|--|--|
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|                       |   |   |  |  |  |

| Guideline ID GL-136538 |                       |  |
|------------------------|-----------------------|--|
| <b>Guideline Name</b>  | Belsomra (suvorexant) |  |
| Formulary              | Quartz                |  |

# **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

# 1. Criteria

| Product Name: Belsomra                                  |  |
|---|--|
| Approval Length 12 month(s)                             |  |
| Therapy Stage Initial Authorization                     |  |
| Guideline Type Prior Authorization-IL and MN Plans Only |  |

| Product<br>Name | Generic Name         | GPI            | Brand/Generic |
|-----------------|----------------------|----------------|---------------|
| BELSOMRA        | SUVOREXANT TAB 5 MG  | 60500070000305 | Brand         |
| BELSOMRA        | SUVOREXANT TAB 10 MG | 60500070000310 | Brand         |
| BELSOMRA        | SUVOREXANT TAB 15 MG | 60500070000315 | Brand         |
| BELSOMRA        | SUVOREXANT TAB 20 MG | 60500070000320 | Brand         |

1 - Person needs the medication for sleep

#### **AND**

**2** - Trial and failure, contraindication, or intolerance to two preferred alternatives (e.g., zolpidem, eszopiclone, zaleplon, trazodone, mirtazapine, quetiapine, temazepam, etc.)

| Product Name: Belsomra                                  |  |
|---|--|
| Approval Length 12 month(s)                             |  |
| Therapy Stage Reauthorization                           |  |
| Guideline Type Prior Authorization-IL and MN Plans Only |  |

| Product<br>Name | Generic Name         | GPI            | Brand/Generic |
|-----------------|----------------------|----------------|---------------|
| BELSOMRA        | SUVOREXANT TAB 5 MG  | 60500070000305 | Brand         |
| BELSOMRA        | SUVOREXANT TAB 10 MG | 60500070000310 | Brand         |
| BELSOMRA        | SUVOREXANT TAB 15 MG | 60500070000315 | Brand         |
| BELSOMRA        | SUVOREXANT TAB 20 MG | 60500070000320 | Brand         |

### **Approval Criteria**

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug.

| Product Name: Belsomra  |  |
|---|--|
| Approval Length 12/31/2039                                    |  |
| Guideline Type Prior Authorization-All plans except IL and MN |  |

| Product<br>Name | Generic Name         | GPI            | Brand/Generic |
|-----------------|----------------------|----------------|---------------|
| BELSOMRA        | SUVOREXANT TAB 5 MG  | 60500070000305 | Brand         |
| BELSOMRA        | SUVOREXANT TAB 10 MG | 60500070000310 | Brand         |
| BELSOMRA        | SUVOREXANT TAB 15 MG | 60500070000315 | Brand         |
| BELSOMRA        | SUVOREXANT TAB 20 MG | 60500070000320 | Brand         |

1 - Person needs the medication for sleep

### **AND**

**2** - Trial and failure, contraindication, or intolerance to two preferred alternatives (e.g., zolpidem, eszopiclone, zaleplon, trazodone, mirtazapine, quetiapine, temazepam, etc.)

| Date      | Notes                              |
|-----------|------------------------------------|
| 12/8/2023 | Examples included in the criteria. |

| Bexarotene  |
|---|
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|   |

| Guideline ID          | GL-128907  |
|-----------------------|------------|
| <b>Guideline Name</b> | Bexarotene |
| Formulary             | Quartz     |

# **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

### 1. Criteria

| Product Name: Generic Bexarotene Gel |  |                                       |     |               |
|--------------------------------------|--|---------------------------------------|-----|---------------|
| Approval Length                      |  | 12 month(s)                           |     |               |
| Guideline Type                       |  | Prior authorization - IL and MN Plans | 3   |               |
| Product Generic                      |  | Name                                  | GPI | Brand/Generic |

| Product<br>Name | Generic Name      | GPI            | Brand/Generic |
|-----------------|-------------------|----------------|---------------|
| BEXAROTENE      | BEXAROTENE GEL 1% | 90376220004020 | Generic       |

### **Approval Criteria**

- **1** All of the following:
- **1.1** One of the following:
- 1.1.1 The requested drug is being used alone or in a combination regimen that is FDA-

| labeled for the treatment of the specific condition the person presents with*  |
|--|
| OR   |
| <b>1.1.2</b> The requested drug is being used alone or in a combination regimen that has a class 1 or 2 recommendation for use from the National Comprehensive Cancer Network (NCCN) in the specific condition of the person*  |
| AND  |
| <b>1.2</b> Prescribed and monitored by an Oncologist, Hematologist, or other specialist in the treatment of malignancy   |
| OR   |
| 2 - One of the following:  |
| 2.1 Both of the following:   |
| <b>2.1.1</b> If the request is for Minnesota Plans only, the requested drug is being used alone or in a combination regimen that is recommended for use in the specific condition of the person based on one of the following:   |
| <ul> <li>United States Pharmacopeia Drug Information</li> <li>The American Hospital Formulary Service Drug Information</li> <li>One article in a major peer- reviewed medical journal recognizes the safety and efficacy of the requested drug in the person's specific condition</li> </ul> |
| AND  |
| <b>2.1.2</b> Prescribed and monitored by an Oncologist, Hematologist, or other specialist in the treatment of malignancy   |
| OR   |
| 2.2 Both of the following:   |
| <b>2.2.1</b> If the request is for IL plans only, the requested drug is being used alone or in a combination regimen that is recommended for use in the specific condition of the person based   |

on one of the following:

- Thomson Micromedex Drugdex
- The American Hospital Formulary Service Drug Information
- Elsevier Gold Standard's Clinical Pharmacology
- Two articles in a peer- reviewed medical journal from the United States or Great Britain recognize the safety and efficacy of the requested drug in the person's specific condition

#### **AND**

**2.2.2** Prescribed and monitored by an Oncologist, Hematologist, or other specialist in the treatment of malignancy

| I     | l.,   |
|-------|---|
| Notes | *includes any relevant genetic testing, mutations, etc. |
|       | miora account for tank gone accurring, maka accirc, cac |

| Product Name: Generic Bexarotene Gel |  |
|--------------------------------------|--|
| Approval Length                      | 12/31/2039                                       |
| Guideline Type                       | Prior authorization - All plans except IL and MN |

| Product<br>Name | Generic Name      | GPI            | Brand/Generic |
|-----------------|-------------------|----------------|---------------|
| BEXAROTENE      | BEXAROTENE GEL 1% | 90376220004020 | Generic       |

#### **Approval Criteria**

- 1 One of the following:
- **1.1** The requested drug is being used alone or in a combination regimen that is FDA-labeled for the treatment of the specific condition the person presents with\*

#### OR

**1.2** The requested drug is being used alone or in a combination regimen that has a class 1 or 2 recommendation for use from the National Comprehensive Cancer Network (NCCN) in the specific condition of the person\*

#### **AND**

2 - Prescribed and monitored by an Oncologist, Hematologist, or other specialist in the

| treatment of malignancy |   |
|-------------------------|---|
| Notes                   | *includes any relevant genetic testing, mutations, etc. |

| Date      | Notes       |
|-----------|-------------|
| 11/3/2023 | New Program |

| Briviact (Brivaracetam)  |  |  |
|--|--|--|
| (S) has been proved to the second control and |  |  |
|  |  |  |

| Guideline ID          | GL-127878               |  |
|-----------------------|-------------------------|--|
| <b>Guideline Name</b> | Briviact (Brivaracetam) |  |
| Formulary             | Quartz                  |  |

# **Guideline Note:**

| Effective Date: |
|-----------------|
|-----------------|

# 1. Criteria

| Product Name: Briviact |                                |
|------------------------|--------------------------------|
| Approval Length        | 12 month(s)                    |
| Therapy Stage          | Initial Authorization          |
| Guideline Type         | Step Therapy - IL and MN Plans |

| Product<br>Name | Generic Name                    | GPI            | Brand/Generic |
|-----------------|---------------------------------|----------------|---------------|
| BRIVIACT        | BRIVARACETAM TAB 10 MG          | 72600015000310 | Brand         |
| BRIVIACT        | BRIVARACETAM TAB 25 MG          | 72600015000320 | Brand         |
| BRIVIACT        | BRIVARACETAM TAB 50 MG          | 72600015000330 | Brand         |
| BRIVIACT        | BRIVARACETAM TAB 75 MG          | 72600015000340 | Brand         |
| BRIVIACT        | BRIVARACETAM TAB 100 MG         | 72600015000350 | Brand         |
| BRIVIACT        | BRIVARACETAM ORAL SOLN 10 MG/ML | 72600015002020 | Brand         |

- **1** Trial and failure, contraindication, or intolerance to at least TWO preferred anticonvulsants:
  - lamotrigine
  - levetiracetam
  - carbamazepine
  - valproate
  - oxcarbazepine
  - gabapentin
  - pregabalin
  - topiramate
  - phenytoin
  - zonisamide
  - primidone

| Product Name: Briviact |                                |
|------------------------|--------------------------------|
| Approval Length        | 12 month(s)                    |
| Therapy Stage          | Reauthorization                |
| Guideline Type         | Step Therapy - IL and MN Plans |

| Product<br>Name | Generic Name                    | GPI            | Brand/Generic |
|-----------------|---------------------------------|----------------|---------------|
| BRIVIACT        | BRIVARACETAM TAB 10 MG          | 72600015000310 | Brand         |
| BRIVIACT        | BRIVARACETAM TAB 25 MG          | 72600015000320 | Brand         |
| BRIVIACT        | BRIVARACETAM TAB 50 MG          | 72600015000330 | Brand         |
| BRIVIACT        | BRIVARACETAM TAB 75 MG          | 72600015000340 | Brand         |
| BRIVIACT        | BRIVARACETAM TAB 100 MG         | 72600015000350 | Brand         |
| BRIVIACT        | BRIVARACETAM ORAL SOLN 10 MG/ML | 72600015002020 | Brand         |

### **Approval Criteria**

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug

Product Name: Briviact

| Approval Length | 12/31/2039                                |
|-----------------|---|
| Guideline Type  | Step Therapy - All Plans Except IL and MN |

| Product<br>Name | Generic Name                    | GPI            | Brand/Generic |
|-----------------|---------------------------------|----------------|---------------|
| BRIVIACT        | BRIVARACETAM TAB 10 MG          | 72600015000310 | Brand         |
| BRIVIACT        | BRIVARACETAM TAB 25 MG          | 72600015000320 | Brand         |
| BRIVIACT        | BRIVARACETAM TAB 50 MG          | 72600015000330 | Brand         |
| BRIVIACT        | BRIVARACETAM TAB 75 MG          | 72600015000340 | Brand         |
| BRIVIACT        | BRIVARACETAM TAB 100 MG         | 72600015000350 | Brand         |
| BRIVIACT        | BRIVARACETAM ORAL SOLN 10 MG/ML | 72600015002020 | Brand         |

- **1** Trial and failure, contraindication, or intolerance to at least TWO preferred anticonvulsants:
  - lamotrigine
  - levetiracetam
  - carbamazepine
  - valproate
  - oxcarbazepine
  - gabapentin
  - pregabalin
  - topiramate
  - phenytoin
  - zonisamide
  - primidone

| Date      | Notes       |
|-----------|-------------|
| 8/25/2023 | New Program |

| Broad Spectrum Antifungal                                  |  |  |
|--|--|--|
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|  |  |  |

| Guideline ID          | GL-129108                 |  |
|-----------------------|---------------------------|--|
| <b>Guideline Name</b> | Broad Spectrum Antifungal |  |
| Formulary             | Quartz                    |  |

# **Guideline Note:**

| Effective Date: |
|-----------------|
|-----------------|

# 1. Criteria

| Product Name: Cresemba, Generic posaconazole tablet, Generic voriconazole |             |  |                |               |  |
|---|-------------|--|----------------|---------------|--|
| Approval Length   |             | 12 month(s)  |                |               |  |
| Guideline Type  |             | Prior Authorization                                  |                |               |  |
| Product Name  | Gener       | ic Name  | GPI            | Brand/Generic |  |
| CRESEMBA  |             | CONAZONIUM SULFATE CAP 186 MG<br>CONAZOLE 100 MG)    | 11407030100120 | Brand         |  |
| CRESEMBA  | _           | CONAZONIUM SULF FOR IV SOL 372 MG<br>CONAZOLE 200MG) | 11407030102130 | Brand         |  |
| POSACONAZOLE  | POSAC<br>MG | CONAZOLE TAB DELAYED RELEASE 100                     | 11407060000620 | Generic       |  |
| POSACONAZOLE<br>DR  | MG          |  | 11407060000620 | Generic       |  |
| VORICONAZOLE  |             |  | 11407080000320 | Generic       |  |
| VORICONAZOLE VORICONAZOLE TAB 200 MG 1140                                 |             | 11407080000340                                       | Generic        |               |  |

| VORICONAZOLE | VORICONAZOLE FOR SUSP 40 MG/ML | 11407080001920 | Generic |
|--------------|--------------------------------|----------------|---------|
|--------------|--------------------------------|----------------|---------|

**1** - Diagnosis of confirmed (or suspected) serious fungal infection with probable resistance to other preferred antifungals, or other antifungals have been not tolerated, or significant drugdrug interactions exist with other antifungals

OR

2 - Prescribed by or in consultation with an Infectious Disease specialist

OR

**3** - For generic posaconazole tablet only, used for prophylaxis of serious fungal infections in patients with hematologic malignancies with severely compromised immunity

OR

**4** - For continuation of therapy initiated as an inpatient

OR

**5** - For Illinois plans only - the requested FDA approved drug is being used for the long-term treatment of tick-borne disease.

OR

**6** - For Minnesota plans only - member has stage four metastatic cancer and the requested drug is being used to prevent or treat cancer-related fungal infections

| Product Name: Generic posaconazole suspension, Noxafil suspension packet |                     |
|--|---------------------|
| Approval Length 12 month(s)  |                     |
| Guideline Type   | Prior Authorization |

| Product Name | Generic Name   | GPI            | Brand/Generic |
|--------------|--|----------------|---------------|
| POSACONAZOLE | POSACONAZOLE SUSP 40 MG/ML                             | 11407060001820 | Generic       |
| NOXAFIL      | POSACONAZOLE FOR DELAYED RELEASE<br>SUSP PACKET 300 MG | 11407060003020 | Brand         |

|   |   | $\sim$  | •        |      |      |          |         |  |
|---|---|---------|----------|------|------|----------|---------|--|
| 7 |   | One     | $\sim$ t | tha  | +~1  |          | -       |  |
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|   |   |         |          |      |      |          |         |  |
|   |   |         |          |      |      |          |         |  |

**1.1** Diagnosis of confirmed (or suspected) serious fungal infection with probable resistance to other preferred antifungals, or other antifungals have been not tolerated, or significant drugdrug interactions exist with other antifungals

OR

1.2 Prescribed by or in consultation with an Infectious Disease specialist

OR

**1.3** Used for prophylaxis of serious fungal infections in patients with hematologic malignancies with severely compromised immunity

OR

**1.4** For continuation of therapy initiated as an inpatient

OR

**1.5** For Minnesota plans only - member has stage four metastatic cancer and the requested drug is being used to prevent or treat cancer-related fungal infections

OR

**1.6** For Illinois plans only - the requested FDA approved drug is being used for the long-term treatment of tick-borne disease.

## AND

2 - Member is unable to tolerate solid dosage form

| Date     | Notes                   |
|----------|-------------------------|
| 9/7/2023 | 2024 New Implementation |

| Bylvay (odevixibat)   |  |
|---|--|
| (3) will strange some helighed. North was bestem stand, densed a stand helighed has should be a strained. |  |
|   |  |

| Guideline ID          | GL-135532           |  |
|-----------------------|---------------------|--|
| <b>Guideline Name</b> | Bylvay (odevixibat) |  |
| Formulary             | Quartz              |  |

# **Guideline Note:**

| Effective Date: |
|-----------------|
|-----------------|

# 1. Criteria

| Product Name: Bylvay |   |
|----------------------|---|
| Diagnosis            | Progressive Familial Intrahepatic Cholestasis (PFIC)) |
| Approval Length      | 12 month(s)   |
| Therapy Stage        | Initial Authorization                                 |
| Guideline Type       | Prior Authorization                                   |

| Product<br>Name     | Generic Name                            | GPI            | Brand/Generic |
|---------------------|---|----------------|---------------|
| BYLVAY              | ODEVIXIBAT CAP 400 MCG                  | 52350060000120 | Brand         |
| BYLVAY              | ODEVIXIBAT CAP 1200 MCG                 | 52350060000140 | Brand         |
| BYLVAY<br>(PELLETS) | ODEVIXIBAT PELLETS CAP SPRINKLE 200 MCG | 52350060006810 | Brand         |
| BYLVAY<br>(PELLETS) | ODEVIXIBAT PELLETS CAP SPRINKLE 600 MCG | 52350060006830 | Brand         |

| Approval Criteria   |
|---|
| 1 - Diagnosis of progressive familial intrahepatic cholestasis (PFIC)   |
| AND   |
| 2 - Disease is confirmed by one of the following:   |
| <ul> <li>Genetic testing</li> <li>Diagnostic test (e.g., liver function test, liver ultrasound and biopsy, bile analysis)</li> </ul>                          |
| AND   |
| <b>3</b> - Genetic testing does not indicate PFIC type 2 with ABCB11 variant encoding for nonfunctioning or absence of bile salt export pump protein (BSEP-3) |
| AND   |
| 4 - Member is experiencing moderate to severe cholestatic pruritus  |
| AND   |
| 5 - Member has serum bile acid greater than 3x the upper limit of normal (ULN)  |
| AND   |
| <b>6</b> - Member has not had a liver transplant, biliary diversion surgery within the past 6 months, or decompensated liver disease                          |
| AND   |
| 7 - Trial and failure, contraindication or intolerance to TWO of the following medications for pruritis:  |

- Ursodeoxycholic acid (e.g., Ursodiol) Antihistamines (e.g., diphenhydramine, hydroxyzine)
- Rifampin
- Bile acid sequestrants (e.g., Questran, Colestid, Welchol)

### AND

- 8 Prescribed by or in consultation with one of the following:
  - hepatologist
  - gastroenterologist

| Notes | *Member new to the plan (as evidenced by coverage effective date of I ess than or equal to 90 days) who initiated therapy using a manufactur er-sponsored free drug program, provider samples, and/or vouchers wil I go through initial criteria, otherwise for continuation of therapy for new to plan, reauthorization criteria applies.  **For members new to plan (as evidenced by coverage effective date of less than or equal to 90 days) prescriber provides submission of medical records (e.g., chart notes) documenting that from the previous 12 months, member demonstrates an improvement or stabilization in pruritus and the member is tolerating therapy. |
|-------|--|

| Product Name: Bylvay |                       |
|----------------------|-----------------------|
| Diagnosis            | Alagille syndrome)    |
| Approval Length      | 12 month(s)           |
| Therapy Stage        | Initial Authorization |
| Guideline Type       | Prior Authorization   |

| Product<br>Name     | Generic Name                            | GPI            | Brand/Generic |
|---------------------|---|----------------|---------------|
| BYLVAY              | ODEVIXIBAT CAP 400 MCG                  | 52350060000120 | Brand         |
| BYLVAY              | ODEVIXIBAT CAP 1200 MCG                 | 52350060000140 | Brand         |
| BYLVAY<br>(PELLETS) | ODEVIXIBAT PELLETS CAP SPRINKLE 200 MCG | 52350060006810 | Brand         |
| BYLVAY<br>(PELLETS) | ODEVIXIBAT PELLETS CAP SPRINKLE 600 MCG | 52350060006830 | Brand         |

### **Approval Criteria**

| 1 - Diagnosis of Alagille syndrome (ALGS)   |  |  |  |
|---|--|--|--|
| AND   |  |  |  |
| 2 - Molecular genetic testing confirms mutations in the JAG1 or NOTCH2 gene   |  |  |  |
| AND   |  |  |  |
| 3 - One of the following:   |  |  |  |
| <ul> <li>Total serum bile acid greater than 3x the upper limit of normal (ULN)</li> <li>Conjugated bilirubin greater than 1 mg/dL</li> <li>Fat soluble vitamin deficiency otherwise unexplainable</li> <li>Gamma-glutamyl transpeptidase (GGT) greater than 3x ULN</li> </ul> |  |  |  |
| AND   |  |  |  |
| 4 - Member is experiencing moderate to severe cholestatic pruritus  |  |  |  |
| AND   |  |  |  |
| 5 - Member has not had a liver transplant or decompensated liver disease  |  |  |  |
| AND   |  |  |  |
| <b>6</b> - Trial and failure, contraindication or intolerance to TWO of the following medications for pruritis:   |  |  |  |
| <ul> <li>Ursodeoxycholic acid (e.g., Ursodiol)</li> <li>Antihistamines (e.g., diphenhydramine, hydroxyzine)</li> <li>Rifampin</li> </ul>  |  |  |  |
| Bile acid sequestrants (e.g., Questran, Colestid, Welchol)  |  |  |  |
| AND   |  |  |  |
| 7 - Trial and failure, contraindication or intolerance to maralixibat   |  |  |  |

### AND

- 8 Prescribed by or in consultation with one of the following:
  - hepatologist
  - Expert in the treatment of cholestasis

| *Member new to the plan (as evidenced by coverage effective date of I ess than or equal to 90 days) who initiated therapy using a manufactur er-sponsored free drug program, provider samples, and/or vouchers wil I go through initial criteria, otherwise for continuation of therapy for new to plan, reauthorization criteria applies.  **For members new to plan (as evidenced by coverage effective date of less than or equal to 90 days) prescriber provides submission of medical records (e.g., chart notes) documenting that from the previous 12 months, member demonstrates an improvement or stabilization in pruritues and the member is tolerating therapy. |
|---|

| Product Name: Bylvay |                     |  |
|----------------------|---------------------|--|
| Diagnosis            | All Indications)    |  |
| Approval Length      | 12 month(s)         |  |
| Therapy Stage        | Reauthorization     |  |
| Guideline Type       | Prior Authorization |  |

| Product<br>Name     | Generic Name                            | GPI            | Brand/Generic |
|---------------------|---|----------------|---------------|
| BYLVAY              | ODEVIXIBAT CAP 400 MCG                  | 52350060000120 | Brand         |
| BYLVAY              | ODEVIXIBAT CAP 1200 MCG                 | 52350060000140 | Brand         |
| BYLVAY<br>(PELLETS) | ODEVIXIBAT PELLETS CAP SPRINKLE 200 MCG | 52350060006810 | Brand         |
| BYLVAY<br>(PELLETS) | ODEVIXIBAT PELLETS CAP SPRINKLE 600 MCG | 52350060006830 | Brand         |

### **Approval Criteria**

1 - Submission of medical records (e.g., chart notes) documenting that within the past 12 months of therapy, member is experiencing improvement or stabilization in pruritus compared to baseline (e.g., change in member reported pruritus, change in sleeping habits due to itch) and the member is tolerating therapy (e.g., does not have chronic diarrhea requiring ongoing

| intravenous fluids, bile acid reduction) |  |  |
|--|--|--|
| Notes                                    | *Member new to the plan (as evidenced by coverage effective date of I ess than or equal to 90 days) who initiated therapy using a manufactur er-sponsored free drug program, provider samples, and/or vouchers wil I go through initial criteria, otherwise for continuation of therapy for new to plan, reauthorization criteria applies.  **For members new to plan (as evidenced by coverage effective date of less than or equal to 90 days) prescriber provides submission of medical records (e.g., chart notes) documenting that from the previous 12 months, member demonstrates an improvement or stabilization in pruritus and the member is tolerating therapy. |  |

| Date      | Notes                   |
|-----------|-------------------------|
| 11/2/2023 | 2024 New Implementation |

| Cablivi (caplacizumab-yhdp)   |  |  |  |
|---|--|--|--|
| The Section of Section Sect | and a filled to the fill before the control of the fill before |  |  |

| Guideline ID   | GL-128994                   |  |
|----------------|-----------------------------|--|
| Guideline Name | Cablivi (caplacizumab-yhdp) |  |
| Formulary      | Quartz                      |  |

## **Guideline Note:**

| Effective Date: |
|-----------------|
|-----------------|

### 1. Criteria

| Product Na                                     | roduct Name: Cablivi |  |                 |               |
|--|----------------------|--|-----------------|---------------|
| Approval Le                                    | ength                | 1 month (30days)                       |                 |               |
| Guideline Type Prior Authorization - All Plans |                      | Prior Authorization - All Plans Except | IL and MN Plans |               |
| Product Generic Name<br>Name                   |                      | ime                                    | GPI             | Brand/Generic |

85151020806420

Brand

CAPLACIZUMAB-YHDP FOR INJ KIT 11 MG

### **Approval Criteria**

CABLIVI

**1** - Diagnosis of severe acquired thrombotic thrombocytopenic purpura (aTTP) with at least one ADAMST13 level below 20 percent

|   | N I | _ |
|---|-----|---|
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| ~ | 14  | u |
|   |     |   |

2 - Member is 18 years of age or older

#### **AND**

- **3** Both of the following:
- **3.1** Member had been receiving plasma exchange (PEX) in combination with Cablivi (either as an inpatient or in an outpatient clinic setting)

#### **AND**

3.2 PEX has been discontinued and Cablivi therapy will continue

#### **AND**

**4** - Used in combination with immunosuppressive therapy (e.g., systemic corticosteroids or rituximab)

#### **AND**

5 - Member has not had greater than 2 recurrences of aTTP while on Cablivi therapy

| Product Name: Cablivi |                                       |
|-----------------------|---------------------------------------|
| Approval Length       | 12 month(s)                           |
| Guideline Type        | Prior Authorization - IL and MN Plans |

| Product<br>Name | Generic Name                        | GPI            | Brand/Generic |
|-----------------|-------------------------------------|----------------|---------------|
| CABLIVI         | CAPLACIZUMAB-YHDP FOR INJ KIT 11 MG | 85151020806420 | Brand         |

### **Approval Criteria**

**1** - Diagnosis of severe acquired thrombotic thrombocytopenic purpura (aTTP) with at least one

| ADAMST13 level below 20 percent  |
|--|
| AND  |
| 2 - Member is 18 years of age or older   |
| AND  |
| 3 - Both of the following:   |
| <b>3.1</b> Member had been receiving plasma exchange (PEX) in combination with Cablivi (either as an inpatient or in an outpatient clinic setting) |
| AND  |
| 3.2 PEX has been discontinued and Cablivi therapy will continue  |
| AND  |
| <b>4</b> - Used in combination with immunosuppressive therapy (e.g., systemic corticosteroids or rituximab)  |
| AND  |
| 5 - Member has not had greater than 2 recurrences of aTTP while on Cablivi therapy   |
| AND  |
| 6 - Cablivi (caplacizumab) will be self-administered   |
|  |

| Date | Notes |
|------|-------|
|      |       |

| 9/8/2023 | 2024 New Implementation |
|----------|-------------------------|
|          |                         |

| Camzyos (mavacamten)   |  |  |  |  |
|--|--|--|--|--|
| Substitution and tradiques for the squares and country a data and particle prints do consolidate trades. |  |  |  |  |
|  |  |  |  |  |

| Guideline ID          | GL-130131 Camzyos (mavacamten) • Quartz |  |
|-----------------------|---|--|
| <b>Guideline Name</b> |   |  |
| Formulary             |   |  |

# **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

# 1. Criteria

| Approval Length 12 month  | Product Name: Camzyos |  |
|---------------------------|-----------------------|--|
|                           | n(s)                  |  |
| Therapy Stage Initial Aut | horization            |  |
| Guideline Type Prior Autl | norization            |  |

| Product<br>Name | Generic Name          | GPI            | Brand/Generic |
|-----------------|-----------------------|----------------|---------------|
| CAMZYOS         | MAVACAMTEN CAP 2.5 MG | 40190050000110 | Brand         |
| CAMZYOS         | MAVACAMTEN CAP 5 MG   | 40190050000120 | Brand         |
| CAMZYOS         | MAVACAMTEN CAP 10 MG  | 40190050000130 | Brand         |
| CAMZYOS         | MAVACAMTEN CAP 15 MG  | 40190050000140 | Brand         |

**1** - Diagnosis of obstructive hypertrophic cardiomyopathy with New York Heart Association (NYHA) class II-III symptoms

#### **AND**

2 - Left ventricular ejection fraction (LVEF) greater than or equal to 55%

#### **AND**

**3** - Member is 18 years of age or older

#### AND

**4** - Prescribed by, or in consultation with, a Cardiologist or other expert in the treatment of hypertrophic cardiomyopathy

#### **AND**

- **5** Submission of medical records (e.g., chart notes) documenting trial and failure, contraindication, or intolerance to BOTH of the following:
  - Beta-blockers (i.e., carvedilol, labetalol, metoprolol, propranolol)
  - Calcium channel blockers (i.e., diltiazem, verapamil)

|  | Member new to the plan (as evidenced by coverage effective date of le ss than or equal to 90 days) who initiated therapy using a manufacturer -sponsored free drug program, provider samples, and/or vouchers will go through initial criteria, otherwise for continuation of therapy for new to plan, reauthorization criteria applies |
|--|---|
|  | go through initial criteria, otherwise for continuation of therapy for new  |

| Product Name: Camzyos |                     |
|-----------------------|---------------------|
| Approval Length       | 12 month(s)         |
| Therapy Stage         | Reauthorization     |
| Guideline Type        | Prior Authorization |

| Product<br>Name | Generic Name          | GPI            | Brand/Generic |
|-----------------|-----------------------|----------------|---------------|
| CAMZYOS         | MAVACAMTEN CAP 2.5 MG | 40190050000110 | Brand         |
| CAMZYOS         | MAVACAMTEN CAP 5 MG   | 40190050000120 | Brand         |
| CAMZYOS         | MAVACAMTEN CAP 10 MG  | 40190050000130 | Brand         |
| CAMZYOS         | MAVACAMTEN CAP 15 MG  | 40190050000140 | Brand         |

**1** - Diagnosis of obstructive hypertrophic cardiomyopathy with New York Heart Association (NYHA) class II-III symptoms

**AND** 

2 - Member is 18 years of age or older

#### **AND**

**3** - Person has been evaluated by a cardiologist, or other expert in the treatment of hypertrophic cardiomyopathy, within the previous 12 months

#### **AND**

**4** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member demonstrates positive clinical response to therapy

| Member new to the plan (as evidenced by coverage effective date of le ss than or equal to 90 days) who initiated therapy using a manufacturer -sponsored free drug program, provider samples, and/or vouchers will go through initial criteria, otherwise for continuation of therapy for new to |
|--|
| go through initial criteria, otherwise for continuation of therapy for new t<br>o plan, reauthorization criteria applies   |

| Date | Notes |
|------|-------|
|      |       |

| 10/25/2023 | 2024 New Implementation |
|------------|-------------------------|
|            |                         |

| Cardura XL (doxazosin ER)   |  |  |  |
|---|--|--|--|
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|   |  |  |  |

| Guideline ID          | GL-129156                 |
|-----------------------|---------------------------|
| <b>Guideline Name</b> | Cardura XL (doxazosin ER) |
| Formulary             | Quartz                    |

# **Guideline Note:**

| Effective Date: |
|-----------------|
|-----------------|

## 1. Criteria

| Product Name: Cardura XL |                                       |
|--------------------------|---------------------------------------|
| Approval Length          | 12 month(s)                           |
| Therapy Stage            | Initial Authorization                 |
| Guideline Type           | Prior Authorization - IL and MN Plans |

| Product<br>Name | Generic Name                                      | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| CARDURA<br>XL   | DOXAZOSIN MESYLATE TAB ER 24 HR 4 MG (BASE EQUIV) | 56852025207520 | Brand         |
| CARDURA<br>XL   | DOXAZOSIN MESYLATE TAB ER 24 HR 8 MG (BASE EQUIV) | 56852025207530 | Brand         |

## **Approval Criteria**

**1** - The prescriber provides an evidence-based clinical rationale for why the side effects are not likely to occur with the extended-release formulation

#### AND

**2** - Use of at least one additional preferred alpha blocker (such as terazosin or prazosin) did not control symptoms or caused side effects

#### **AND**

**3** - Trial and failure, contraindication or intolerance of immediate-release doxazosin (unable to achieve symptom control due to therapy-limiting side effects)

| Product Name: Cardura XL    |                                       |  |  |
|-----------------------------|---------------------------------------|--|--|
| Approval Length 12 month(s) |                                       |  |  |
| Therapy Stage               | Reauthorization                       |  |  |
| Guideline Type              | Prior Authorization - IL and MN Plans |  |  |

| Product<br>Name | Generic Name                                      | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| CARDURA<br>XL   | DOXAZOSIN MESYLATE TAB ER 24 HR 4 MG (BASE EQUIV) | 56852025207520 | Brand         |
| CARDURA<br>XL   | DOXAZOSIN MESYLATE TAB ER 24 HR 8 MG (BASE EQUIV) | 56852025207530 | Brand         |

### **Approval Criteria**

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug.

| Product Name: Cardura XL  |  |  |
|---|--|--|
| Approval Length 12/31/2039  |  |  |
| Guideline Type Prior Authorization - All Plans except IL and MN Plans |  |  |

| Product<br>Name | Generic Name                               | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| CARDURA         | DOXAZOSIN MESYLATE TAB ER 24 HR 4 MG (BASE | 56852025207520 | Brand         |

| XL            | EQUIV)  |                |       |
|---------------|---|----------------|-------|
| CARDURA<br>XL | DOXAZOSIN MESYLATE TAB ER 24 HR 8 MG (BASE EQUIV) | 56852025207530 | Brand |

**1** - The prescriber provides an evidence-based clinical rationale for why the side effects are not likely to occur with the extended-release formulation

#### **AND**

**2** - Use of at least one additional preferred alpha blocker (such as terazosin or prazosin) did not control symptoms or caused side effects

#### **AND**

**3** - Trial and failure, contraindication or intolerance of immediate-release doxazosin (unable to achieve symptom control due to therapy-limiting side effects)

| Date      | Notes       |
|-----------|-------------|
| 9/11/2023 | New Program |

| Cayston (Aztreonam Inhalation Solution   | n) |
|--|----|
| (3) "Selection-controlled Solds to Select code of the Select Code of t |    |

| Guideline ID          | GL-129106                               |
|-----------------------|---|
| <b>Guideline Name</b> | Cayston (Aztreonam Inhalation Solution) |
| Formulary             | Quartz                                  |

## **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

## 1. Criteria

| Product Name: Cayston |  |                 |  |  |  |
|-----------------------|--|-----------------|--|--|--|
| Approval Length       | 12/31/2039                             |                 |  |  |  |
| Guideline Type        | Prior Authorization - All plans except | IL and MN Plans |  |  |  |
|                       |  |                 |  |  |  |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| CAYSTON         | AZTREONAM LYSINE FOR INHAL SOLN 75 MG (BASE EQUIVALENT) | 16140010402120 | Brand         |

## **Approval Criteria**

1 - Diagnosis of cystic fibrosis

#### **AND**

2 - Member has a history of recurrent Pseudomonas aeruginosa lung infections

#### **AND**

3 - Medication will be used for inhalation only

#### **AND**

- 4 One of the following:
  - Recurrence despite prior use of tobramycin inhalation solution
  - Submission of medical records (e.g., chart notes) documenting tobramycin resistance

| Product Name: Cayston |                                       |  |
|-----------------------|---------------------------------------|--|
| Approval Length       | 12 month(s)                           |  |
| Therapy Stage         | Initial Authorization                 |  |
| Guideline Type        | Prior Authorization - IL and MN Plans |  |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| CAYSTON         | AZTREONAM LYSINE FOR INHAL SOLN 75 MG (BASE EQUIVALENT) | 16140010402120 | Brand         |

### **Approval Criteria**

1 - Diagnosis of cystic fibrosis

#### **AND**

2 - Member has a history of recurrent Pseudomonas aeruginosa lung infections

#### AND

3 - Medication will be used for inhalation only

#### AND

- 4 One of the following:
  - Recurrence despite prior use of tobramycin inhalation solution
  - Submission of medical records (e.g., chart notes) documenting tobramycin resistance

| Product Name: Cayston |                                       |  |
|-----------------------|---------------------------------------|--|
| Approval Length       | 12 month(s)                           |  |
| Therapy Stage         | Reauthorization                       |  |
| Guideline Type        | Prior Authorization - IL and MN Plans |  |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| CAYSTON         | AZTREONAM LYSINE FOR INHAL SOLN 75 MG (BASE EQUIVALENT) | 16140010402120 | Brand         |

### **Approval Criteria**

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug

| Date      | Notes                   |
|-----------|-------------------------|
| 7/31/2023 | 2024 New Implementation |

| Chronic Constipation Medications   |  |
|--|--|
| (2) Indicating work indiged. This is the latter mode work a state that the parts the country and many and a state to the parts the country and the parts and |  |
|  |  |

# **Prior Authorization Guideline**

| Guideline ID          | GL-132716                        |
|-----------------------|----------------------------------|
| <b>Guideline Name</b> | Chronic Constipation Medications |
| Formulary             | Quartz                           |

# **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

# 1. Criteria

| Product Name: Linzess, Trulance, Motegrity                            |            |  |
|---|------------|--|
| Diagnosis Chronic Constipation  |            |  |
| Approval Length   | 12/31/2039 |  |
| Guideline Type Prior Authorization - All plans except IL and MN Plans |            |  |

| Product<br>Name | Generic Name                                      | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| LINZESS         | LINACLOTIDE CAP 72 MCG                            | 52557050000110 | Brand         |
| LINZESS         | LINACLOTIDE CAP 145 MCG                           | 52557050000120 | Brand         |
| LINZESS         | LINACLOTIDE CAP 290 MCG                           | 52557050000140 | Brand         |
| TRULANCE        | PLECANATIDE TAB 3 MG                              | 52543060000320 | Brand         |
| MOTEGRITY       | PRUCALOPRIDE SUCCINATE TAB 1 MG (BASE EQUIVALENT) | 52560060200320 | Brand         |

| MOTEGRITY | PRUCALOPRIDE SUCCINATE TAB 2 MG (BASE | 52560060200330 | Brand |
|-----------|---------------------------------------|----------------|-------|
|           | EQUIVALENT)                           |                |       |

1 - Diagnosis of Chronic Constipation

### **AND**

2 - Member is 18 years of age or older

#### **AND**

**3** - Trial and failure, contraindication or intolerance to two first line therapies (e.g., Miralax, stimulants, fiber supplements, stool softeners)

#### **AND**

4 - For Linzess Only - Trial and failure, contraindication or intolerance to lubiprostone

#### **AND**

**5** - For Trulance and Motegrity Only - Trial and failure, contraindication or intolerance to lubiprostone and linaclotide

| Product Name: Linzess, Trulance, Motegrity           |                       |  |  |
|--|-----------------------|--|--|
| Diagnosis  | Chronic Constipation  |  |  |
| Approval Length                                      | 12 month(s)           |  |  |
| Therapy Stage  | Initial Authorization |  |  |
| Guideline Type Prior Authorization - IL and MN Plans |                       |  |  |
|  |                       |  |  |

| Product<br>Name | Generic Name           | GPI            | Brand/Generic |
|-----------------|------------------------|----------------|---------------|
| LINZESS         | LINACLOTIDE CAP 72 MCG | 52557050000110 | Brand         |

| LINZESS   | LINACLOTIDE CAP 145 MCG                           | 52557050000120 | Brand |
|-----------|---|----------------|-------|
| LINZESS   | LINACLOTIDE CAP 290 MCG                           | 52557050000140 | Brand |
| TRULANCE  | PLECANATIDE TAB 3 MG                              | 52543060000320 | Brand |
| MOTEGRITY | PRUCALOPRIDE SUCCINATE TAB 1 MG (BASE EQUIVALENT) | 52560060200320 | Brand |
| MOTEGRITY | PRUCALOPRIDE SUCCINATE TAB 2 MG (BASE EQUIVALENT) | 52560060200330 | Brand |

1 - Diagnosis of Chronic Constipation

#### **AND**

2 - Member is 18 years of age or older

#### AND

**3** - Trial and failure, contraindication or intolerance to two first line therapies (e.g., Miralax, stimulants, fiber supplements, stool softeners)

#### **AND**

4 - For Linzess Only - Trial and failure, contraindication or intolerance to lubiprostone

#### **AND**

**5** - For Trulance and Motegrity Only - Trial and failure, contraindication or intolerance to lubiprostone and linaclotide

| Product Name: Linzess, Trulance |  |
|---------------------------------|--|
| Diagnosis                       | Irritable Bowel Syndrome - Constipation (IBS-C)        |
| Approval Length                 | 12/31/2039   |
| Guideline Type                  | Prior Authorization - All plans except IL and MN Plans |

| Product<br>Name | Generic Name            | GPI            | Brand/Generic |
|-----------------|-------------------------|----------------|---------------|
| LINZESS         | LINACLOTIDE CAP 72 MCG  | 52557050000110 | Brand         |
| LINZESS         | LINACLOTIDE CAP 145 MCG | 52557050000120 | Brand         |
| LINZESS         | LINACLOTIDE CAP 290 MCG | 52557050000140 | Brand         |
| TRULANCE        | PLECANATIDE TAB 3 MG    | 52543060000320 | Brand         |

1 - Diagnosis of Irritable Bowel Syndrome - Constipation (IBS-C)

#### **AND**

2 - Member is 18 years of age or older

#### **AND**

**3** - Trial and failure, contraindication or intolerance of at least two alternative therapies (e.g., Miralax, fiber, stimulants, dicyclomine, hyoscyamine, tricyclic or SSRI antidepressants)

#### **AND**

4 - For Linzess Only - Trial and failure, contraindication or intolerance to lubiprostone

#### **AND**

**5** - For Trulance Only - Trial and failure, contraindication or intolerance to lubiprostone and linaclotide

| Product Name: Linzess, Trulance                           |  |
|---|--|
| Diagnosis Irritable Bowel Syndrome - Constipation (IBS-C) |  |
| Approval Length 12 month(s)                               |  |
| Therapy Stage Initial Authorization                       |  |

| Guideline Type  |             | Prior Authorization - IL and MN Plans |                |               |
|-----------------|-------------|---------------------------------------|----------------|---------------|
| Product<br>Name | Generic Na  | me                                    | GPI            | Brand/Generic |
| LINZESS         | LINACLOTIDI | E CAP 72 MCG                          | 52557050000110 | Brand         |
| LINZESS         | LINACLOTIDI | E CAP 145 MCG                         | 52557050000120 | Brand         |
| LINZESS         | LINACLOTIDI | E CAP 290 MCG                         | 52557050000140 | Brand         |
| TRULANCE        | PLECANATIO  | E TAB 3 MG                            | 52543060000320 | Brand         |

1 - Diagnosis of Irritable Bowel Syndrome - Constipation (IBS-C)

#### AND

2 - Member is 18 years of age or older

#### **AND**

**3** - Trial and failure, contraindication or intolerance of at least two alternative therapies (e.g., Miralax, fiber, stimulants, dicyclomine, hyoscyamine, tricyclic or SSRI antidepressants)

#### **AND**

4 - For Linzess Only - Trial and failure, contraindication or intolerance to lubiprostone

#### **AND**

**5** - For Trulance Only - Trial and failure, contraindication or intolerance to lubiprostone and linaclotide

| Product Name: Symproic, Movantik |                             |
|----------------------------------|-----------------------------|
| Diagnosis                        | Opioid-Induced Constipation |
| Approval Length                  | 12/31/2039                  |

| Guideline T  | Guideline Type Prior Authorization - All plans except IL and MN Plans  |  |                     |             |
|--|--|--|---------------------|-------------|
| Product<br>Name  | Generic Name GPI Brand/G   |  | Brand/Generic       |             |
| MOVANTIK   | NALOXEGOL<br>EQUIVALENT  | OXALATE TAB 12.5 MG (BASE                | 52580060300320      | Brand       |
| MOVANTIK   | NALOXEGOL<br>EQUIVALENT  | OXALATE TAB 25 MG (BASE                  | 52580060300330      | Brand       |
| SYMPROIC   | NALDEMEDIN<br>EQUIVALENT   | NE TOSYLATE TAB 0.2 MG (BASE             | 52580057200320      | Brand       |
| <b>Approval ( 1</b> - Diagnos  |  | Induced Constipation                     |                     |             |
|  |  | AND                                      |                     |             |
| 2 - Member   | is on chron  | ic opioid therapy                        |                     |             |
|  |  | AND                                      |                     |             |
| 3 - Member is 18 years of age or older   |  |  |                     |             |
|  |  | AND                                      |                     |             |
|  | I - Trial and failure, contraindication or intolerance to a concurrent combination of a stimulant e.g., Senna) and an osmotic laxative (e.g., Miralax) |  |                     |             |
|  | AND  |  |                     |             |
| 5 - For Movantik Only - Trial and failure, contraindication or intolerance to lubiprostone |  |  |                     |             |
|  |  | AND                                      |                     |             |
| <b>6</b> - For Symnaloxegol  | nproic Only -  | Trial and failure, contraindication or i | ntolerance to lubip | rostone and |

| Product Name: Symproic, Movantik |                                       |  |
|----------------------------------|---------------------------------------|--|
| Diagnosis                        | Opioid-Induced Constipation           |  |
| Approval Length                  | 12 month(s)                           |  |
| Therapy Stage                    | Initial Authorization                 |  |
| Guideline Type                   | Prior Authorization - IL and MN Plans |  |

| Product<br>Name | Generic Name                                      | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| MOVANTIK        | NALOXEGOL OXALATE TAB 12.5 MG (BASE EQUIVALENT)   | 52580060300320 | Brand         |
| MOVANTIK        | NALOXEGOL OXALATE TAB 25 MG (BASE EQUIVALENT)     | 52580060300330 | Brand         |
| SYMPROIC        | NALDEMEDINE TOSYLATE TAB 0.2 MG (BASE EQUIVALENT) | 52580057200320 | Brand         |

1 - Diagnosis of Opioid-Induced Constipation

**AND** 

2 - Member is on chronic opioid therapy

**AND** 

3 - Member is 18 years of age or older

**AND** 

**4** - Trial and failure, contraindication or intolerance to a concurrent combination of a stimulant (e.g., Senna) and an osmotic laxative (e.g., Miralax)

**AND** 

5 - For Movantik Only - Trial and failure, contraindication or intolerance to lubiprostone

#### AND

**6** - For Symproic Only - Trial and failure, contraindication or intolerance to lubiprostone and naloxegol

| Product Name: Linzess, Trulance, Motegrity, Symproic, Movantik |                                |  |
|--|--------------------------------|--|
| Diagnosis  | Metastatic Cancer              |  |
| Approval Length  | 12 month(s)                    |  |
| Therapy Stage  | Initial Authorization          |  |
| Guideline Type   | Prior Authorization - MN Plans |  |

| Product<br>Name | Generic Name                                      | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| LINZESS         | LINACLOTIDE CAP 72 MCG                            | 52557050000110 | Brand         |
| LINZESS         | LINACLOTIDE CAP 145 MCG                           | 52557050000120 | Brand         |
| LINZESS         | LINACLOTIDE CAP 290 MCG                           | 52557050000140 | Brand         |
| MOVANTIK        | NALOXEGOL OXALATE TAB 12.5 MG (BASE EQUIVALENT)   | 52580060300320 | Brand         |
| MOVANTIK        | NALOXEGOL OXALATE TAB 25 MG (BASE<br>EQUIVALENT)  | 52580060300330 | Brand         |
| SYMPROIC        | NALDEMEDINE TOSYLATE TAB 0.2 MG (BASE EQUIVALENT) | 52580057200320 | Brand         |
| TRULANCE        | PLECANATIDE TAB 3 MG                              | 52543060000320 | Brand         |
| MOTEGRITY       | PRUCALOPRIDE SUCCINATE TAB 1 MG (BASE EQUIVALENT) | 52560060200320 | Brand         |
| MOTEGRITY       | PRUCALOPRIDE SUCCINATE TAB 2 MG (BASE EQUIVALENT) | 52560060200330 | Brand         |

## **Approval Criteria**

1 - Diagnosis of stage four metastatic cancer

#### **AND**

2 - Member is on opioid therapy to treat cancer-related pain with opioid-induced constipation

| Product Name: Linzess, Trulance, Motegrity, Symproic, Movantik |                                       |  |
|--|---------------------------------------|--|
| Diagnosis  | All Indications                       |  |
| Approval Length  | 12 month(s)                           |  |
| Therapy Stage  | Reauthorization                       |  |
| Guideline Type   | Prior Authorization - IL and MN Plans |  |

| Product<br>Name | Generic Name                                      | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| LINZESS         | LINACLOTIDE CAP 72 MCG                            | 52557050000110 | Brand         |
| LINZESS         | LINACLOTIDE CAP 145 MCG                           | 52557050000120 | Brand         |
| LINZESS         | LINACLOTIDE CAP 290 MCG                           | 52557050000140 | Brand         |
| MOVANTIK        | NALOXEGOL OXALATE TAB 12.5 MG (BASE EQUIVALENT)   | 52580060300320 | Brand         |
| MOVANTIK        | NALOXEGOL OXALATE TAB 25 MG (BASE EQUIVALENT)     | 52580060300330 | Brand         |
| SYMPROIC        | NALDEMEDINE TOSYLATE TAB 0.2 MG (BASE EQUIVALENT) | 52580057200320 | Brand         |
| TRULANCE        | PLECANATIDE TAB 3 MG                              | 52543060000320 | Brand         |
| MOTEGRITY       | PRUCALOPRIDE SUCCINATE TAB 1 MG (BASE EQUIVALENT) | 52560060200320 | Brand         |
| MOTEGRITY       | PRUCALOPRIDE SUCCINATE TAB 2 MG (BASE EQUIVALENT) | 52560060200330 | Brand         |

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug

| Product Name: Linzess   |            |
|---|------------|
| Diagnosis Functional Constipation                                     |            |
| Approval Length   | 12/31/2039 |
| Guideline Type Prior Authorization - All plans except IL and MN Plans |            |

| Product<br>Name | Generic Name            | GPI            | Brand/Generic |
|-----------------|-------------------------|----------------|---------------|
| LINZESS         | LINACLOTIDE CAP 72 MCG  | 52557050000110 | Brand         |
| LINZESS         | LINACLOTIDE CAP 145 MCG | 52557050000120 | Brand         |
| LINZESS         | LINACLOTIDE CAP 290 MCG | 52557050000140 | Brand         |

1 - Diagnosis of Functional Constipation

#### **AND**

2 - Member is between the age of 6 and 17 years of age

#### **AND**

**3** - Trial and failure, contraindication or intolerance to an adequate trial of over-the-counter osmotic laxatives (e.g., polyethylene glycol, magnesium hydroxide)

#### **AND**

**4** - Trial and failure, contraindication or intolerance to an adequate trial of over-the-counter stimulant laxative (e.g. bisacodyl, senna)

| Product Name: Linzess |                                       |
|-----------------------|---------------------------------------|
| Diagnosis             | Functional Constipation               |
| Approval Length       | 12 month(s)                           |
| Guideline Type        | Prior Authorization - IL and MN Plans |

| Product<br>Name | Generic Name            | GPI            | Brand/Generic |
|-----------------|-------------------------|----------------|---------------|
| LINZESS         | LINACLOTIDE CAP 72 MCG  | 52557050000110 | Brand         |
| LINZESS         | LINACLOTIDE CAP 145 MCG | 52557050000120 | Brand         |
| LINZESS         | LINACLOTIDE CAP 290 MCG | 52557050000140 | Brand         |

## **Approval Criteria**

1 - Diagnosis of Functional Constipation

## AND

2 - Member is between the age of 6 and 17 years of age

#### AND

**3** - Trial and failure, contraindication or intolerance to an adequate trial of over-the-counter osmotic laxatives (e.g., polyethylene glycol, magnesium hydroxide)

#### **AND**

**4** - Trial and failure, contraindication or intolerance to an adequate trial of over-the-counter stimulant laxative (e.g. bisacodyl, senna)

# 2. Revision History

| Date      | Notes                   |
|-----------|-------------------------|
| 9/19/2023 | 2024 New Implementation |

| Cimzia (certolizumab)   |  |  |  |  |
|---|--|--|--|--|
| (3) Intercongruence highest body to the control course a course of the first high provide country and |  |  |  |  |

# **Prior Authorization Guideline**

| Guideline ID   | GL-137231             |
|----------------|-----------------------|
| Guideline Name | Cimzia (certolizumab) |
| Formulary      | Quartz                |

# **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

## Note:

Member new to the plan (as evidenced by coverage effective date of less than or equal to 90 days) who initiated therapy using a manufacturer-sponsored free drug program, provider samples, and/or vouchers will go through initial criteria, otherwise for continuation of therapy for new to plan, reauthorization criteria applies.

## 1. Criteria

| Product Name: Cimzia |  |  |                |               |
|----------------------|--|--|----------------|---------------|
| Diagnosis            |  | Plaque Psoriasis                                       |                |               |
| Approval Length      |  | 12/31/2039   |                |               |
| Guideline Type       |  | Prior Authorization – All Plans except IL and MN Plans |                |               |
| Product<br>Name      | Generic Name   |  | GPI            | Brand/Generic |
| CIMZIA               | CERTOLIZUMAB PEGOL PREFILLED SYRINGE KIT 2 X 200 MG/ML |  | 5250502010F840 | Brand         |

| CIMZIA<br>STARTER<br>KIT | CERTOLIZUMAB PEGOL PREFILLED SYRINGE KIT 6 X 200 MG/ML | 5250502010F860 | Brand |
|--------------------------|--|----------------|-------|
| CIMZIA                   | CERTOLIZUMAB PEGOL FOR INJ KIT 2 X 200 MG              | 52505020106420 | Brand |

1 - Diagnosis of moderate to severe plaque psoriasis

#### **AND**

- **2** One of the following:
  - Significant functional disability
  - Body surface area (BSA) involvement of greater than or equal to 3%
  - Debilitating palmer/plantar psoriasis or other vulnerable areas that are difficult to treat (e.g. nails, scalp, genitals, or intertriginous areas

#### **AND**

3 - Prescribed by or in consultation with a dermatologist

#### AND

**4** - Trial and failure, contraindication, or intolerance to topical treatment (e.g. topical corticosteroids, calcipotriene, retinoids)

## **AND**

**5** - Not used in combination with other biologic disease modifying anti-rheumatic drugs (DMARDs) (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

#### **AND**

6 - Medication will be self-administered

| Product Name: Cimzia |                                       |  |
|----------------------|---------------------------------------|--|
| Diagnosis            | Plaque Psoriasis                      |  |
| Approval Length      | 12 month(s)                           |  |
| Therapy Stage        | Initial Authorization                 |  |
| Guideline Type       | Prior Authorization – IL and MN Plans |  |

| Product<br>Name          | Generic Name   | GPI            | Brand/Generic |
|--------------------------|--|----------------|---------------|
| CIMZIA                   | CERTOLIZUMAB PEGOL PREFILLED SYRINGE KIT 2 X 200 MG/ML | 5250502010F840 | Brand         |
| CIMZIA<br>STARTER<br>KIT | CERTOLIZUMAB PEGOL PREFILLED SYRINGE KIT 6 X 200 MG/ML | 5250502010F860 | Brand         |
| CIMZIA                   | CERTOLIZUMAB PEGOL FOR INJ KIT 2 X 200 MG              | 52505020106420 | Brand         |

1 - Diagnosis of moderate to severe plaque psoriasis

## **AND**

- 2 One of the following:
  - Significant functional disability
  - Body surface area (BSA) involvement of greater than or equal to 3%
  - Debilitating palmer/plantar psoriasis or other vulnerable areas that are difficult to treat (e.g. nails, scalp, genitals, or intertriginous areas

#### **AND**

3 - Prescribed by or in consultation with a dermatologist

#### **AND**

**4** - Trial and failure, contraindication, or intolerance to topical treatment (e.g. topical corticosteroids, calcipotriene, retinoids)

#### **AND**

**5** - Not used in combination with other biologic disease modifying anti-rheumatic drugs (DMARDs) (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

#### **AND**

6 - Medication will be self-administered

| Product Name: Cimzia |  |  |
|----------------------|--|--|
| Diagnosis            | Psoriatic Arthritis (PsA)                              |  |
| Approval Length      | 12/31/2039   |  |
| Guideline Type       | Prior Authorization – All Plans except IL and MN Plans |  |

| Product<br>Name          | Generic Name   | GPI            | Brand/Generic |
|--------------------------|--|----------------|---------------|
| CIMZIA                   | CERTOLIZUMAB PEGOL PREFILLED SYRINGE KIT 2 X 200 MG/ML | 5250502010F840 | Brand         |
| CIMZIA<br>STARTER<br>KIT | CERTOLIZUMAB PEGOL PREFILLED SYRINGE KIT 6 X 200 MG/ML | 5250502010F860 | Brand         |
| CIMZIA                   | CERTOLIZUMAB PEGOL FOR INJ KIT 2 X 200 MG              | 52505020106420 | Brand         |

## **Approval Criteria**

1 - Diagnosis of moderate to severely active psoriatic arthritis (PsA)

#### **AND**

2 - Prescribed by or in consultation with a dermatologist or rheumatologist

#### **AND**

**3** - Submission of medical records (e.g., chart notes) documenting at least ONE of the following:

- actively inflamed joints
- axial disease
- active skin, nail, or scalp psoriasis involvement
- dactylitis
- enthesitis

#### AND

**4** - Not used in combination with other biologic DMARDs (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

#### AND

**5** - Medication will be self-administered

| Product Name: Cimzia |                                       |  |
|----------------------|---------------------------------------|--|
| Diagnosis            | Psoriatic Arthritis (PsA)             |  |
| Approval Length      | 12 month(s)                           |  |
| Therapy Stage        | Initial Authorization                 |  |
| Guideline Type       | Prior Authorization – IL and MN Plans |  |

| Product<br>Name          | Generic Name   | GPI            | Brand/Generic |
|--------------------------|--|----------------|---------------|
| CIMZIA                   | CERTOLIZUMAB PEGOL PREFILLED SYRINGE KIT 2 X 200 MG/ML | 5250502010F840 | Brand         |
| CIMZIA<br>STARTER<br>KIT | CERTOLIZUMAB PEGOL PREFILLED SYRINGE KIT 6 X 200 MG/ML | 5250502010F860 | Brand         |
| CIMZIA                   | CERTOLIZUMAB PEGOL FOR INJ KIT 2 X 200 MG              | 52505020106420 | Brand         |

# **Approval Criteria**

1 - Diagnosis of moderate to severely active psoriatic arthritis (PsA)

#### AND

2 - Prescribed by or in consultation with a dermatologist or rheumatologist

#### **AND**

- **3** Submission of medical records (e.g., chart notes) documenting at least ONE of the following:
  - actively inflamed joints
  - axial disease
  - active skin, nail, or scalp psoriasis involvement
  - dactylitis
  - enthesitis

#### **AND**

**4** - Not used in combination with other biologic DMARDs (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

#### **AND**

5 - Medication will be self-administered

| Product Name: Cimzia |  |  |
|----------------------|--|--|
| Diagnosis            | Moderate to Severely Active Rheumatoid Arthritis (RA)  |  |
| Approval Length      | 12/31/2039   |  |
| Guideline Type       | Prior Authorization – All Plans except IL and MN Plans |  |

| Product<br>Name          | Generic Name   | GPI            | Brand/Generic |
|--------------------------|--|----------------|---------------|
| CIMZIA                   | CERTOLIZUMAB PEGOL PREFILLED SYRINGE KIT 2 X 200 MG/ML | 5250502010F840 | Brand         |
| CIMZIA<br>STARTER<br>KIT | CERTOLIZUMAB PEGOL PREFILLED SYRINGE KIT 6 X 200 MG/ML | 5250502010F860 | Brand         |
| CIMZIA                   | CERTOLIZUMAB PEGOL FOR INJ KIT 2 X 200 MG              | 52505020106420 | Brand         |

## **Approval Criteria**

1 - Diagnosis of moderate to severely active Rheumatoid arthritis (RA)

#### **AND**

- **2** Submission of medical records (e.g., chart notes) documenting a 3-month trial and failure, intolerance, or contraindication to ONE of the following:
  - Methotrexate (MTX)\*
  - Leflunomide
  - Hydroxychloroquine
  - Sulfasalazine

#### **AND**

**3** - Medication will be self-administered (not in clinic or provider office)

#### **AND**

**4** - Prescribed by or in consultation with a rheumatologist

#### **AND**

**5** - Not used in combination with other biologic DMARDs (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

| Notes | *Absolute contraindications to methotrexate are pregnancy, nursing, al   |
|-------|--|
|       | coholism, alcoholic liver disease or other chronic liver disease, immuno |
|       | deficiency syndromes, bone marrow hyperplasia, leukopenia, thromboc      |
|       | ytopenia or significant anemia, or hypersensitivity to methotrexate.     |

| Product Name: Cimzia        |            |   |  |  |
|-----------------------------|------------|---|--|--|
| Diagnosis                   |            | Moderate to Severely Active Rheumatoid Arthritis (RA) |  |  |
| Approval Length 12 month(s) |            |   |  |  |
| Therapy Stage               |            | Initial Authorization                                 |  |  |
| Guideline Type              |            | Prior Authorization – IL and MN Plans                 |  |  |
| Product                     | Generic Na | me GPI Brand/Generic                                  |  |  |

| Name                     |  |                |       |
|--------------------------|--|----------------|-------|
| CIMZIA                   | CERTOLIZUMAB PEGOL PREFILLED SYRINGE KIT 2 X 200 MG/ML | 5250502010F840 | Brand |
| CIMZIA<br>STARTER<br>KIT | CERTOLIZUMAB PEGOL PREFILLED SYRINGE KIT 6 X 200 MG/ML | 5250502010F860 | Brand |
| CIMZIA                   | CERTOLIZUMAB PEGOL FOR INJ KIT 2 X 200 MG              | 52505020106420 | Brand |

1 - Diagnosis of moderate to severely active Rheumatoid arthritis (RA)

#### **AND**

- **2** Submission of medical records (e.g., chart notes) documenting a 3-month trial and failure, intolerance, or contraindication to ONE of the following:
  - Methotrexate (MTX)\*
  - Leflunomide
  - Hydroxychloroquine
  - Sulfasalazine

#### **AND**

3 - Medication will be self-administered (not in clinic or provider office)

#### AND

4 - Prescribed by or in consultation with a rheumatologist

#### **AND**

**5** - Not used in combination with other biologic DMARDs (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

| Notes | *Absolute contraindications to methotrexate are pregnancy, nursing, al   |
|-------|--|
|       | coholism, alcoholic liver disease or other chronic liver disease, immuno |
|       | deficiency syndromes, bone marrow hyperplasia, leukopenia, thromboc      |

| ytopenia or significant anemia, or hypersensitivity to methotrexate. |
|--|
| ,                              |

| Product Name: Cimzia |  |  |
|----------------------|--|--|
| Diagnosis            | Ankylosing Spondylitis (AS)                            |  |
| Approval Length      | 12/31/2039   |  |
| Guideline Type       | Prior Authorization – All Plans except IL and MN Plans |  |

| Product<br>Name          | Generic Name   | GPI            | Brand/Generic |
|--------------------------|--|----------------|---------------|
| CIMZIA                   | CERTOLIZUMAB PEGOL PREFILLED SYRINGE KIT 2 X 200 MG/ML | 5250502010F840 | Brand         |
| CIMZIA<br>STARTER<br>KIT | CERTOLIZUMAB PEGOL PREFILLED SYRINGE KIT 6 X 200 MG/ML | 5250502010F860 | Brand         |
| CIMZIA                   | CERTOLIZUMAB PEGOL FOR INJ KIT 2 X 200 MG              | 52505020106420 | Brand         |

**1** - Diagnosis of ankylosing spondylitis (AS)

#### **AND**

**2** - Prescribed by or in consultation with a rheumatologist

#### AND

**3** - Minimum duration of a 1-month trial and failure, contraindication, or intolerance of scheduled prescription doses of TWO different NSAIDs (e.g., naproxen, nabumetone, diclofenac)

#### AND

**4** - Not used in combination with other biologic DMARDs (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

## **AND**

#### 5 - Medication will be self-administered

| Product Name: Cimzia |                                       |  |
|----------------------|---------------------------------------|--|
| Diagnosis            | Ankylosing Spondylitis (AS)           |  |
| Approval Length      | 12 month(s)                           |  |
| Therapy Stage        | Initial Authorization                 |  |
| Guideline Type       | Prior Authorization – IL and MN Plans |  |

| Product<br>Name          | Generic Name   | GPI            | Brand/Generic |
|--------------------------|--|----------------|---------------|
| CIMZIA                   | CERTOLIZUMAB PEGOL PREFILLED SYRINGE KIT 2 X 200 MG/ML | 5250502010F840 | Brand         |
| CIMZIA<br>STARTER<br>KIT | CERTOLIZUMAB PEGOL PREFILLED SYRINGE KIT 6 X 200 MG/ML | 5250502010F860 | Brand         |
| CIMZIA                   | CERTOLIZUMAB PEGOL FOR INJ KIT 2 X 200 MG              | 52505020106420 | Brand         |

## **Approval Criteria**

1 - Diagnosis of ankylosing spondylitis (AS)

#### **AND**

2 - Prescribed by or in consultation with a rheumatologist

### **AND**

**3** - Minimum duration of a 1-month trial and failure, contraindication, or intolerance of scheduled prescription doses of TWO different NSAIDs (e.g., naproxen, nabumetone, diclofenac)

## **AND**

**4** - Not used in combination with other biologic DMARDs (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

#### AND

5 - Medication will be self-administered

| Product Name: Cimzia |  |
|----------------------|--|
| Diagnosis            | Non-radiographic axial spondyloarthritis (nr-axSpA)    |
| Approval Length      | 12/31/2039   |
| Guideline Type       | Prior Authorization – All Plans except IL and MN Plans |

| Product<br>Name          | Generic Name   | GPI            | Brand/Generic |
|--------------------------|--|----------------|---------------|
| CIMZIA                   | CERTOLIZUMAB PEGOL PREFILLED SYRINGE KIT 2 X 200 MG/ML | 5250502010F840 | Brand         |
| CIMZIA<br>STARTER<br>KIT | CERTOLIZUMAB PEGOL PREFILLED SYRINGE KIT 6 X 200 MG/ML | 5250502010F860 | Brand         |
| CIMZIA                   | CERTOLIZUMAB PEGOL FOR INJ KIT 2 X 200 MG              | 52505020106420 | Brand         |

## **Approval Criteria**

**1** - Diagnosis of active non-radiographic axial spondyloarthritis (nr-axSpA) with elevated labs (e.g. C-reactive protein) and/or sacroiliitis on imaging

#### AND

2 - Prescribed by or in consultation with a rheumatologist

#### **AND**

**3** - Minimum duration of a 1-month trial and failure, contraindication, or intolerance of scheduled prescription doses of TWO different NSAIDs (e.g., naproxen, nabumetone, diclofenac)

#### **AND**

**4** - Not used in combination with other biologic DMARDs (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

#### **AND**

5 - Medication will be self-administered

| Product Name: Cimzia |   |
|----------------------|---|
| Diagnosis            | Non-radiographic axial spondyloarthritis (nr-axSpA) |
| Approval Length      | 12 month(s)   |
| Therapy Stage        | Initial Authorization                               |
| Guideline Type       | Prior Authorization – IL and MN Plans               |

| Product<br>Name          | Generic Name   | GPI            | Brand/Generic |
|--------------------------|--|----------------|---------------|
| CIMZIA                   | CERTOLIZUMAB PEGOL PREFILLED SYRINGE KIT 2 X 200 MG/ML | 5250502010F840 | Brand         |
| CIMZIA<br>STARTER<br>KIT | CERTOLIZUMAB PEGOL PREFILLED SYRINGE KIT 6 X 200 MG/ML | 5250502010F860 | Brand         |
| CIMZIA                   | CERTOLIZUMAB PEGOL FOR INJ KIT 2 X 200 MG              | 52505020106420 | Brand         |

## **Approval Criteria**

**1** - Diagnosis of active non-radiographic axial spondyloarthritis (nr-axSpA) with elevated labs (e.g. C-reactive protein) and/or sacroillitis on imaging

### **AND**

2 - Prescribed by or in consultation with a rheumatologist

#### **AND**

**3** - Minimum duration of a 1-month trial and failure, contraindication, or intolerance of scheduled prescription doses of TWO different NSAIDs (e.g., naproxen, nabumetone, diclofenac)

#### **AND**

**4** - Not used in combination with other biologic DMARDs (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

#### **AND**

5 - Medication will be self-administered

| Product Name: Cimzia |  |
|----------------------|--|
| Diagnosis            | Moderate to Severely Active Crohn's Disease (CD)       |
| Approval Length      | 12/31/2039   |
| Guideline Type       | Prior Authorization – All Plans except IL and MN Plans |

| Product<br>Name          | Generic Name   | GPI            | Brand/Generic |
|--------------------------|--|----------------|---------------|
| CIMZIA                   | CERTOLIZUMAB PEGOL PREFILLED SYRINGE KIT 2 X 200 MG/ML | 5250502010F840 | Brand         |
| CIMZIA<br>STARTER<br>KIT | CERTOLIZUMAB PEGOL PREFILLED SYRINGE KIT 6 X 200 MG/ML | 5250502010F860 | Brand         |
| CIMZIA                   | CERTOLIZUMAB PEGOL FOR INJ KIT 2 X 200 MG              | 52505020106420 | Brand         |

## **Approval Criteria**

1 - Diagnosis of moderate to severely active Crohn's disease (CD)

#### **AND**

2 - Prescribed by or in consultation with a gastroenterologist

### **AND**

- **3** One of the following:
- **3.1** Member is considered high-risk based on ONE of the following characteristics:
  - Age less than 30 years at diagnosis

- Extensive anatomic involvement
- Perianal and/or severe rectal disease
- Deep ulcers
- Prior surgical resection
- Stricturing and/or penetrating behavior
- Fistulizing disease
- Extraintestinal manifestations of inflammation (e.g., uveitis, erythema nodosum, pyoderma gangrenosum, spondyloarthropathy)

OR

- **3.2** Both of the following:
- **3.2.1** Member is considered low-risk

#### AND

#### **3.2.2** One of the following:

- Trial and failure, contraindication, or intolerance to one conventional therapy (e.g., azathioprine, balsalazide, corticosteroids, mesalamine, mercaptopurine, methotrexate, sulfasalazine)
- Inadequate disease control or inability to achieve remission after an adequate trial of 3 months with one conventional therapy
- Demonstrated steroid dependence
- Conventional therapy clinically inappropriate based on location of disease

#### **AND**

**4** - Not used in combination with other biologic DMARDs (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

#### AND

5 - Medication will be self-administered

| Product Name: Cimzia |  |
|----------------------|--|
| Diagnosis            | Moderate to Severely Active Crohn's Disease (CD) |
| Approval Length      | 12 month(s)                                      |

| Therapy Stage  | Initial Authorization                 |
|----------------|---------------------------------------|
| Guideline Type | Prior Authorization – IL and MN Plans |

| Product<br>Name          | Generic Name   | GPI            | Brand/Generic |
|--------------------------|--|----------------|---------------|
| CIMZIA                   | CERTOLIZUMAB PEGOL PREFILLED SYRINGE KIT 2 X 200 MG/ML | 5250502010F840 | Brand         |
| CIMZIA<br>STARTER<br>KIT | CERTOLIZUMAB PEGOL PREFILLED SYRINGE KIT 6 X 200 MG/ML | 5250502010F860 | Brand         |
| CIMZIA                   | CERTOLIZUMAB PEGOL FOR INJ KIT 2 X 200 MG              | 52505020106420 | Brand         |

**1** - Diagnosis of moderate to severely active Crohn's disease (CD)

#### AND

**2** - Prescribed by or in consultation with a gastroenterologist

#### **AND**

- **3** One of the following:
- 3.1 Member is considered high-risk based on ONE of the following characteristics:
  - Age less than 30 years at diagnosis
  - Extensive anatomic involvement
  - Perianal and/or severe rectal disease
  - Deep ulcers
  - Prior surgical resection
  - Stricturing and/or penetrating behavior
  - Fistulizing disease
  - Extraintestinal manifestations of inflammation (e.g., uveitis, erythema nodosum, pyoderma gangrenosum, spondyloarthropathy)

OR

**3.2** Both of the following:

#### **3.2.1** Member is considered low-risk

#### **AND**

#### **3.2.2** One of the following:

- Trial and failure, contraindication, or intolerance to one conventional therapy (e.g., azathioprine, balsalazide, corticosteroids, mesalamine, mercaptopurine, methotrexate, sulfasalazine)
- Inadequate disease control or inability to achieve remission after an adequate trial of 3 months with one conventional therapy
- Demonstrated steroid dependence
- Conventional therapy clinically inappropriate based on location of disease

#### **AND**

**4** - Not used in combination with other biologic DMARDs (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

#### **AND**

5 - Medication will be self-administered

| Product Name: Cimzia |                                       |
|----------------------|---------------------------------------|
| Diagnosis            | All Indications                       |
| Approval Length      | 12 month(s)                           |
| Therapy Stage        | Reauthorization                       |
| Guideline Type       | Prior Authorization – IL and MN Plans |

| Product<br>Name          | Generic Name   | GPI            | Brand/Generic |
|--------------------------|--|----------------|---------------|
| CIMZIA                   | CERTOLIZUMAB PEGOL PREFILLED SYRINGE KIT 2 X 200 MG/ML | 5250502010F840 | Brand         |
| CIMZIA<br>STARTER<br>KIT | CERTOLIZUMAB PEGOL PREFILLED SYRINGE KIT 6 X 200 MG/ML | 5250502010F860 | Brand         |
| CIMZIA                   | CERTOLIZUMAB PEGOL FOR INJ KIT 2 X 200 MG              | 52505020106420 | Brand         |

**1** - Prescriber provides clinical documentation from the previous 12 months of the member's response to therapy including individual improvements in functional status related to therapeutic response

|  | *Member new to the plan (as evidenced by coverage effective date of I ess than or equal to 90 days) who initiated therapy using a manufactur er-sponsored free drug program, provider samples, and/or vouchers wil I go through initial criteria, otherwise for continuation of therapy for new to plan, reauthorization criteria applies |
|--|---|
|--|---|

| Product Name: Cimzia |   |
|----------------------|---|
| Diagnosis            | Moderate to Severely Active Rheumatoid Arthritis, PSA, AS, nr-axSpA, plaque psoriasis |
| Approval Length      | 12 month(s)   |
| Guideline Type       | Quantity Exception - IL and MN Plans  |

| Product<br>Name          | Generic Name   | GPI            | Brand/Generic |
|--------------------------|--|----------------|---------------|
| CIMZIA                   | CERTOLIZUMAB PEGOL PREFILLED SYRINGE KIT 2 X 200 MG/ML | 5250502010F840 | Brand         |
| CIMZIA<br>STARTER<br>KIT | CERTOLIZUMAB PEGOL PREFILLED SYRINGE KIT 6 X 200 MG/ML | 5250502010F860 | Brand         |
| CIMZIA                   | CERTOLIZUMAB PEGOL FOR INJ KIT 2 X 200 MG              | 52505020106420 | Brand         |

## **Approval Criteria**

**1** - Failure of an adherent 3-month trial of standard maintenance dosing with concomitant methotrexate (unless contraindicated or not appropriate for indication being requested)

| Product Na      | me: Cimzia |   |  |  |
|-----------------|------------|---|--|--|
| Diagnosis       |            | Moderate to Severely Active Rheumatoid Arthritis, PSA, AS, nr-axSpA, plaque psoriasis |  |  |
| Approval Le     | ength      | 12/31/2099  |  |  |
| Guideline T     | уре        | Quantity Exception – All Plans except IL and MN Plans                                 |  |  |
| Product<br>Name | Generic Na | me GPI Brand/Generic  |  |  |

| CIMZIA                   | CERTOLIZUMAB PEGOL PREFILLED SYRINGE KIT 2 X 200 MG/ML | 5250502010F840 | Brand |
|--------------------------|--|----------------|-------|
| CIMZIA<br>STARTER<br>KIT | CERTOLIZUMAB PEGOL PREFILLED SYRINGE KIT 6 X 200 MG/ML | 5250502010F860 | Brand |
| CIMZIA                   | CERTOLIZUMAB PEGOL FOR INJ KIT 2 X 200 MG              | 52505020106420 | Brand |

**1** - Failure of an adherent 3-month trial of standard maintenance dosing with concomitant methotrexate (unless contraindicated or not appropriate for indication being requested)

| Product Name: Cimzia |                                      |
|----------------------|--------------------------------------|
| Diagnosis            | Crohn's disease                      |
| Approval Length      | 12 month(s)                          |
| Guideline Type       | Quantity Exception - IL and MN Plans |

| Product<br>Name          | Generic Name   | GPI            | Brand/Generic |
|--------------------------|--|----------------|---------------|
| CIMZIA                   | CERTOLIZUMAB PEGOL PREFILLED SYRINGE KIT 2 X 200 MG/ML | 5250502010F840 | Brand         |
| CIMZIA<br>STARTER<br>KIT | CERTOLIZUMAB PEGOL PREFILLED SYRINGE KIT 6 X 200 MG/ML | 5250502010F860 | Brand         |
| CIMZIA                   | CERTOLIZUMAB PEGOL FOR INJ KIT 2 X 200 MG              | 52505020106420 | Brand         |

# **Approval Criteria**

1 - Failure of a two-month trial of monthly therapy after completion of induction dosing regimen

#### **AND**

2 - Based on subtherapeutic drug concentrations and absence (or low levels) of drug antibodies

| Product Name: Cimzia |                 |
|----------------------|-----------------|
| Diagnosis            | Crohn's disease |
| Approval Length      | 12/31/2099      |

| Guideline T              | Type Quantity Exception – All Plans except IL and MN Plans |                                     | }              |               |
|--------------------------|--|-------------------------------------|----------------|---------------|
| Product<br>Name          | Generic Na   | me                                  | GPI            | Brand/Generic |
| CIMZIA                   | CERTOLIZUN<br>200 MG/ML                                    | MAB PEGOL PREFILLED SYRINGE KIT 2 X | 5250502010F840 | Brand         |
| CIMZIA<br>STARTER<br>KIT | CERTOLIZUN<br>200 MG/ML                                    | 1AB PEGOL PREFILLED SYRINGE KIT 6 X | 5250502010F860 | Brand         |
| CIMZIA                   | CERTOLIZUN   | IAB PEGOL FOR INJ KIT 2 X 200 MG    | 52505020106420 | Brand         |

1 - Failure of a two-month trial of monthly therapy after completion of induction dosing regimen

## **AND**

2 - Based on subtherapeutic drug concentrations and absence (or low levels) of drug antibodies

# 2. Revision History

| Date      | Notes                   |
|-----------|-------------------------|
| 12/4/2023 | 2024 New Implementation |

| Clom                                  | ipramine (ana   | afranil) |  |
|---------------------------------------|---|----------|--|
| The bits of large current for display | uri. Turbi may karaban mand, coranis, a dilikali belih pad belap pada bir semendik ad bad |          |  |

# **Prior Authorization Guideline**

| Guideline ID          | GL-128188                |
|-----------------------|--------------------------|
| <b>Guideline Name</b> | Clomipramine (anafranil) |
| Formulary             | Quartz                   |

# **Guideline Note:**

| Effective Date: |
|-----------------|
|-----------------|

# 1. Criteria

| Product Name: Generic Clomipramine                   |                                |  |
|--|--------------------------------|--|
| Diagnosis  | Obsessive compulsive disorder: |  |
| Approval Length                                      | 12 month(s)                    |  |
| Therapy Stage  | Initial Authorization          |  |
| Guideline Type Prior Authorization - IL and MN Plans |                                |  |

| Product Name                  | Generic Name               | GPI            | Brand/Generic |
|-------------------------------|----------------------------|----------------|---------------|
| CLOMIPRAMINE<br>HCL           | CLOMIPRAMINE HCL CAP 25 MG | 58200025100120 | Generic       |
| CLOMIPRAMINE<br>HYDROCHLORIDE | CLOMIPRAMINE HCL CAP 25 MG | 58200025100120 | Generic       |
| CLOMIPRAMINE<br>HCL           | CLOMIPRAMINE HCL CAP 50 MG | 58200025100130 | Generic       |
| CLOMIPRAMINE<br>HYDROCHLORIDE | CLOMIPRAMINE HCL CAP 50 MG | 58200025100130 | Generic       |

| CLOMIPRAMINE<br>HCL           | CLOMIPRAMINE HCL CAP 75 MG | 58200025100140 | Generic |
|-------------------------------|----------------------------|----------------|---------|
| CLOMIPRAMINE<br>HYDROCHLORIDE | CLOMIPRAMINE HCL CAP 75 MG | 58200025100140 | Generic |

**1** - Trial and failure, contraindication or intolerance to, two preferred antidepressants within the Serotonin Selective Reuptake Inhibitor (SSRI) category category (e.g. citalopram, escitalopram, sertraline, fluoxetine, paroxetine)

| Product Name: Generic Clomipramine        |                                       |  |
|---|---------------------------------------|--|
| Diagnosis Other mood or anxiety disorders |                                       |  |
| Approval Length                           | 12 month(s)                           |  |
| Therapy Stage                             | Initial Authorization                 |  |
| Guideline Type                            | Prior Authorization - IL and MN Plans |  |

| Product Name                  | Generic Name               | GPI            | Brand/Generic |
|-------------------------------|----------------------------|----------------|---------------|
| CLOMIPRAMINE<br>HCL           | CLOMIPRAMINE HCL CAP 25 MG | 58200025100120 | Generic       |
| CLOMIPRAMINE<br>HYDROCHLORIDE | CLOMIPRAMINE HCL CAP 25 MG | 58200025100120 | Generic       |
| CLOMIPRAMINE<br>HCL           | CLOMIPRAMINE HCL CAP 50 MG | 58200025100130 | Generic       |
| CLOMIPRAMINE<br>HYDROCHLORIDE | CLOMIPRAMINE HCL CAP 50 MG | 58200025100130 | Generic       |
| CLOMIPRAMINE<br>HCL           | CLOMIPRAMINE HCL CAP 75 MG | 58200025100140 | Generic       |
| CLOMIPRAMINE<br>HYDROCHLORIDE | CLOMIPRAMINE HCL CAP 75 MG | 58200025100140 | Generic       |

## **Approval Criteria**

1 - Trial and failure, contraindication or intolerance to, two preferred antidepressants within the Serotonin Selective Reuptake Inhibitor (SSRI) or Selective Norepinephrine Reuptake Inhibitor (SNRI) categories (e.g. citalopram, escitalopram, sertraline, fluoxetine, paroxetine, duloxetine, venlafaxine)

Product Name: Generic Clomipramine

| Diagnosis       | Obsessive compulsive disorder, Other mood or anxiety disorders, non-behavioral heatlh/mood disorders |
|-----------------|--|
| Approval Length | 12 month(s)  |
| Therapy Stage   | Reauthorization  |
| Guideline Type  | Prior Authorization - IL and MN Plans  |

| Product Name                  | Generic Name               | GPI            | Brand/Generic |
|-------------------------------|----------------------------|----------------|---------------|
| CLOMIPRAMINE<br>HCL           | CLOMIPRAMINE HCL CAP 25 MG | 58200025100120 | Generic       |
| CLOMIPRAMINE<br>HYDROCHLORIDE | CLOMIPRAMINE HCL CAP 25 MG | 58200025100120 | Generic       |
| CLOMIPRAMINE<br>HCL           | CLOMIPRAMINE HCL CAP 50 MG | 58200025100130 | Generic       |
| CLOMIPRAMINE<br>HYDROCHLORIDE | CLOMIPRAMINE HCL CAP 50 MG | 58200025100130 | Generic       |
| CLOMIPRAMINE<br>HCL           | CLOMIPRAMINE HCL CAP 75 MG | 58200025100140 | Generic       |
| CLOMIPRAMINE<br>HYDROCHLORIDE | CLOMIPRAMINE HCL CAP 75 MG | 58200025100140 | Generic       |

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug

| Product Name: Generic Clomipramine                              |                                |  |
|---|--------------------------------|--|
| Diagnosis   | Obsessive compulsive disorder: |  |
| Approval Length   | 12/31/2039                     |  |
| Guideline Type Prior Authorization - All plans except IL and MN |                                |  |

| Product Name                  | Generic Name               | GPI            | Brand/Generic |
|-------------------------------|----------------------------|----------------|---------------|
| CLOMIPRAMINE<br>HCL           | CLOMIPRAMINE HCL CAP 25 MG | 58200025100120 | Generic       |
| CLOMIPRAMINE<br>HYDROCHLORIDE | CLOMIPRAMINE HCL CAP 25 MG | 58200025100120 | Generic       |
| CLOMIPRAMINE<br>HCL           | CLOMIPRAMINE HCL CAP 50 MG | 58200025100130 | Generic       |
| CLOMIPRAMINE<br>HYDROCHLORIDE | CLOMIPRAMINE HCL CAP 50 MG | 58200025100130 | Generic       |
| CLOMIPRAMINE<br>HCL           | CLOMIPRAMINE HCL CAP 75 MG | 58200025100140 | Generic       |

| CLOMIPRAMINE HCL CAP 75 MG<br>HYDROCHLORIDE | 58200025100140 | Generic |
|---|----------------|---------|
|---|----------------|---------|

**1** - Trial and failure, contraindication or intolerance to, two preferred antidepressants within the Serotonin Selective Reuptake Inhibitor (SSRI) category (e.g. citalopram, escitalopram, sertraline, fluoxetine, paroxetine

| Product Name: Generic Clomipramine        |  |  |
|---|--|--|
| Diagnosis Other mood or anxiety disorders |  |  |
| Approval Length                           | 12/31/2039                                       |  |
| Guideline Type                            | Prior Authorization - All plans except IL and MN |  |

| Product Name                  | Generic Name               | GPI            | Brand/Generic |
|-------------------------------|----------------------------|----------------|---------------|
| CLOMIPRAMINE<br>HCL           | CLOMIPRAMINE HCL CAP 25 MG | 58200025100120 | Generic       |
| CLOMIPRAMINE<br>HYDROCHLORIDE | CLOMIPRAMINE HCL CAP 25 MG | 58200025100120 | Generic       |
| CLOMIPRAMINE<br>HCL           | CLOMIPRAMINE HCL CAP 50 MG | 58200025100130 | Generic       |
| CLOMIPRAMINE<br>HYDROCHLORIDE | CLOMIPRAMINE HCL CAP 50 MG | 58200025100130 | Generic       |
| CLOMIPRAMINE<br>HCL           | CLOMIPRAMINE HCL CAP 75 MG | 58200025100140 | Generic       |
| CLOMIPRAMINE<br>HYDROCHLORIDE | CLOMIPRAMINE HCL CAP 75 MG | 58200025100140 | Generic       |

## **Approval Criteria**

1 - Trial and failure, contraindication or intolerance to, two preferred antidepressants within the Serotonin Selective Reuptake Inhibitor (SSRI) or Selective Norepinephrine Reuptake Inhibitor (SNRI) categories (e.g. citalopram, escitalopram, sertraline, fluoxetine, paroxetine, duloxetine, venlafaxine)

# 2. Revision History

| Date | Notes |
|------|-------|
|      |       |

| 9/24/2023 | New Program |
|-----------|-------------|
|           |             |

| Codeine and Tramadol-Containing Product   |  |  |  |  |  |
|---|--|--|--|--|--|
| (3) hadroning-manifolds being states and a sour a sour a sour and the best sources a month actions. |  |  |  |  |  |

# **Prior Authorization Guideline**

| Guideline ID          | GL-129741                                |
|-----------------------|--|
| <b>Guideline Name</b> | Codeine and Tramadol-Containing Products |
| Formulary             | Quartz                                   |

# **Guideline Note:**

| Effective Date: |
|-----------------|
|-----------------|

# 1. Criteria

| Approval Length | 12 month(s)                           |
|-----------------|---------------------------------------|
| Therapy Stage   | Initial Authorization                 |
| Guideline Type  | Prior Authorization - IL and MN Plans |

| Product Name                    | Generic Name                                 | GPI            | Brand/Generi<br>c |
|---------------------------------|--|----------------|-------------------|
| ACETAMINOPHEN/CODEINE PHOSPHATE | ACETAMINOPHEN<br>W/ CODEINE TAB<br>300-15 MG | 65991002050310 | Generic           |
| ACETAMINOPHEN/CODEINE           | ACETAMINOPHEN<br>W/ CODEINE TAB<br>300-15 MG | 65991002050310 | Generic           |
| ACETAMINOPHEN/CODEINE PHOSPHATE | ACETAMINOPHEN<br>W/ CODEINE TAB<br>300-30 MG | 65991002050315 | Generic           |
| ACETAMINOPHEN/CODEINE           | ACETAMINOPHEN                                | 65991002050315 | Generic           |

|  | W/ CODEINE TAB<br>300-30 MG  |                |         |
|--|--|----------------|---------|
| ACETAMINOPHEN/CODEINE #3                   | ACETAMINOPHEN<br>W/ CODEINE TAB<br>300-30 MG                         | 65991002050315 | Generic |
| ACETAMINOPHEN/CODEINE PHOSPHATE            | ACETAMINOPHEN<br>W/ CODEINE TAB<br>300-60 MG                         | 65991002050320 | Generic |
| ACETAMINOPHEN/CODEINE                      | ACETAMINOPHEN<br>W/ CODEINE TAB<br>300-60 MG                         | 65991002050320 | Generic |
| RYDEX                                      | PSEUDOEPHEDRIN<br>E-BROMPHEN-<br>CODEINE LIQ 10-<br>1.33-6.33 MG/5ML | 43995303190922 | Brand   |
| BUTALBITAL/ACETAMINOPHEN/CAFFEINE/CODE INE | BUTALBITAL-<br>ACETAMINOPHEN-<br>CAFF W/ COD CAP<br>50-300-40-30 MG  | 65991004100113 | Generic |
| BUTALBITAL/ACETAMINOPHEN/CAFFEINE/CODE INE | BUTALBITAL-<br>ACETAMINOPHEN-<br>CAFF W/ COD CAP<br>50-325-40-30 MG  | 65991004100115 | Generic |
| CAPCOF                                     | PHENYLEPHRINE-<br>CHLORPHEN W/<br>CODEINE SYRUP 5-<br>2-10 MG/5ML    | 43995303141220 | Brand   |
| VIRTUSSIN A/C                              | GUAIFENESIN-<br>CODEINE SOLN<br>100-10 MG/5ML                        | 43997002282020 | Generic |
| CODEINE/GUAIFENESIN                        | GUAIFENESIN-<br>CODEINE SOLN<br>100-10 MG/5ML                        | 43997002282020 | Generic |
| MAXI-TUSS AC                               | GUAIFENESIN-<br>CODEINE SOLN<br>100-10 MG/5ML                        | 43997002282020 | Generic |
| GUAIFENESIN/CODEINE                        | GUAIFENESIN-<br>CODEINE SOLN<br>100-10 MG/5ML                        | 43997002282020 | Generic |
| GUAIATUSSIN AC                             | GUAIFENESIN-<br>CODEINE SOLN<br>100-10 MG/5ML                        | 43997002282020 | Generic |
| G TUSSIN AC                                | GUAIFENESIN-<br>CODEINE SOLN<br>100-10 MG/5ML                        | 43997002282020 | Generic |
| GUAIFENESIN AC                             | GUAIFENESIN-<br>CODEINE SOLN<br>100-10 MG/5ML                        | 43997002282020 | Generic |

| GUAIFENESIN/CODEINE PHOSPHATE       | GUAIFENESIN-<br>CODEINE SOLN<br>100-10 MG/5ML                          | 43997002282020 | Generic |
|-------------------------------------|--|----------------|---------|
| M-CLEAR WC                          | GUAIFENESIN-<br>CODEINE SOLN<br>100-6.33 MG/5ML                        | 43997002282018 | Brand   |
| NINJACOF-XG                         | GUAIFENESIN-<br>CODEINE LIQUID<br>200-8 MG/5ML                         | 43997002280942 | Brand   |
| CODEINE SULFATE                     | CODEINE SULFATE<br>TAB 15 MG   | 65100020200305 | Generic |
| CODEINE SULFATE                     | CODEINE SULFATE TAB 30 MG  | 65100020200310 | Generic |
| CODEINE SULFATE                     | CODEINE SULFATE<br>TAB 60 MG   | 65100020200315 | Generic |
| ASCOMP/CODEINE                      | BUTALBITAL-<br>ASPIRIN-CAFF W/<br>CODEINE CAP 50-<br>325-40-30 MG      | 65991004300115 | Generic |
| BUTALBITAL/ASPIRIN/CAFFEINE/CODEINE | BUTALBITAL-<br>ASPIRIN-CAFF W/<br>CODEINE CAP 50-<br>325-40-30 MG      | 65991004300115 | Generic |
| PROMETHAZINE/CODEINE                | PROMETHAZINE W/<br>CODEINE SYRUP<br>6.25-10 MG/5ML                     | 43995202341210 | Generic |
| PROMETHAZINE VC/CODEINE             | PROMETHAZINE-<br>PHENYLEPHRINE-<br>CODEINE SYRUP<br>6.25-5-10 MG/5ML   | 43995303101210 | Generic |
| TUXARIN ER                          | CODEINE PHOS-<br>CHLORPHENIRAMI<br>NE MALEATE TAB<br>ER 12HR 54.3-8 MG | 43995202327430 | Brand   |
| TRAMADOL HYDROCHLORIDE              | TRAMADOL HCL<br>TAB 50 MG  | 65100095100320 | Generic |
| TRAMADOL HCL                        | TRAMADOL HCL<br>TAB 50 MG  | 65100095100320 | Generic |
| TRAMADOL HYDROCHLORIDE              | TRAMADOL HCL<br>TAB 100 MG   | 65100095100340 | Generic |
| TRAMADOL HYDROCHLORIDE              | TRAMADOL HCL<br>ORAL SOLN 5<br>MG/ML                                   | 65100095102005 | Generic |

1 - Age greater than11 years

| Approval Length | 12 month(s)                           |
|-----------------|---------------------------------------|
| Therapy Stage   | Reauthorization                       |
| Guideline Type  | Prior Authorization - IL and MN Plans |

| Product Name                               | Generic Name   | GPI            | Brand/Generi<br>c |
|--|--|----------------|-------------------|
| ACETAMINOPHEN/CODEINE PHOSPHATE            | ACETAMINOPHEN<br>W/ CODEINE TAB<br>300-15 MG                         | 65991002050310 | Generic           |
| ACETAMINOPHEN/CODEINE                      | ACETAMINOPHEN<br>W/ CODEINE TAB<br>300-15 MG                         | 65991002050310 | Generic           |
| ACETAMINOPHEN/CODEINE PHOSPHATE            | ACETAMINOPHEN<br>W/ CODEINE TAB<br>300-30 MG                         | 65991002050315 | Generic           |
| ACETAMINOPHEN/CODEINE                      | ACETAMINOPHEN<br>W/ CODEINE TAB<br>300-30 MG                         | 65991002050315 | Generic           |
| ACETAMINOPHEN/CODEINE #3                   | ACETAMINOPHEN<br>W/ CODEINE TAB<br>300-30 MG                         | 65991002050315 | Generic           |
| ACETAMINOPHEN/CODEINE PHOSPHATE            | ACETAMINOPHEN<br>W/ CODEINE TAB<br>300-60 MG                         | 65991002050320 | Generic           |
| ACETAMINOPHEN/CODEINE                      | ACETAMINOPHEN<br>W/ CODEINE TAB<br>300-60 MG                         | 65991002050320 | Generic           |
| RYDEX                                      | PSEUDOEPHEDRIN<br>E-BROMPHEN-<br>CODEINE LIQ 10-<br>1.33-6.33 MG/5ML | 43995303190922 | Brand             |
| BUTALBITAL/ACETAMINOPHEN/CAFFEINE/CODE INE | BUTALBITAL-<br>ACETAMINOPHEN-<br>CAFF W/ COD CAP<br>50-300-40-30 MG  | 65991004100113 | Generic           |
| BUTALBITAL/ACETAMINOPHEN/CAFFEINE/CODE INE | BUTALBITAL-<br>ACETAMINOPHEN-<br>CAFF W/ COD CAP<br>50-325-40-30 MG  | 65991004100115 | Generic           |
| CAPCOF                                     | PHENYLEPHRINE-<br>CHLORPHEN W/<br>CODEINE SYRUP 5-<br>2-10 MG/5ML    | 43995303141220 | Brand             |
| VIRTUSSIN A/C                              | GUAIFENESIN-<br>CODEINE SOLN<br>100-10 MG/5ML                        | 43997002282020 | Generic           |
| CODEINE/GUAIFENESIN                        | GUAIFENESIN-   | 43997002282020 | Generic           |

|                                     | CODEINE SOLN<br>100-10 MG/5ML  |                |         |
|-------------------------------------|--|----------------|---------|
| MAXI-TUSS AC                        | GUAIFENESIN-<br>CODEINE SOLN<br>100-10 MG/5ML                        | 43997002282020 | Generic |
| GUAIFENESIN/CODEINE                 | GUAIFENESIN-<br>CODEINE SOLN<br>100-10 MG/5ML                        | 43997002282020 | Generic |
| GUAIATUSSIN AC                      | GUAIFENESIN-<br>CODEINE SOLN<br>100-10 MG/5ML                        | 43997002282020 | Generic |
| G TUSSIN AC                         | GUAIFENESIN-<br>CODEINE SOLN<br>100-10 MG/5ML                        | 43997002282020 | Generic |
| GUAIFENESIN AC                      | GUAIFENESIN-<br>CODEINE SOLN<br>100-10 MG/5ML                        | 43997002282020 | Generic |
| GUAIFENESIN/CODEINE PHOSPHATE       | GUAIFENESIN-<br>CODEINE SOLN<br>100-10 MG/5ML                        | 43997002282020 | Generic |
| M-CLEAR WC                          | GUAIFENESIN-<br>CODEINE SOLN<br>100-6.33 MG/5ML                      | 43997002282018 | Brand   |
| NINJACOF-XG                         | GUAIFENESIN-<br>CODEINE LIQUID<br>200-8 MG/5ML                       | 43997002280942 | Brand   |
| CODEINE SULFATE                     | CODEINE SULFATE<br>TAB 15 MG   | 65100020200305 | Generic |
| CODEINE SULFATE                     | CODEINE SULFATE<br>TAB 30 MG   | 65100020200310 | Generic |
| CODEINE SULFATE                     | CODEINE SULFATE<br>TAB 60 MG   | 65100020200315 | Generic |
| ASCOMP/CODEINE                      | BUTALBITAL-<br>ASPIRIN-CAFF W/<br>CODEINE CAP 50-<br>325-40-30 MG    | 65991004300115 | Generic |
| BUTALBITAL/ASPIRIN/CAFFEINE/CODEINE | BUTALBITAL-<br>ASPIRIN-CAFF W/<br>CODEINE CAP 50-<br>325-40-30 MG    | 65991004300115 | Generic |
| PROMETHAZINE/CODEINE                | PROMETHAZINE W/<br>CODEINE SYRUP<br>6.25-10 MG/5ML                   | 43995202341210 | Generic |
| PROMETHAZINE VC/CODEINE             | PROMETHAZINE-<br>PHENYLEPHRINE-<br>CODEINE SYRUP<br>6.25-5-10 MG/5ML | 43995303101210 | Generic |
| TUXARIN ER                          | CODEINE PHOS-<br>CHLORPHENIRAMI                                      | 43995202327430 | Brand   |

|                        | NE MALEATE TAB<br>ER 12HR 54.3-8 MG  |                |         |
|------------------------|--------------------------------------|----------------|---------|
| TRAMADOL HYDROCHLORIDE | TRAMADOL HCL<br>TAB 50 MG            | 65100095100320 | Generic |
| TRAMADOL HCL           | TRAMADOL HCL<br>TAB 50 MG            | 65100095100320 | Generic |
| TRAMADOL HYDROCHLORIDE | TRAMADOL HCL<br>TAB 100 MG           | 65100095100340 | Generic |
| TRAMADOL HYDROCHLORIDE | TRAMADOL HCL<br>ORAL SOLN 5<br>MG/ML | 65100095102005 | Generic |

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug

| Approval Length | 12/31/2039                                       |
|-----------------|--|
| Guideline Type  | Prior Authorization - All plans except IL and MN |

| Product Name                    | Generic Name                                 | GPI            | Brand/Generi<br>c |
|---------------------------------|--|----------------|-------------------|
| ACETAMINOPHEN/CODEINE PHOSPHATE | ACETAMINOPHEN<br>W/ CODEINE TAB<br>300-15 MG | 65991002050310 | Generic           |
| ACETAMINOPHEN/CODEINE           | ACETAMINOPHEN<br>W/ CODEINE TAB<br>300-15 MG | 65991002050310 | Generic           |
| ACETAMINOPHEN/CODEINE PHOSPHATE | ACETAMINOPHEN<br>W/ CODEINE TAB<br>300-30 MG | 65991002050315 | Generic           |
| ACETAMINOPHEN/CODEINE           | ACETAMINOPHEN<br>W/ CODEINE TAB<br>300-30 MG | 65991002050315 | Generic           |
| ACETAMINOPHEN/CODEINE #3        | ACETAMINOPHEN<br>W/ CODEINE TAB<br>300-30 MG | 65991002050315 | Generic           |
| ACETAMINOPHEN/CODEINE PHOSPHATE | ACETAMINOPHEN<br>W/ CODEINE TAB<br>300-60 MG | 65991002050320 | Generic           |
| ACETAMINOPHEN/CODEINE           | ACETAMINOPHEN<br>W/ CODEINE TAB<br>300-60 MG | 65991002050320 | Generic           |
| RYDEX                           | PSEUDOEPHEDRIN                               | 43995303190922 | Brand             |

|  | 1   |                |         |
|--|---|----------------|---------|
|  | E-BROMPHEN-<br>CODEINE LIQ 10-<br>1.33-6.33 MG/5ML                  |                |         |
| BUTALBITAL/ACETAMINOPHEN/CAFFEINE/CODE INE | BUTALBITAL-<br>ACETAMINOPHEN-<br>CAFF W/ COD CAP<br>50-300-40-30 MG | 65991004100113 | Generic |
| BUTALBITAL/ACETAMINOPHEN/CAFFEINE/CODE INE | BUTALBITAL-<br>ACETAMINOPHEN-<br>CAFF W/ COD CAP<br>50-325-40-30 MG | 65991004100115 | Generic |
| CAPCOF                                     | PHENYLEPHRINE-<br>CHLORPHEN W/<br>CODEINE SYRUP 5-<br>2-10 MG/5ML   | 43995303141220 | Brand   |
| VIRTUSSIN A/C                              | GUAIFENESIN-<br>CODEINE SOLN<br>100-10 MG/5ML                       | 43997002282020 | Generic |
| CODEINE/GUAIFENESIN                        | GUAIFENESIN-<br>CODEINE SOLN<br>100-10 MG/5ML                       | 43997002282020 | Generic |
| MAXI-TUSS AC                               | GUAIFENESIN-<br>CODEINE SOLN<br>100-10 MG/5ML                       | 43997002282020 | Generic |
| GUAIFENESIN/CODEINE                        | GUAIFENESIN-<br>CODEINE SOLN<br>100-10 MG/5ML                       | 43997002282020 | Generic |
| GUAIATUSSIN AC                             | GUAIFENESIN-<br>CODEINE SOLN<br>100-10 MG/5ML                       | 43997002282020 | Generic |
| G TUSSIN AC                                | GUAIFENESIN-<br>CODEINE SOLN<br>100-10 MG/5ML                       | 43997002282020 | Generic |
| GUAIFENESIN AC                             | GUAIFENESIN-<br>CODEINE SOLN<br>100-10 MG/5ML                       | 43997002282020 | Generic |
| GUAIFENESIN/CODEINE PHOSPHATE              | GUAIFENESIN-<br>CODEINE SOLN<br>100-10 MG/5ML                       | 43997002282020 | Generic |
| M-CLEAR WC                                 | GUAIFENESIN-<br>CODEINE SOLN<br>100-6.33 MG/5ML                     | 43997002282018 | Brand   |
| NINJACOF-XG                                | GUAIFENESIN-<br>CODEINE LIQUID<br>200-8 MG/5ML                      | 43997002280942 | Brand   |
| CODEINE SULFATE                            | CODEINE SULFATE<br>TAB 15 MG  | 65100020200305 | Generic |
| CODEINE SULFATE                            | CODEINE SULFATE<br>TAB 30 MG  | 65100020200310 | Generic |

| CODEINE SULFATE                     | CODEINE SULFATE<br>TAB 60 MG   | 65100020200315 | Generic |
|-------------------------------------|--|----------------|---------|
| ASCOMP/CODEINE                      | BUTALBITAL-<br>ASPIRIN-CAFF W/<br>CODEINE CAP 50-<br>325-40-30 MG    | 65991004300115 | Generic |
| BUTALBITAL/ASPIRIN/CAFFEINE/CODEINE | BUTALBITAL-<br>ASPIRIN-CAFF W/<br>CODEINE CAP 50-<br>325-40-30 MG    | 65991004300115 | Generic |
| PROMETHAZINE/CODEINE                | PROMETHAZINE W/<br>CODEINE SYRUP<br>6.25-10 MG/5ML                   | 43995202341210 | Generic |
| PROMETHAZINE VC/CODEINE             | PROMETHAZINE-<br>PHENYLEPHRINE-<br>CODEINE SYRUP<br>6.25-5-10 MG/5ML | 43995303101210 | Generic |
| TRAMADOL HCL ER                     | TRAMADOL HCL<br>CAP ER 24HR<br>BIPHASIC RELEASE<br>100 MG            | 65100095107070 | Generic |
| TRAMADOL HCL ER                     | TRAMADOL HCL<br>CAP ER 24HR<br>BIPHASIC RELEASE<br>200 MG            | 65100095107080 | Generic |
| TRAMADOL HCL ER                     | TRAMADOL HCL<br>CAP ER 24HR<br>BIPHASIC RELEASE<br>300 MG            | 65100095107090 | Generic |
| TRAMADOL HCL ER                     | TRAMADOL HCL<br>TAB ER 24HR 100<br>MG                                | 65100095107520 | Generic |
| TRAMADOL HCL ER                     | TRAMADOL HCL<br>TAB ER 24HR 200<br>MG                                | 65100095107530 | Generic |
| TRAMADOL HCL ER                     | TRAMADOL HCL<br>TAB ER 24HR 300<br>MG                                | 65100095107540 | Generic |
| TRAMADOL HCL ER                     | TRAMADOL HCL<br>TAB ER 24HR<br>BIPHASIC RELEASE<br>100 MG            | 65100095107560 | Generic |
| TRAMADOL HCL ER                     | TRAMADOL HCL<br>TAB ER 24HR<br>BIPHASIC RELEASE<br>200 MG            | 65100095107570 | Generic |
| TRAMADOL HCL ER                     | TRAMADOL HCL<br>TAB ER 24HR<br>BIPHASIC RELEASE<br>300 MG            | 65100095107580 | Generic |
| TUXARIN ER                          | CODEINE PHOS-  | 43995202327430 | Brand   |

|                        | CHLORPHENIRAMI<br>NE MALEATE TAB<br>ER 12HR 54.3-8 MG |                |         |
|------------------------|---|----------------|---------|
| TRAMADOL HYDROCHLORIDE | TRAMADOL HCL<br>TAB 50 MG                             | 65100095100320 | Generic |
| TRAMADOL HCL           | TRAMADOL HCL<br>TAB 50 MG                             | 65100095100320 | Generic |
| TRAMADOL HYDROCHLORIDE | TRAMADOL HCL<br>TAB 100 MG                            | 65100095100340 | Generic |
| TRAMADOL HYDROCHLORIDE | TRAMADOL HCL<br>ORAL SOLN 5<br>MG/ML                  | 65100095102005 | Generic |

1 - Age greater than11 years

# 2. Revision History

| Date       | Notes       |
|------------|-------------|
| 10/24/2023 | New Program |

| Compounded Hormones  |  |
|--|--|
| [2] The State of Suppose and State of S |  |
|  |  |
|  |  |

# **Prior Authorization Guideline**

| Guideline ID          | GL-129116           |
|-----------------------|---------------------|
| <b>Guideline Name</b> | Compounded Hormones |
| Formulary             | Quartz              |

# **Guideline Note:**

| Effective Date: |
|-----------------|
|-----------------|

# 1. Criteria

| Product Name: Compounded progesterone to maintain pregnancy in the first trimester |                                 |  |                |               |  |
|--|---------------------------------|--|----------------|---------------|--|
| Approval Length  |                                 | 4 month(s)                                       |                |               |  |
| Guideline Type   |                                 | Prior Authorization - All plans except IL and MN |                |               |  |
| Product Name   | Generic Name                    |  | GPI            | Brand/Generic |  |
| PROGESTERONE   | PROG                            | ESTERONE CAP 100 MG                              | 26000040000120 | Generic       |  |
| PROGESTERONE   | PROG                            | ESTERONE CAP 200 MG                              | 26000040000140 | Generic       |  |
| PROGESTERONE   | PROGESTERONE IM IN OIL 50 MG/ML |  | 26000040001705 | Generic       |  |
| PROGESTERONE<br>WETTABLE   | PROGE                           | ESTERONE (BULK) POWDER                           | 96727643212900 | Brand         |  |
| PROGESTERONE<br>MILLED   | PROGESTERONE (BULK) POWDER      |  | 96727643212900 | Brand         |  |
| PROGESTERONE<br>WETTABLE<br>(YAM)  | PROGESTERONE (BULK) POWDER      |  | 96727643212900 | Brand         |  |

| PROGESTERONE PROGESTERONE (BULK) POWDER WETTABLE (SOY) | 96727643212900 | Brand |
|--|----------------|-------|
|--|----------------|-------|

1 - Medication will be used to maintain pregnancy

#### AND

**2** - Submission of medical records (e.g., chart notes) documenting the woman is currently pregnant in her 1st trimester

| Product Name: Compounded progesterone to maintain pregnancy beyond the first trimester |  |  |  |
|--|--|--|--|
| Approval Length 6 month(s)   |  |  |  |
| Guideline Type Prior Authorization – All plans except MN and IL                        |  |  |  |

| Product Name                      | Generic Name                    | GPI            | Brand/Generic |
|-----------------------------------|---------------------------------|----------------|---------------|
| PROGESTERONE                      | PROGESTERONE CAP 100 MG         | 26000040000120 | Generic       |
| PROGESTERONE                      | PROGESTERONE CAP 200 MG         | 26000040000140 | Generic       |
| PROGESTERONE                      | PROGESTERONE IM IN OIL 50 MG/ML | 26000040001705 | Generic       |
| PROGESTERONE<br>WETTABLE          | PROGESTERONE (BULK) POWDER      | 96727643212900 | Brand         |
| PROGESTERONE<br>MILLED            | PROGESTERONE (BULK) POWDER      | 96727643212900 | Brand         |
| PROGESTERONE<br>WETTABLE<br>(YAM) | PROGESTERONE (BULK) POWDER      | 96727643212900 | Brand         |
| PROGESTERONE<br>WETTABLE (SOY)    | PROGESTERONE (BULK) POWDER      | 96727643212900 | Brand         |

#### **Approval Criteria**

1 - Medication will be used to maintain pregnancy

#### **AND**

2 - Submission of medical records (e.g., chart notes) documenting the woman has a singleton

pregnancy

**AND** 

**3** - Woman is beyond the 1st trimester

**AND** 

4 - Submission of medical records (e.g., chart notes) documenting a history of preterm birth

| Product Name: Compounded progesterone to maintain pregnancy |  |  |  |
|---|--|--|--|
| Approval Length 12 month(s)                                 |  |  |  |
| Guideline Type Prior Authorization - IL and MN plans        |  |  |  |

| Product Name                      | Generic Name                    | GPI            | Brand/Generic |
|-----------------------------------|---------------------------------|----------------|---------------|
| PROGESTERONE                      | PROGESTERONE CAP 100 MG         | 26000040000120 | Generic       |
| PROGESTERONE                      | PROGESTERONE CAP 200 MG         | 26000040000140 | Generic       |
| PROGESTERONE                      | PROGESTERONE IM IN OIL 50 MG/ML | 26000040001705 | Generic       |
| PROGESTERONE<br>WETTABLE          | PROGESTERONE (BULK) POWDER      | 96727643212900 | Brand         |
| PROGESTERONE<br>MILLED            | PROGESTERONE (BULK) POWDER      | 96727643212900 | Brand         |
| PROGESTERONE<br>WETTABLE<br>(YAM) | PROGESTERONE (BULK) POWDER      | 96727643212900 | Brand         |
| PROGESTERONE<br>WETTABLE (SOY)    | PROGESTERONE (BULK) POWDER      | 96727643212900 | Brand         |

#### **Approval Criteria**

- **1** BOTH of the following:
  - Medication will be used to maintain pregnancy
  - Submission of medical records (e.g., chart notes) documenting the woman is currently pregnant in her 1st trimester

OR

## 2 - All of the following:

- Medication will be used to maintain pregnancy
- Submission of medical records (e.g., chart notes) woman has a singleton pregnancy
- Woman is beyond the 1st trimester
- Submission of medical records (e.g., chart notes) documenting a history of preterm birth

| Product Name: Compounded progesterone to treat infertility |       |                             |                |               |
|--|-------|-----------------------------|----------------|---------------|
| Approval Length 12 month(s)                                |       |                             |                |               |
| Guideline Type Prior Authorization - IL Plans              |       |                             |                |               |
| Product Name   | Gene  | ric Name                    | GPI            | Brand/Generic |
| PROGESTERONE   | PROG  | ESTERONE CAP 100 MG         | 26000040000120 | Generic       |
| PROGESTERONE   | PROG  | ESTERONE CAP 200 MG         | 26000040000140 | Generic       |
| PROGESTERONE   | PROG  | ESTERONE IM IN OIL 50 MG/ML | 26000040001705 | Generic       |
| PROGESTERONE<br>WETTABLE                                   | PROGI | ESTERONE (BULK) POWDER      | 96727643212900 | Brand         |
| PROGESTERONE<br>MILLED                                     | PROGI | ESTERONE (BULK) POWDER      | 96727643212900 | Brand         |
| PROGESTERONE<br>WETTABLE<br>(YAM)                          | PROGI | ESTERONE (BULK) POWDER      | 96727643212900 | Brand         |
| PROGESTERONE<br>WETTABLE (SOY)                             |       | ESTERONE (BULK) POWDER      | 96727643212900 | Brand         |

## **Approval Criteria**

1 - Infertility coverage as outlined in Illinois Insurance Code 215 ILCS 5/356m

| Product Name: Estrogen, testosterone, and progesterone use outside of pregnancy |       |  |                |               |
|---|-------|--|----------------|---------------|
| Approval Length   |       | 12 month(s)                                  |                |               |
| Therapy Stage   |       | Initial Authorization                        |                |               |
| Guideline Type  |       | Prior Authorization                          |                |               |
| Product Name  | Gene  | ric Name                                     | GPI            | Brand/Generic |
| PROGESTERONE  | PROGI | ESTERONE CAP 100 MG                          | 26000040000120 | Generic       |
| PROMETRIUM  | PROGI | PROGESTERONE CAP 100 MG 26000040000120 Brand |                | Brand         |

| PROGESTERONE                          | PROGESTERONE CAP 200 MG                           | 26000040000140 | Generic |
|---------------------------------------|---|----------------|---------|
| PROMETRIUM                            | PROGESTERONE CAP 200 MG                           | 26000040000140 | Brand   |
| PROGESTERONE                          | PROGESTERONE IM IN OIL 50 MG/ML                   | 26000040001705 | Generic |
| PROGESTERONE<br>10% KIT               | *PROGESTERONE MICRONIZED TD CREAM 10% (CMPD KIT)* | 26000040103730 | Brand   |
| EC-RX<br>PROGESTERONE<br>10%          | *PROGESTERONE MICRONIZED TD CREAM 10% (CMPD KIT)* | 26000040103730 | Brand   |
| PROGESTERONE<br>WETTABLE              | PROGESTERONE (BULK) POWDER                        | 96727643212900 | Brand   |
| PROGESTERONE<br>MILLED                | PROGESTERONE (BULK) POWDER                        | 96727643212900 | Brand   |
| PROGESTERONE<br>WETTABLE<br>(YAM)     | PROGESTERONE (BULK) POWDER                        | 96727643212900 | Brand   |
| PROGESTERONE<br>WETTABLE (SOY)        | , ,   | 96727643212900 | Brand   |
| PROGESTERONE                          | PROGESTERONE (BULK) POWDER                        | 96727643212900 | Brand   |
| PROGESTERONE<br>ULTRA<br>MICRONIZED   | PROGESTERONE MICRONIZED (BULK)<br>POWDER          | 96727643252900 | Brand   |
| PROGESTERONE<br>MICRONIZED            | PROGESTERONE MICRONIZED (BULK) POWDER             | 96727643252900 | Brand   |
| PROGESTERONE<br>MICRONIZED<br>PREMIUM | PROGESTERONE MICRONIZED (BULK)<br>POWDER          | 96727643252900 | Brand   |
| PROGESTERONE<br>MICRONIZED<br>(SOY)   | PROGESTERONE MICRONIZED (BULK)<br>POWDER          | 96727643252900 | Brand   |
| PROGESTERONE<br>MICRONIZED<br>(YAM)   | PROGESTERONE MICRONIZED (BULK)<br>POWDER          | 96727643252900 | Brand   |
| TESTOSTERONE                          | TESTOSTERONE TD SOLN 30 MG/ACT                    | 23100030002020 | Generic |
| TESTOSTERONE<br>TOPICAL<br>SOLUTION   | TESTOSTERONE TD SOLN 30 MG/ACT                    | 23100030002020 | Generic |
| TESTOSTERONE                          | TESTOSTERONE TD GEL 25 MG/2.5GM (1%)              | 23100030004025 | Generic |
| TESTIM                                | TESTOSTERONE TD GEL 50 MG/5GM (1%)                | 23100030004030 | Brand   |
| TESTOSTERONE                          | TESTOSTERONE TD GEL 50 MG/5GM (1%)                | 23100030004030 | Generic |
| VOGELXO                               | TESTOSTERONE TD GEL 50 MG/5GM (1%)                | 23100030004030 | Brand   |
| TESTOSTERONE<br>PUMP                  | TESTOSTERONE TD GEL 12.5 MG/ACT (1%)              | 23100030004040 | Generic |
| VOGELXO PUMP                          | TESTOSTERONE TD GEL 12.5 MG/ACT (1%)              | 23100030004040 | Brand   |

| TESTOSTERONE                              | TESTOSTERONE TD GEL 20.25 MG/1.25GM (1.62%)              | 23100030004044 | Generic |
|---|--|----------------|---------|
| TESTOSTERONE                              | TESTOSTERONE TD GEL 40.5 MG/2.5GM (1.62%)                | 23100030004047 | Generic |
| TESTOSTERONE                              | TESTOSTERONE TD GEL 20.25 MG/ACT (1.62%)                 | 23100030004050 | Generic |
| TESTOSTERONE<br>PUMP                      | TESTOSTERONE TD GEL 20.25 MG/ACT (1.62%)                 | 23100030004050 | Generic |
| ANDROGEL<br>PUMP                          | TESTOSTERONE TD GEL 20.25 MG/ACT (1.62%)                 | 23100030004050 | Brand   |
| FORTESTA                                  | TESTOSTERONE TD GEL 10MG/ACT (2%)                        | 23100030004070 | Brand   |
| TESTOSTERONE                              | TESTOSTERONE TD GEL 10MG/ACT (2%)                        | 23100030004070 | Generic |
| TESTOSTERONE                              | TESTOSTERONE IMPLANT PELLETS 25 MG                       | 23100030008910 | Brand   |
| TESTOSTERONE                              | TESTOSTERONE IMPLANT PELLETS 50 MG                       | 23100030008915 | Brand   |
| TESTOSTERONE                              | TESTOSTERONE IMPLANT PELLETS 100 MG                      | 23100030008930 | Brand   |
| TESTOSTERONE                              | TESTOSTERONE IMPLANT PELLETS 200 MG                      | 23100030008940 | Brand   |
| DEPO-<br>TESTOSTERONE                     | TESTOSTERONE CYPIONATE IM INJ IN OIL 100 MG/ML           | 23100030102010 | Brand   |
| TESTOSTERONE<br>CYPIONATE                 | TESTOSTERONE CYPIONATE IM INJ IN OIL 100 MG/ML           | 23100030102010 | Generic |
| DEPO-<br>TESTOSTERONE                     | TESTOSTERONE CYPIONATE IM INJ IN OIL 200 MG/ML           | 23100030102015 | Brand   |
| TESTOSTERONE<br>CYPIONATE                 | TESTOSTERONE CYPIONATE IM INJ IN OIL 200 MG/ML           | 23100030102015 | Generic |
| TESTOSTERONE<br>CYPIONATE                 | TESTOSTERONE CYP IM OR SUBCUTANEOUS INJ IN OIL 200 MG/ML | 23100030102070 | Brand   |
| TESTOSTERONE<br>ENANTHATE                 | TESTOSTERONE ENANTHATE IM INJ IN OIL 200 MG/ML           | 23100030202010 | Generic |
| TESTOSTERONE<br>NON-<br>MICRONIZED<br>SOY | TESTOSTERONE (BULK) POWDER                               | 96805050502900 | Brand   |
| TESTOSTERONE<br>MICRONIZED<br>SOY         | TESTOSTERONE (BULK) POWDER                               | 96805050502900 | Brand   |
| TESTOSTERONE<br>NON-<br>MICRONIZED        | TESTOSTERONE (BULK) POWDER                               | 96805050502900 | Brand   |
| TESTOSTERONE                              | TESTOSTERONE (BULK) POWDER                               | 96805050502900 | Brand   |
| TESTOSTERONE<br>MICRONIZED                | TESTOSTERONE MICRONIZED (BULK) POWDER                    | 96805050522900 | Brand   |
| TESTOSTERONE<br>MICRONIZED<br>(YAM)       | TESTOSTERONE MICRONIZED (BULK) POWDER                    | 96805050522900 | Brand   |
| TESTOSTERONE                              | TESTOSTERONE MICRONIZED (BULK) POWDER                    | 96805050522900 | Brand   |

| MICRONIZED<br>(SOY)               |  |                |         |
|-----------------------------------|--|----------------|---------|
| TESTOSTERONE<br>MICRONIZED<br>YAM | TESTOSTERONE MICRONIZED (BULK) CRYSTALS                    | 96805050523800 | Brand   |
| TESTOSTERONE<br>CYPIONATE         | TESTOSTERONE CYPIONATE (BULK) POWDER                       | 96805050552900 | Brand   |
| TESTOSTERONE<br>ENANTHATE         | TESTOSTERONE ENANTHATE (BULK) POWDER                       | 96805050602900 | Brand   |
| ESTRADIOL<br>BENZOATE             | ESTRADIOL BENZOATE (BULK) POWDER                           | 96507860062900 | Brand   |
| ESTRADIOL<br>CYPIONATE            | ESTRADIOL CYPIONATE (BULK) POWDER                          | 96507860092900 | Brand   |
| ELESTRIN                          | ESTRADIOL GEL 0.06% (0.52 MG/0.87 GM<br>METERED-DOSE PUMP) | 24000035004008 | Brand   |
| ESTROGEL                          | ESTRADIOL GEL 0.06% (0.75 MG/1.25 GM<br>METERED-DOSE PUMP) | 24000035004010 | Brand   |
| ESTRADIOL                         | ESTRADIOL MICRONIZED (BULK) POWDER                         | 96507860172900 | Brand   |
| ESTRADIOL<br>MICRONIZED           | ESTRADIOL MICRONIZED (BULK) POWDER                         | 96507860172900 | Brand   |
| ESTRADIOL                         | ESTRADIOL TAB 0.5 MG                                       | 24000035000303 | Generic |
| ESTRADIOL                         | ESTRADIOL TAB 1 MG   | 24000035000305 | Generic |
| ESTRADIOL                         | ESTRADIOL TAB 2 MG   | 24000035000310 | Generic |
| ESTRADIOL                         | ESTRADIOL TD GEL 0.25 MG/0.25GM (0.1%)                     | 24000035004035 | Generic |
| ESTRADIOL                         | ESTRADIOL TD GEL 0.5 MG/0.5GM (0.1%)                       | 24000035004040 | Generic |
| ESTRADIOL                         | ESTRADIOL TD GEL 0.75 MG/0.75GM (0.1%)                     | 24000035004042 | Generic |
| ESTRADIOL                         | ESTRADIOL TD GEL 1 MG/GM (0.1%)                            | 24000035004045 | Generic |
| ESTRADIOL                         | ESTRADIOL TD GEL 1.25 MG/1.25GM (0.1%)                     | 24000035004050 | Generic |
| ESTRADIOL                         | ESTRADIOL VAGINAL CREAM 0.1 MG/GM                          | 55350020003705 | Generic |
| ESTRADIOL                         | ESTRADIOL VAGINAL TAB 10 MCG                               | 55350020000310 | Generic |
| YUVAFEM                           | ESTRADIOL VAGINAL TAB 10 MCG                               | 55350020000310 | Generic |
| ESTRADIOL<br>VALERATE             | ESTRADIOL VALERATE (BULK) CRYSTALS                         | 96507860243800 | Brand   |
| ESTRADIOL<br>VALERATE             | ESTRADIOL VALERATE (BULK) POWDER                           | 96507860242900 | Brand   |
| ESTRIOL                           | ESTRIOL MICRONIZED (BULK) POWDER                           | 96507861572900 | Brand   |
| ESTRIOL<br>MICRONIZED             | ESTRIOL MICRONIZED (BULK) POWDER                           | 96507861572900 | Brand   |
| ESTRONE                           | ESTRONE (BULK) CRYSTALS                                    | 96507862423800 | Brand   |
| ESTRONE                           | ESTRONE (BULK) POWDER                                      | 96507862422900 | Brand   |

| CRINONE   | PROGESTERONE VAGINAL GEL 4%             | 55370060004010 | Brand |
|---|---|----------------|-------|
| CRINONE   | PROGESTERONE VAGINAL GEL 8%             | 55370060004020 | Brand |
| FIRST-<br>PROGESTERONE<br>VGS 100<br>COMPOUNDING<br>KIT | PROGESTERONE VAGINAL SUPPOSITORY 100 MG | 55370060005210 | Brand |
| FIRST-<br>PROGESTERONE<br>VGS 200<br>COMPOUNDING<br>KIT | PROGESTERONE VAGINAL SUPPOSITORY 200 MG | 55370060005220 | Brand |

**1** - Trial and failure to all preferred alternatives available on the formulary of the requested hormone

**AND** 

2 - Meets off-label criteria

**AND** 

- **3** For testosterone only, both of the following:
- **3.1** Submission of medical records (e.g., chart notes) documenting a diagnosis of primary or secondary hypogonadism or mixed hypogonadism that clinically appropriate laboratory data demonstrate androgen deficiency\*

#### **AND**

**3.2** Member is symptomatic with symptoms other than sexual dysfunction

| * Androgen deficiency is defined as a fasting, morning testosterone lev el (drawn between 7 and 10 AM or within 3 hours of waking for shift wo rkers) below the lower limit of normal as defined by the laboratory refer ence range. A single low testosterone is not diagnostic for androgen de ficiency and must be confirmed with a second fasting, morning |
|--|
| testosterone level.  |

| Product Name: Estrogen, testosterone, and progesterone use outside of pregnancy |                     |  |
|---|---------------------|--|
| Approval Length   | 12 month(s)         |  |
| Therapy Stage   | Reauthorization     |  |
| Guideline Type  | Prior Authorization |  |

| Product Name                          | Generic Name                                      | GPI            | Brand/Generic |
|---------------------------------------|---|----------------|---------------|
| PROGESTERONE                          | PROGESTERONE CAP 100 MG                           | 26000040000120 | Generic       |
| PROMETRIUM                            | PROGESTERONE CAP 100 MG                           | 26000040000120 | Brand         |
| PROGESTERONE                          | PROGESTERONE CAP 200 MG                           | 26000040000140 | Generic       |
| PROMETRIUM                            | PROGESTERONE CAP 200 MG                           | 26000040000140 | Brand         |
| PROGESTERONE                          | PROGESTERONE IM IN OIL 50 MG/ML                   | 26000040001705 | Generic       |
| PROGESTERONE<br>10% KIT               | *PROGESTERONE MICRONIZED TD CREAM 10% (CMPD KIT)* | 26000040103730 | Brand         |
| EC-RX<br>PROGESTERONE<br>10%          | *PROGESTERONE MICRONIZED TD CREAM 10% (CMPD KIT)* | 26000040103730 | Brand         |
| PROGESTERONE<br>WETTABLE              | PROGESTERONE (BULK) POWDER                        | 96727643212900 | Brand         |
| PROGESTERONE<br>MILLED                | PROGESTERONE (BULK) POWDER                        | 96727643212900 | Brand         |
| PROGESTERONE<br>WETTABLE<br>(YAM)     | PROGESTERONE (BULK) POWDER                        | 96727643212900 | Brand         |
| PROGESTERONE<br>WETTABLE (SOY)        | - ' ' - ' '                                       | 96727643212900 | Brand         |
| PROGESTERONE                          | PROGESTERONE (BULK) POWDER                        | 96727643212900 | Brand         |
| PROGESTERONE<br>ULTRA<br>MICRONIZED   | PROGESTERONE MICRONIZED (BULK) POWDER             | 96727643252900 | Brand         |
| PROGESTERONE<br>MICRONIZED            | PROGESTERONE MICRONIZED (BULK)<br>POWDER          | 96727643252900 | Brand         |
| PROGESTERONE<br>MICRONIZED<br>PREMIUM | PROGESTERONE MICRONIZED (BULK) POWDER             | 96727643252900 | Brand         |
| PROGESTERONE<br>MICRONIZED<br>(SOY)   | PROGESTERONE MICRONIZED (BULK) POWDER             | 96727643252900 | Brand         |
| PROGESTERONE<br>MICRONIZED<br>(YAM)   | PROGESTERONE MICRONIZED (BULK)<br>POWDER          | 96727643252900 | Brand         |
| TESTOSTERONE                          | TESTOSTERONE TD SOLN 30 MG/ACT                    | 23100030002020 | Generic       |
| TESTOSTERONE<br>TOPICAL               | TESTOSTERONE TD SOLN 30 MG/ACT                    | 23100030002020 | Generic       |

| SOLUTION                                  |  |                |         |
|---|--|----------------|---------|
| TESTOSTERONE                              | TESTOSTERONE TD GEL 25 MG/2.5GM (1%)                     | 23100030004025 | Generic |
| TESTIM                                    | TESTOSTERONE TD GEL 50 MG/5GM (1%)                       | 23100030004030 | Brand   |
| TESTOSTERONE                              | TESTOSTERONE TD GEL 50 MG/5GM (1%)                       | 23100030004030 | Generic |
| VOGELXO                                   | TESTOSTERONE TD GEL 50 MG/5GM (1%)                       | 23100030004030 | Brand   |
| TESTOSTERONE<br>PUMP                      | TESTOSTERONE TD GEL 12.5 MG/ACT (1%)                     | 23100030004040 | Generic |
| VOGELXO PUMP                              | TESTOSTERONE TD GEL 12.5 MG/ACT (1%)                     | 23100030004040 | Brand   |
| TESTOSTERONE                              | TESTOSTERONE TD GEL 20.25 MG/1.25GM (1.62%)              | 23100030004044 | Generic |
| TESTOSTERONE                              | TESTOSTERONE TD GEL 40.5 MG/2.5GM (1.62%)                | 23100030004047 | Generic |
| TESTOSTERONE                              | TESTOSTERONE TD GEL 20.25 MG/ACT (1.62%)                 | 23100030004050 | Generic |
| TESTOSTERONE<br>PUMP                      | TESTOSTERONE TD GEL 20.25 MG/ACT (1.62%)                 | 23100030004050 | Generic |
| ANDROGEL<br>PUMP                          | TESTOSTERONE TD GEL 20.25 MG/ACT (1.62%)                 | 23100030004050 | Brand   |
| FORTESTA                                  | TESTOSTERONE TD GEL 10MG/ACT (2%)                        | 23100030004070 | Brand   |
| TESTOSTERONE                              | TESTOSTERONE TD GEL 10MG/ACT (2%)                        | 23100030004070 | Generic |
| TESTOSTERONE                              | TESTOSTERONE IMPLANT PELLETS 25 MG                       | 23100030008910 | Brand   |
| TESTOSTERONE                              | TESTOSTERONE IMPLANT PELLETS 50 MG                       | 23100030008915 | Brand   |
| TESTOSTERONE                              | TESTOSTERONE IMPLANT PELLETS 100 MG                      | 23100030008930 | Brand   |
| TESTOSTERONE                              | TESTOSTERONE IMPLANT PELLETS 200 MG                      | 23100030008940 | Brand   |
| DEPO-<br>TESTOSTERONE                     | TESTOSTERONE CYPIONATE IM INJ IN OIL 100 MG/ML           | 23100030102010 | Brand   |
| TESTOSTERONE<br>CYPIONATE                 | TESTOSTERONE CYPIONATE IM INJ IN OIL 100 MG/ML           | 23100030102010 | Generic |
| DEPO-<br>TESTOSTERONE                     | TESTOSTERONE CYPIONATE IM INJ IN OIL 200 MG/ML           | 23100030102015 | Brand   |
| TESTOSTERONE<br>CYPIONATE                 | TESTOSTERONE CYPIONATE IM INJ IN OIL 200 MG/ML           | 23100030102015 | Generic |
| TESTOSTERONE<br>CYPIONATE                 | TESTOSTERONE CYP IM OR SUBCUTANEOUS INJ IN OIL 200 MG/ML | 23100030102070 | Brand   |
| TESTOSTERONE<br>ENANTHATE                 | TESTOSTERONE ENANTHATE IM INJ IN OIL 200 MG/ML           | 23100030202010 | Generic |
| TESTOSTERONE<br>NON-<br>MICRONIZED<br>SOY | TESTOSTERONE (BULK) POWDER                               | 96805050502900 | Brand   |
| TESTOSTERONE<br>MICRONIZED<br>SOY         | TESTOSTERONE (BULK) POWDER                               | 96805050502900 | Brand   |

|                                     |  |                | _       |
|-------------------------------------|--|----------------|---------|
| TESTOSTERONE<br>NON-<br>MICRONIZED  | TESTOSTERONE (BULK) POWDER                                 | 96805050502900 | Brand   |
| TESTOSTERONE                        | TESTOSTERONE (BULK) POWDER                                 | 96805050502900 | Brand   |
| TESTOSTERONE<br>MICRONIZED          | TESTOSTERONE MICRONIZED (BULK) POWDER                      | 96805050522900 | Brand   |
| TESTOSTERONE<br>MICRONIZED<br>(YAM) | TESTOSTERONE MICRONIZED (BULK) POWDER                      | 96805050522900 | Brand   |
| TESTOSTERONE<br>MICRONIZED<br>(SOY) | TESTOSTERONE MICRONIZED (BULK) POWDER                      | 96805050522900 | Brand   |
| TESTOSTERONE<br>MICRONIZED<br>YAM   | TESTOSTERONE MICRONIZED (BULK) CRYSTALS                    | 96805050523800 | Brand   |
| TESTOSTERONE<br>CYPIONATE           | TESTOSTERONE CYPIONATE (BULK) POWDER                       | 96805050552900 | Brand   |
| TESTOSTERONE<br>ENANTHATE           | TESTOSTERONE ENANTHATE (BULK) POWDER                       | 96805050602900 | Brand   |
| ESTRADIOL<br>BENZOATE               | ESTRADIOL BENZOATE (BULK) POWDER                           | 96507860062900 | Brand   |
| ESTRADIOL<br>CYPIONATE              | ESTRADIOL CYPIONATE (BULK) POWDER                          | 96507860092900 | Brand   |
| ELESTRIN                            | ESTRADIOL GEL 0.06% (0.52 MG/0.87 GM<br>METERED-DOSE PUMP) | 24000035004008 | Brand   |
| ESTROGEL                            | ESTRADIOL GEL 0.06% (0.75 MG/1.25 GM<br>METERED-DOSE PUMP) | 24000035004010 | Brand   |
| ESTRADIOL                           | ESTRADIOL MICRONIZED (BULK) POWDER                         | 96507860172900 | Brand   |
| ESTRADIOL<br>MICRONIZED             | ESTRADIOL MICRONIZED (BULK) POWDER                         | 96507860172900 | Brand   |
| ESTRADIOL                           | ESTRADIOL TAB 0.5 MG                                       | 24000035000303 | Generic |
| ESTRADIOL                           | ESTRADIOL TAB 1 MG   | 24000035000305 | Generic |
| ESTRADIOL                           | ESTRADIOL TAB 2 MG   | 24000035000310 | Generic |
| ESTRADIOL                           | ESTRADIOL TD GEL 0.25 MG/0.25GM (0.1%)                     | 24000035004035 | Generic |
| ESTRADIOL                           | ESTRADIOL TD GEL 0.5 MG/0.5GM (0.1%)                       | 24000035004040 | Generic |
| ESTRADIOL                           | ESTRADIOL TD GEL 0.75 MG/0.75GM (0.1%)                     | 24000035004042 | Generic |
| ESTRADIOL                           | ESTRADIOL TD GEL 1 MG/GM (0.1%)                            | 24000035004045 | Generic |
| ESTRADIOL                           | ESTRADIOL TD GEL 1.25 MG/1.25GM (0.1%)                     | 24000035004050 | Generic |
| ESTRADIOL                           | ESTRADIOL VAGINAL CREAM 0.1 MG/GM                          | 55350020003705 | Generic |
| ESTRADIOL                           | ESTRADIOL VAGINAL TAB 10 MCG                               | 55350020000310 | Generic |
| YUVAFEM                             | ESTRADIOL VAGINAL TAB 10 MCG                               | 55350020000310 | Generic |

| ESTRADIOL<br>VALERATE                                   | ESTRADIOL VALERATE (BULK) CRYSTALS      | 96507860243800 | Brand |
|---|---|----------------|-------|
| ESTRADIOL<br>VALERATE                                   | ESTRADIOL VALERATE (BULK) POWDER        | 96507860242900 | Brand |
| ESTRIOL   | ESTRIOL MICRONIZED (BULK) POWDER        | 96507861572900 | Brand |
| ESTRIOL<br>MICRONIZED                                   | ESTRIOL MICRONIZED (BULK) POWDER        | 96507861572900 | Brand |
| ESTRONE   | ESTRONE (BULK) CRYSTALS                 | 96507862423800 | Brand |
| ESTRONE   | ESTRONE (BULK) POWDER                   | 96507862422900 | Brand |
| CRINONE   | PROGESTERONE VAGINAL GEL 4%             | 55370060004010 | Brand |
| CRINONE   | PROGESTERONE VAGINAL GEL 8%             | 55370060004020 | Brand |
| FIRST-<br>PROGESTERONE<br>VGS 100<br>COMPOUNDING<br>KIT | PROGESTERONE VAGINAL SUPPOSITORY 100 MG | 55370060005210 | Brand |
| FIRST-<br>PROGESTERONE<br>VGS 200<br>COMPOUNDING<br>KIT | PROGESTERONE VAGINAL SUPPOSITORY 200 MG | 55370060005220 | Brand |

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member demonstrates positive clinical response to therapy

| * Androgen deficiency is defined as a fasting, morning testosterone lev el (drawn between 7 and 10 AM or within 3 hours of waking for shift wo rkers) below the lower limit of normal as defined by the laboratory refer ence range. A single low testosterone is not diagnostic for androgen de ficiency and must be confirmed with a second fasting, morning |
|--|
| testosterone level.  |

# 2. Revision History

| Date      | Notes                   |
|-----------|-------------------------|
| 12/8/2023 | 2024 New Implementation |

| Compounded Prescriptions                              |  |  |  |  |
|---|--|--|--|--|
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# **Prior Authorization Guideline**

| Guideline ID          | GL-129124                |
|-----------------------|--------------------------|
| <b>Guideline Name</b> | Compounded Prescriptions |
| Formulary             | Quartz                   |

## **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

## Note:

These criteria will be applied only if a compound claim requires prior authorization (e.g., most expensive ingredient requires prior authorization)

## 1. Criteria

| Product Name: Compounded Prescription                |      |                             |  |               |
|--|------|-----------------------------|--|---------------|
| Approval Length                                      |      | 12 month(s)                 |  |               |
| Guideline Type Prior Authorization – MN plans only   |      |                             |  |               |
| Product Name   | Gene | Generic Name GPI Brand/Gene |  | Brand/Generic |
|  |      |                             |  |               |
|  |      |                             |  |               |
| Approval Criteria                                    |      |                             |  |               |
| 1 - For Minnesota plans only - One of the following: |      |                             |  |               |

#### **1.1** Both of the following:

1.1.1 The compound is prescribed for a member with emotional disturbance or mental illness

#### AND

#### **1.1.2** One of the following:

- Submission of medical records (e.g., chart notes) documenting that all equivalent drugs in the formulary for each active ingredient were considered and it has been determined that the compound prescribed will best treat the person's condition
- For continuation of care (formulary changes or new member) the member has been treated for 90 days prior to the change, the medication is working, and the prescriber attests that the compound prescribed will best treat the member's condition.

#### OR

#### **1.2** ALL of the following:

- Stage four metastatic cancer and prescribed drug is used for cancer related treatment including but not limited to: pain, constipation, nausea, fatigue related to chemotherapy or bacterial, fungal or viral infection
- Medication is not commercially available in a formulation that is suitable for the person
- Medication is on the formulary or the medication is considered medically necessary by Quartz
- None of the products in the compound are otherwise excluded from coverage as defined by the person's benefit

#### OR

#### **1.3** All of the following:

- Each active ingredient in the compounded drug is FDA-approved or national compendia\* supported for the condition being treated
- The therapeutic amounts are supported by national compendia\* or two peer-reviewed literature for the condition being treated in the requested route of delivery
- Compound is not commercially available in a formulation that is suitable for the person
- Each active ingredient in the compounded drug is on the formulary or meets the nonformulary criteria
- None of the active ingredient(s) in the compound are otherwise excluded from coverage as defined by the person's benefit
- None of the active ingredient(s) in the compound are experimental or limited by the FDA

to investigational use only

| Product Name: Compounded Prescription              |             |     |               |
|--|-------------|-----|---------------|
| Approval Length                                    | 12 month(s) |     |               |
| Guideline Type Prior Authorization – IL plans only |             |     |               |
| Product Name Gene                                  | ric Name    | GPI | Brand/Generic |

#### **Approval Criteria**

1 - For Illinois plans only - ONE of the following:

#### **1.1** ALL of the following:

- Diagnosis of long-term treatment of tick-borne disease
- Medication is not commercially available in a formulation that is suitable for the person
- Medication is on the formulary or the medication is considered medically necessary by Quartz
- None of the products in the compound are otherwise excluded from coverage as defined by the person's benefit

OR

#### **1.2** ALL of the following:

- Request is for a medication for a mental health condition under the mental and behavioral disorder chapter of the International Classification of Disease or is listed in the most recent version of the Diagnostic and Statistical Manual of Mental Disorders
- Medication is not commercially available in a formulation that is suitable for the person
- Medication is on the formulary or the medication is considered medically necessary by Quartz
- None of the products in the compound are otherwise excluded from coverage as defined by the person's benefit
- Determination should not be more restrictive than for non-behavioral health or substance use disorder diagnosis

OR

#### **1.3** BOTH of the following:

- Request is for a medication for treating a substance use disorder
- Determination should be based on criteria established by American Society of Addiction Medicine and should not be more restrictive than non-behavioral health or substance use disorder diagnosis

OR

#### **1.4** All of the following:

- Each active ingredient in the compounded drug is FDA-approved or national compendia\* supported for the condition being treated
- The therapeutic amounts are supported by national compendia\* or two peer-reviewed literature for the condition being treated in the requested route of delivery
- Compound is not commercially available in a formulation that is suitable for the person
- Each active ingredient in the compounded drug is on the formulary or meets the nonformulary criteria
- None of the active ingredient(s) in the compound are otherwise excluded from coverage as defined by the person's benefit
- None of the active ingredient(s) in the compound are experimental or limited by the FDA to investigational use only

| Product Name: Compounded Prescription                           |  |  |
|---|--|--|
| Approval Length 12 month(s)                                     |  |  |
| Guideline Type Prior Authorization – All plans except IL and MN |  |  |
| Product Name Generic Name GPI Brand/Generic                     |  |  |

#### **Approval Criteria**

1 - Each active ingredient in the compounded drug is FDA-approved or national compendia\* supported for the condition being treated

#### AND

**2** - The therapeutic amounts are supported by national compendia\* or two peer-reviewed literature for the condition being treated in the requested route of delivery

#### **AND**

**3** - Compound is not commercially available in a formulation that is suitable for the person

#### **AND**

**4** - Each active ingredient in the compounded drug is on the formulary or meets the nonformulary criteria

#### **AND**

**5** - None of the active ingredient(s) in the compound are otherwise excluded from coverage as defined by the person's benefit

#### **AND**

**6** - None of the active ingredient(s) in the compound are experimental or limited by the FDA to investigational use only

# 2. Background

# \*Compendia Requirements For all non-antineoplastic medications • American Hospital Formulary Service Drug Information (AHFSDI); OR • FDA Uses/Non-FDA Uses section in DRUGDEX Evaluation with a Strength of Recommendation rating of Ilb or better (see DRUGDEX Strength of Recommendation table below); OR

|                                  | One major peer reviewed medical journal submitted by the prescriber that presents data supporting the proposed off-label use or uses as generally safe and effective unless there is clear and convincing contradictory evidence presented in a major peer-reviewed medical journal |
|----------------------------------|---|
| For an antineoplastic medication | American Hospital Formulary Service Drug<br>Information (AHFSDI); OR  |
|                                  | National Comprehensive Cancer Network<br>(NCCN) Drugs and Biologics Compendium<br>with a Category of Evidence and Consensus<br>of 1, 2A, or 2B (see NCCN Categories of<br>Evidence and Consensus table below); OR   |
|                                  | FDA Uses/Non-FDA Uses section in<br>DRUGDEX Evaluation with a Strength of<br>Recommendation rating of IIb or better (see<br>DRUGDEX Strength of Recommendation<br>table below); OR  |
|                                  | Clinical Pharmacology (Gold Standard); OR   |
|                                  | One peer-reviewed published medical literature submitted by the prescriber:   |
|                                  | American Journal of Medicine  |
|                                  | o Annals of Internal Medicine   |
|                                  | o Annals of Oncology  |
|                                  | Annals of Surgical Oncology   |
|                                  | <ul> <li>Biology of Blood and Marrow         Transplantation     </li> </ul>  |
|                                  | ∘ Blood   |
|                                  | o Bone Marrow Transplantation   |

| <ul> <li>British Journal of Cancer</li> </ul>   |
|---|
| <ul> <li>British Journal of Hematology</li> </ul>   |
| o British Medical Journal   |
| o Cancer  |
| <ul> <li>Clinical Cancer Research</li> </ul>  |
| o Drugs   |
| <ul> <li>European Journal of Cancer (formerly<br/>the European Journal of Cancer and<br/>Clinical Oncology)</li> </ul>                                |
| <ul> <li>Gynecologic Oncology</li> </ul>  |
| <ul> <li>International Journal of Radiation,</li> <li>Oncology, Biology, and Physics</li> </ul>   |
| <ul> <li>The Journal of the American Medical<br/>Association</li> </ul>   |
| <ul> <li>Journal of Clinical Oncology</li> </ul>  |
| <ul> <li>Journal of the National Cancer Institute</li> </ul>  |
| <ul> <li>Journal of the National Comprehensive<br/>Cancer Network (NCCN)</li> </ul>   |
| ∘ Journal of Urology  |
| o Lancet  |
| <ul> <li>Lancet Oncology</li> </ul>   |
| o Leukemia  |
| o The New England Journal of Medicine   |
| o Radiation Oncology  |
| Wolters Kluwer Lexi-Drugs rated as "Evidence<br>Level A" with a "Strong" recommendation (see<br>Lexi-Drugs Strength of Recommendation<br>table below) |

DRUGDEX Strength of Recommendation:

| Class                  | Recommendation                | Description   |
|------------------------|-------------------------------|---|
| Class I                | Recommended                   | The given test or treatment has been proven useful, and should be performed or administered.      |
| Class IIa              | Recommended, In<br>Most Cases | The given test or treatment is generally considered to be useful, and is indicated in most cases. |
| Class IIb              | Recommended, in Some Cases    | The given test or treatment may be useful, and is indicated in some, but not most, cases.         |
| Class III              | Not Recommended               | The given test or treatment is not useful, and should be avoided                                  |
| Class<br>Indeterminate | Evidence Inconclusive         |   |

## NCCN Categories of Evidence and Consensus:

| Category | Level of Consensus   |
|----------|--|
| 1        | Based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate.    |
| 2A       | Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.   |
| 2B       | Based upon lower-level evidence, there is NCCN consensus that the intervention is appropriate.           |
| 3        | Based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate. |

Lexi-Drugs: Strength of Recommendation for Inclusion in Lexi-Drugs for Oncology Off-Label Use and Level of Evidence Scale for Oncology Off-Label Use

# Strength of Recommendation for Inclusion

| Strong (for proposed off-label use)    | The evidence persuasively supports the off-label use (ie, Level of Evidence A).   |
|--|---|
| Equivocal (for proposed off-label use) | The evidence to support the off-label use is of uncertain clinical significance (ie, Level of Evidence B, C). Additional studies may be necessary to further define the role of this medication for the off-label use.                        |
| Against proposed off-label use         | The evidence either advocates against the off-label use or suggests a lack of support for the off-label use (independent of Level of Evidence). Additional studies are necessary to define the role of this medication for the off-label use. |

# Level of Evidence Scale for Oncology Off-Label Use

| Α | Consistent evidence from well-performed randomized, controlled trials or overwhelming evidence of some other form (eg, results of the introduction of penicillin treatment) to support off-label use. Further research is unlikely to change confidence in the estimate of benefit.   |
|---|---|
| В | Evidence from randomized, controlled trials with important limitations (eg, inconsistent results, methodologic flaws, indirect, imprecise); or very strong evidence of some other research design. Further research (if performed) is likely to have an impact on confidence in the estimate of benefit and risk and may change the estimate. |
| С | Evidence from observational studies (eg, retrospective case series/reports providing significant impact on patient care); unsystematic clinical experience; or potentially flawed randomized, controlled trials (eg, when limited options exist for condition). Any estimate of effect is uncertain.  |
| G | Use has been substantiated by inclusion in at least one evidence-based or consensus-based clinical practice guideline.  |

# 3. Revision History

| Date      | Notes                   |
|-----------|-------------------------|
| 12/8/2023 | 2024 New Implementation |

| ( | Corlanor (ivabradine)   |  |  |  |  |
|---|---|--|--|--|--|
|   | The final standard grown the shall be the final transformer toward, or defined such fracts that product the convertible and definition. |  |  |  |  |
|   |   |  |  |  |  |

# **Prior Authorization Guideline**

| Guideline ID          | GL-129113             |
|-----------------------|-----------------------|
| <b>Guideline Name</b> | Corlanor (ivabradine) |
| Formulary             | Quartz                |

# **Guideline Note:**

| Effective Date: |
|-----------------|
|-----------------|

## 1. Criteria

| Product Name: Corlanor |  |
|------------------------|--|
| Approval Length        | 12/31/2039   |
| Guideline Type         | Prior Authorization - ALL Plans Except IL and MN Plans |
|                        |  |

| Product<br>Name | Generic Name                                   | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| CORLANOR        | IVABRADINE HCL TAB 5 MG (BASE EQUIV)           | 40700035100320 | Brand         |
| CORLANOR        | IVABRADINE HCL TAB 7.5 MG (BASE EQUIV)         | 40700035100330 | Brand         |
| CORLANOR        | IVABRADINE HCL ORAL SOLN 5 MG/5ML (BASE EQUIV) | 40700035102020 | Brand         |

## **Approval Criteria**

1 - ONE of the following:

- **1.1** ALL of the following:
- **1.1.1** Diagnosis of stable, symptomatic heart failure in sinus rhythm

#### **AND**

- **1.1.2** Both of the following:
  - Left ventricular ejection fraction less than or equal to 35%
  - Resting heart rate greater than or equal to 70 beats per minute

#### AND

**1.1.3** Prescribed by or in consultation with a cardiologist

OR

- **1.2** BOTH of the following:
- **1.2.1** Diagnosis of Inappropriate Sinus Tachycardia

#### **AND**

- **1.2.2** One of the following:
- **1.2.2.1** Member has symptoms despite use of maximally tolerated beta blocker therapy

OR

1.2.2.2 Member has contraindication to beta blocker use

| Product Name: Corlanor |  |
|------------------------|--|
| Approval Length        | 12 month(s)                            |
| Therapy Stage          | Initial Authorization                  |
| Guideline Type         | Prior Authorization - IL and MN Plans* |

| Product<br>Name | Generic Name                                   | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| CORLANOR        | IVABRADINE HCL TAB 5 MG (BASE EQUIV)           | 40700035100320 | Brand         |
| CORLANOR        | IVABRADINE HCL TAB 7.5 MG (BASE EQUIV)         | 40700035100330 | Brand         |
| CORLANOR        | IVABRADINE HCL ORAL SOLN 5 MG/5ML (BASE EQUIV) | 40700035102020 | Brand         |

- 1 ONE of the following:
  - **1.1** ALL of the following:
  - 1.1.1 Diagnosis of stable, symptomatic heart failure in sinus rhythm

#### **AND**

- **1.1.2** Both of the following:
  - Left ventricular ejection fraction less than or equal to 35%
  - Resting heart rate greater than or equal to 70 beats per minute

#### **AND**

1.1.3 Prescribed by or in consultation with a cardiologist

OR

- **1.2** BOTH of the following:
- 1.2.1 Diagnosis of Inappropriate Sinus Tachycardia

#### **AND**

- **1.2.2** One of the following:
- 1.2.2.1 Member has symptoms despite use of maximally tolerated beta blocker therapy

| <b>1.2.2.2</b> Member has | OR<br>contraindication to beta blocker use  |
|---------------------------|---|
| Notes                     | *Member new to the plan (as evidenced by coverage effective date of I ess than or equal to 90 days) must meet initial criteria for coverage |

| Product Name: Corlanor |  |
|------------------------|--|
| Approval Length        | 12 month(s)                            |
| Therapy Stage          | Reauthorization                        |
| Guideline Type         | Prior Authorization - IL and MN Plans* |

| Product<br>Name | Generic Name                                   | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| CORLANOR        | IVABRADINE HCL TAB 5 MG (BASE EQUIV)           | 40700035100320 | Brand         |
| CORLANOR        | IVABRADINE HCL TAB 7.5 MG (BASE EQUIV)         | 40700035100330 | Brand         |
| CORLANOR        | IVABRADINE HCL ORAL SOLN 5 MG/5ML (BASE EQUIV) | 40700035102020 | Brand         |

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug

| Notes | *Member new to the plan (as evidenced by coverage effective date of I |  |
|-------|---|--|
|       | ess than or equal to 90 days) must meet initial criteria for coverage |  |

# 2. Revision History

| Date     | Notes               |
|----------|---------------------|
| 9/8/2023 | 2024 implementation |

| Cortico  | otropin Gel  |     |  |
|--|--|-----|--|
| The bit of image current is a display of. The fi | de may have been remost, movement, or allabels. Verily that the list points in the commercial and load | in. |  |
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# **Prior Authorization Guideline**

| Guideline ID          | GL-128962         |
|-----------------------|-------------------|
| <b>Guideline Name</b> | Corticotropin Gel |
| Formulary             | Quartz            |

## **Guideline Note:**

| Effective Date: |
|-----------------|
|-----------------|

## 1. Criteria

| Product Name: Brand Acthar, Generic Corticotropin |                                       |  |
|---|---------------------------------------|--|
| Approval Length                                   | 12 month(s)                           |  |
| Therapy Stage                                     | Initial Authorization                 |  |
| Guideline Type                                    | Prior Authorization - IL and MN Plans |  |

| Product<br>Name | Generic Name                     | GPI            | Brand/Generic |
|-----------------|----------------------------------|----------------|---------------|
| ACTHAR          | CORTICOTROPIN INJ GEL 80 UNIT/ML | 30300010004010 | Brand         |
| CORTROPHIN      | CORTICOTROPIN INJ GEL 80 UNIT/ML | 30300010004010 | Brand         |

## **Approval Criteria**

**1** - One of the following:

- **1.1** All of the following:
- **1.1.1** Diagnosis of infantile spasm with electroencephalogram pattern consistent with hypsarrhythmia

#### **AND**

1.1.2 Prescribed by, or in consultation with a Neurologist

#### **AND**

1.1.3 Member is less than 2 years of age

#### OR

- **1.2** Both of the following:
- 1.2.1 FDA approved diagnosis with evidence-based supporting literature/guideline

#### **AND**

**1.2.2** Trial and failure, contraindication, or intolerance to an adequate trial of preferred formulary medications appropriate for the condition

| Product Name: Brand Acthar, Generic Corticotropin |  |  |
|---|--|--|
| Approval Length                                   | th 3 Month(s) with partial fill (max 15 days/prescription) |  |
| Therapy Stage                                     | Initial Authorization                                      |  |
| Guideline Type                                    | Prior Authorization – All plans except IL and MN           |  |

| Product<br>Name | Generic Name                     | GPI            | Brand/Generic |
|-----------------|----------------------------------|----------------|---------------|
| ACTHAR          | CORTICOTROPIN INJ GEL 80 UNIT/ML | 30300010004010 | Brand         |
| CORTROPHIN      | CORTICOTROPIN INJ GEL 80 UNIT/ML | 30300010004010 | Brand         |

- 1 One of the following:
- **1.1** All of the following:
- **1.1.1** Diagnosis of infantile spasm with electroencephalogram pattern consistent with hypsarrhythmia

### **AND**

1.1.2 Prescribed by, or in consultation with a Neurologist

### **AND**

1.1.3 Member is less than 2 years of age

OR

- **1.2** Both of the following:
- 1.2.1 FDA approved diagnosis with evidence-based supporting literature/guideline

### **AND**

**1.2.2** Trial and failure, contraindication, or intolerance to an adequate trial of preferred formulary medications appropriate for the condition

| Product Name: Brand Acthar, Generic Corticotropin |                                 |  |
|---|---------------------------------|--|
| Approval Length                                   | 12 month(s)                     |  |
| Therapy Stage                                     | Reauthorization                 |  |
| Guideline Type                                    | Prior Authorization - All Plans |  |

| Product<br>Name | Generic Name                     | GPI            | Brand/Generic |
|-----------------|----------------------------------|----------------|---------------|
| ACTHAR          | CORTICOTROPIN INJ GEL 80 UNIT/ML | 30300010004010 | Brand         |
| CORTROPHIN      | CORTICOTROPIN INJ GEL 80 UNIT/ML | 30300010004010 | Brand         |

| Approval Criteria  |
|--|
| 1 - One of the following:  |
| 1.1 All of the following:  |
| <b>1.1.1</b> Diagnosis of infantile spasm with electroencephalogram pattern consistent with hypsarrhythmia   |
| AND  |
| 1.1.2 Prescribed by, or in consultation with a Neurologist   |
| AND  |
| 1.1.3 Member is less than 2 years of age   |
| OR   |
| 1.2 Both of the following:   |
| 1.2.1 FDA approved diagnosis with evidence-based supporting literature/guideline   |
| AND  |
| <b>1.2.2</b> Trial and failure, contraindication, or intolerance to an adequate trial of preferred formulary medications appropriate for the condition   |
| AND  |
| <b>2</b> - Submission of medical records (e.g., chart notes) with documentation of evidence-based rationale for continued use and evidence of member response to therapy from the previous period. |
|  |

# 2. Revision History

| Date     | Notes       |
|----------|-------------|
| 9/7/2023 | New Program |

| Coser                                 | ityx (sec   | ukinum                                   | ab) |  |
|---------------------------------------|---|--|-----|--|
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# **Prior Authorization Guideline**

| Guideline ID          | GL-137445              |  |
|-----------------------|------------------------|--|
| <b>Guideline Name</b> | Cosentyx (secukinumab) |  |
| Formulary             | Quartz                 |  |

# **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

# 1. Criteria

| Product Name: Cosentyx |  |
|------------------------|--|
| Diagnosis              | Plaque Psoriasis                                       |
| Approval Length        | 12/31/2039   |
| Guideline Type         | Prior Authorization - All plans except IL and MN Plans |

| Product<br>Name               | Generic Name   | GPI            | Brand/Generic |
|-------------------------------|--|----------------|---------------|
| COSENTYX<br>SENSOREADY<br>PEN | SECUKINUMAB SUBCUTANEOUS SOLN AUTO-<br>INJECTOR 150 MG/ML    | 9025057500D520 | Brand         |
| COSENTYX<br>SENSOREADY<br>PEN | SECUKINUMAB SUBCUTANEOUS AUTO-INJ 150<br>MG/ML (300 MG DOSE) | 9025057500D530 | Brand         |
| COSENTYX<br>UNOREADY          | SECUKINUMAB SUBCUTANEOUS SOLN AUTO-<br>INJECTOR 300 MG/2ML   | 9025057500D550 | Brand         |
| COSENTYX                      | SECUKINUMAB SUBCUTANEOUS SOLN                                | 9025057500E510 | Brand         |

|          | PREFILLED SYRINGE 75 MG/0.5ML                                |                |       |
|----------|--|----------------|-------|
| COSENTYX | SECUKINUMAB SUBCUTANEOUS SOLN<br>PREFILLED SYRINGE 150 MG/ML | 9025057500E520 | Brand |
| COSENTYX | SECUKINUMAB SUBCUTANEOUS PREF SYR 150<br>MG/ML (300 MG DOSE) | 9025057500E530 | Brand |

- 1 Diagnosis of moderate to severe plaque psoriasis with ONE of the following:
  - Significant functional disability
  - BSA involvement greater than 3%
  - Debilitating palmar/plantar psoriasis or other vulnerable areas that are difficult to treat such as nails, hairy/scalp areas, genitals, or intertriginous areas

#### AND

2 - Member is greater than 6 years old

### **AND**

- 3 Trial and failure, contraindication or intolerance to BOTH of the following:
- **3.1** Topical treatment (e.g., topical corticosteroids, calcipotriene, retinoids, calcineurin inhibitors)

### AND

- **3.2** ONE of the following:
  - Certolizumab
  - Etanercept
  - Adalimumab (biosimilars or Humira)
  - Risankizumab
  - Ustekinumab
  - Guselkumab

### AND

**4** - Therapy must not be used in combination with other biologic disease modifying antirheumatic drug (DMARD) (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

**AND** 

5 - Medication will be self-administered

### **AND**

6 - Prescribed by or in consultation with a dermatologist

| Product Name: Cosentyx |                                       |  |
|------------------------|---------------------------------------|--|
| Diagnosis              | Plaque Psoriasis                      |  |
| Approval Length        | 12 month(s)                           |  |
| Therapy Stage          | Initial Authorization                 |  |
| Guideline Type         | Prior Authorization - IL and MN Plans |  |

| Product<br>Name               | Generic Name   | GPI            | Brand/Generic |
|-------------------------------|--|----------------|---------------|
| COSENTYX<br>SENSOREADY<br>PEN | SECUKINUMAB SUBCUTANEOUS SOLN AUTO-<br>INJECTOR 150 MG/ML      | 9025057500D520 | Brand         |
| COSENTYX<br>SENSOREADY<br>PEN | SECUKINUMAB SUBCUTANEOUS AUTO-INJ 150<br>MG/ML (300 MG DOSE)   | 9025057500D530 | Brand         |
| COSENTYX<br>UNOREADY          | SECUKINUMAB SUBCUTANEOUS SOLN AUTO-<br>INJECTOR 300 MG/2ML     | 9025057500D550 | Brand         |
| COSENTYX                      | SECUKINUMAB SUBCUTANEOUS SOLN<br>PREFILLED SYRINGE 75 MG/0.5ML | 9025057500E510 | Brand         |
| COSENTYX                      | SECUKINUMAB SUBCUTANEOUS SOLN<br>PREFILLED SYRINGE 150 MG/ML   | 9025057500E520 | Brand         |
| COSENTYX                      | SECUKINUMAB SUBCUTANEOUS PREF SYR 150<br>MG/ML (300 MG DOSE)   | 9025057500E530 | Brand         |

## **Approval Criteria**

1 - Diagnosis of moderate to severe plaque psoriasis with ONE of the following:

Significant functional disability BSA involvement greater than 3% Debilitating palmar/plantar psoriasis or other vulnerable areas that are difficult to treat such as nails, hairy/scalp areas, genitals, or intertriginous areas AND 2 - Member is greater than 6 years old **AND** 3 - Trial and failure, contraindication or intolerance to BOTH of the following: **3.1** Topical treatment (e.g., topical corticosteroids, calcipotriene, retinoids) AND **3.2** ONE of the following: Certolizumab Etanercept Adalimumab (biosimilars or Humira) Risankizumab Ustekinumab Guselkumab AND 4 - Therapy must not be used in combination with other biologic disease modifying antirheumatic drug (DMARD) (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.) **AND** 

5 - Medication will be self-administered

### AND

6 - Prescribed by or in consultation with a dermatologist

| Product Name: Cosentyx |  |
|------------------------|--|
| Diagnosis              | Psoriatic Arthritis (PsA)                              |
| Approval Length        | 12/31/2039   |
| Guideline Type         | Prior Authorization - All plans except IL and MN Plans |

| Product<br>Name               | Generic Name   | GPI            | Brand/Generic |
|-------------------------------|--|----------------|---------------|
| COSENTYX<br>SENSOREADY<br>PEN | SECUKINUMAB SUBCUTANEOUS SOLN AUTO-<br>INJECTOR 150 MG/ML      | 9025057500D520 | Brand         |
| COSENTYX<br>SENSOREADY<br>PEN | SECUKINUMAB SUBCUTANEOUS AUTO-INJ 150<br>MG/ML (300 MG DOSE)   | 9025057500D530 | Brand         |
| COSENTYX<br>UNOREADY          | SECUKINUMAB SUBCUTANEOUS SOLN AUTO-<br>INJECTOR 300 MG/2ML     | 9025057500D550 | Brand         |
| COSENTYX                      | SECUKINUMAB SUBCUTANEOUS SOLN<br>PREFILLED SYRINGE 75 MG/0.5ML | 9025057500E510 | Brand         |
| COSENTYX                      | SECUKINUMAB SUBCUTANEOUS SOLN<br>PREFILLED SYRINGE 150 MG/ML   | 9025057500E520 | Brand         |
| COSENTYX                      | SECUKINUMAB SUBCUTANEOUS PREF SYR 150<br>MG/ML (300 MG DOSE)   | 9025057500E530 | Brand         |

# **Approval Criteria**

1 - Diagnosis of moderate to severely active psoriatic arthritis

### **AND**

- **2** Submission of medical records (e.g., chart notes) documenting at least ONE of the following:
  - Actively inflamed joints
  - Axial disease
  - Active skin, nail, or scalp psoriasis involvement
  - Dactylitis
  - Enthesitis

### **AND**

- **3** Trial and failure or intolerance to a minimum 3 month trial or contraindication to ONE of the following:
  - adalimumab
  - certolizumab
  - etanercept
  - upadacitinib
  - risankizumab
  - guselkumab
  - golimumab
  - tofacitinib/tofacitinib XR
  - ustekinumab

### AND

**4** - Not used in combination with other biologic DMARDs (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

### **AND**

5 - Medication will be self-administered

### **AND**

**6** - Prescribed by or in consultation with a Dermatologist or Rheumatologist

| Product Name: Cosentyx |   |                           |     |               |
|------------------------|---|---------------------------|-----|---------------|
| Diagnosis              |   | Psoriatic Arthritis (PsA) |     |               |
| Approval Leng          | gth   | 12 month(s)               |     |               |
| Therapy Stage          | Э   | Initial Authorization     |     |               |
| Guideline Typ          | deline Type Prior Authorization - IL and MN Plans |                           |     |               |
| Product                | Conorio   | Nama                      | CDI | Brand/Conorio |

| Product<br>Name | Generic Name                        | GPI            | Brand/Generic |
|-----------------|-------------------------------------|----------------|---------------|
| COSENTYX        | SECUKINUMAB SUBCUTANEOUS SOLN AUTO- | 9025057500D520 | Brand         |

| SENSOREADY<br>PEN             | INJECTOR 150 MG/ML   |                |       |
|-------------------------------|--|----------------|-------|
| COSENTYX<br>SENSOREADY<br>PEN | SECUKINUMAB SUBCUTANEOUS AUTO-INJ 150<br>MG/ML (300 MG DOSE)   | 9025057500D530 | Brand |
| COSENTYX<br>UNOREADY          | SECUKINUMAB SUBCUTANEOUS SOLN AUTO-<br>INJECTOR 300 MG/2ML     | 9025057500D550 | Brand |
| COSENTYX                      | SECUKINUMAB SUBCUTANEOUS SOLN<br>PREFILLED SYRINGE 75 MG/0.5ML | 9025057500E510 | Brand |
| COSENTYX                      | SECUKINUMAB SUBCUTANEOUS SOLN<br>PREFILLED SYRINGE 150 MG/ML   | 9025057500E520 | Brand |
| COSENTYX                      | SECUKINUMAB SUBCUTANEOUS PREF SYR 150<br>MG/ML (300 MG DOSE)   | 9025057500E530 | Brand |

1 - Diagnosis of moderate to severely active psoriatic arthritis

### AND

- **2** Submission of medical records (e.g., chart notes) documenting at least ONE of the following:
  - Actively inflamed joints
  - Axial disease
  - · Active skin, nail, or scalp psoriasis involvement
  - Dactylitis
  - Enthesitis

### AND

- **3** Trial and failure or intolerance to a minimum 3 month trial or contraindication to ONE of the following:
  - adalimumab
  - certolizumab
  - etanercept
  - upadacitinib
  - risankizumab
  - guselkumab
  - golimumab
  - tofacitinib/tofacitinib XR

ustekinumab

### **AND**

**4** - Not used in combination with other biologic DMARDs (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

### **AND**

5 - Medication will be self-administered

### **AND**

6 - Prescribed by or in consultation with a Dermatologist or Rheumatologist

| Product Name: Cosentyx |  |
|------------------------|--|
| Diagnosis              | Ankylosing spondylitis (AS)                            |
| Approval Length        | 12/31/2039   |
| Guideline Type         | Prior Authorization - All plans except IL and MN Plans |

| Product<br>Name               | Generic Name   | GPI            | Brand/Generic |
|-------------------------------|--|----------------|---------------|
| COSENTYX<br>SENSOREADY<br>PEN | SECUKINUMAB SUBCUTANEOUS SOLN AUTO-<br>INJECTOR 150 MG/ML      | 9025057500D520 | Brand         |
| COSENTYX<br>SENSOREADY<br>PEN | SECUKINUMAB SUBCUTANEOUS AUTO-INJ 150<br>MG/ML (300 MG DOSE)   | 9025057500D530 | Brand         |
| COSENTYX<br>UNOREADY          | SECUKINUMAB SUBCUTANEOUS SOLN AUTO-<br>INJECTOR 300 MG/2ML     | 9025057500D550 | Brand         |
| COSENTYX                      | SECUKINUMAB SUBCUTANEOUS SOLN<br>PREFILLED SYRINGE 75 MG/0.5ML | 9025057500E510 | Brand         |
| COSENTYX                      | SECUKINUMAB SUBCUTANEOUS SOLN<br>PREFILLED SYRINGE 150 MG/ML   | 9025057500E520 | Brand         |
| COSENTYX                      | SECUKINUMAB SUBCUTANEOUS PREF SYR 150<br>MG/ML (300 MG DOSE)   | 9025057500E530 | Brand         |

## **Approval Criteria**

| 1 - Diagnosis of Ankylosing spondylitis (AS)   |
|--|
| AND  |
| <b>2</b> - Trial and failure of a 1-month trial of scheduled prescription doses of two different NSAIDs (e.g., naproxen, nabumetone, diclofenac, etc.)                                       |
| AND  |
| <b>3</b> - Trial and failure or intolerance to a minimum 3 month trial or contraindication to ONE of the following:  |
| <ul> <li>adalimumab</li> <li>certolizumab</li> <li>etanercept</li> <li>upadacitinib</li> <li>golimumab</li> <li>tofacitinib/tofacitinib XR</li> </ul>  |
| AND  |
| <b>4</b> - Therapy must not be used in combination with other biologic disease modifying antirheumatic drug (DMARD) (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.) |
| AND  |
| 5 - Medication will be self-administered   |
| AND  |
| 6 - Prescribed by or in consultation with a Rheumatologist   |
|  |

| Product Name: Cosent | yx                          |
|----------------------|-----------------------------|
| Diagnosis            | Ankylosing spondylitis (AS) |

| Approval Length | 12 month(s)                           |
|-----------------|---------------------------------------|
| Therapy Stage   | Initial Authorization                 |
| Guideline Type  | Prior Authorization - IL and MN Plans |

| Product<br>Name               | Generic Name   | GPI            | Brand/Generic |
|-------------------------------|--|----------------|---------------|
| COSENTYX<br>SENSOREADY<br>PEN | SECUKINUMAB SUBCUTANEOUS SOLN AUTO-<br>INJECTOR 150 MG/ML      | 9025057500D520 | Brand         |
| COSENTYX<br>SENSOREADY<br>PEN | SECUKINUMAB SUBCUTANEOUS AUTO-INJ 150<br>MG/ML (300 MG DOSE)   | 9025057500D530 | Brand         |
| COSENTYX<br>UNOREADY          | SECUKINUMAB SUBCUTANEOUS SOLN AUTO-<br>INJECTOR 300 MG/2ML     | 9025057500D550 | Brand         |
| COSENTYX                      | SECUKINUMAB SUBCUTANEOUS SOLN<br>PREFILLED SYRINGE 75 MG/0.5ML | 9025057500E510 | Brand         |
| COSENTYX                      | SECUKINUMAB SUBCUTANEOUS SOLN<br>PREFILLED SYRINGE 150 MG/ML   | 9025057500E520 | Brand         |
| COSENTYX                      | SECUKINUMAB SUBCUTANEOUS PREF SYR 150<br>MG/ML (300 MG DOSE)   | 9025057500E530 | Brand         |

1 - Diagnosis of Ankylosing spondylitis (AS)

### AND

**2** - Trial and failure of a 1-month trial of scheduled prescription doses of two different NSAIDs (e.g., naproxen, nabumetone, diclofenac, etc.)

### **AND**

- **3** Trial and failure or intolerance to a minimum 3 month trial or contraindication to ONE of the following:
  - adalimumab
  - certolizumab
  - etanercept
  - upadacitinib
  - golimumab

• tofacitinib/tofacitinib XR

### **AND**

**4** - Therapy must not be used in combination with other biologic disease modifying antirheumatic drug (DMARD) (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

### **AND**

5 - Medication will be self-administered

### **AND**

**6** - Prescribed by or in consultation with a Rheumatologist

| Product Name: Cosentyx |  |
|------------------------|--|
| Diagnosis              | Non-radiographic axial spondyloarthritis (nr-axSpA)    |
| Approval Length        | 12/31/2039   |
| Guideline Type         | Prior Authorization - All plans except IL and MN Plans |

| Product<br>Name               | Generic Name   | GPI            | Brand/Generic |
|-------------------------------|--|----------------|---------------|
| COSENTYX<br>SENSOREADY<br>PEN | SECUKINUMAB SUBCUTANEOUS SOLN AUTO-<br>INJECTOR 150 MG/ML      | 9025057500D520 | Brand         |
| COSENTYX<br>SENSOREADY<br>PEN | SECUKINUMAB SUBCUTANEOUS AUTO-INJ 150<br>MG/ML (300 MG DOSE)   | 9025057500D530 | Brand         |
| COSENTYX<br>UNOREADY          | SECUKINUMAB SUBCUTANEOUS SOLN AUTO-<br>INJECTOR 300 MG/2ML     | 9025057500D550 | Brand         |
| COSENTYX                      | SECUKINUMAB SUBCUTANEOUS SOLN<br>PREFILLED SYRINGE 75 MG/0.5ML | 9025057500E510 | Brand         |
| COSENTYX                      | SECUKINUMAB SUBCUTANEOUS SOLN<br>PREFILLED SYRINGE 150 MG/ML   | 9025057500E520 | Brand         |
| COSENTYX                      | SECUKINUMAB SUBCUTANEOUS PREF SYR 150<br>MG/ML (300 MG DOSE)   | 9025057500E530 | Brand         |

**1** - Diagnosis of active Non-radiographic axial spondyloarthritis (nr-axSpA)

#### **AND**

**2** - Trial and failure of a 1-month trial of scheduled prescription doses of two different NSAIDs (e.g., naproxen, nabumetone, diclofenac, etc.)

### **AND**

- **3** Trial and failure or intolerance to a minimum 3 month trial or contraindication to ONE of the following:
  - certolizumab
  - upadacitinib

### **AND**

**4** - Therapy must not be used in combination with other biologic disease modifying anti-rheumatic drug (DMARD) (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

### **AND**

5 - Medication will be self-administered

#### **AND**

6 - Prescribed by or in consultation with a Rheumatologist

| Product Name: Cosentyx |   |  |
|------------------------|---|--|
| Diagnosis              | Non-radiographic axial spondyloarthritis (nr-axSpA) |  |
| Approval Length        | 12 month(s)   |  |
| Therapy Stage          | Initial Authorization                               |  |

| Guideline Type Prior Authorization - IL and MN Plans |  |  |                |               |
|--|--|--|----------------|---------------|
| Product<br>Name                                      | Generic Name   |  | GPI            | Brand/Generic |
| COSENTYX<br>SENSOREADY<br>PEN                        | SECUKINUMAB SUBCUTANEOUS SOLN AUTO-<br>INJECTOR 150 MG/ML      |  | 9025057500D520 | Brand         |
| COSENTYX<br>SENSOREADY<br>PEN                        | SECUKINUMAB SUBCUTANEOUS AUTO-INJ 150<br>MG/ML (300 MG DOSE)   |  | 9025057500D530 | Brand         |
| COSENTYX<br>UNOREADY                                 | SECUKINUMAB SUBCUTANEOUS SOLN AUTO-<br>INJECTOR 300 MG/2ML     |  | 9025057500D550 | Brand         |
| COSENTYX   | SECUKINUMAB SUBCUTANEOUS SOLN<br>PREFILLED SYRINGE 75 MG/0.5ML |  | 9025057500E510 | Brand         |
| COSENTYX   | SECUKINUMAB SUBCUTANEOUS SOLN<br>PREFILLED SYRINGE 150 MG/ML   |  | 9025057500E520 | Brand         |
| COSENTYX   | SECUKINUMAB SUBCUTANEOUS PREF SYR 150<br>MG/ML (300 MG DOSE)   |  | 9025057500E530 | Brand         |

**1** - Diagnosis of active Non-radiographic axial spondyloarthritis (nr-axSpA)

### **AND**

**2** - Trial and failure of a 1-month trial of scheduled prescription doses of two different NSAIDs (e.g., naproxen, nabumetone, diclofenac, etc.)

### **AND**

- **3** Trial and failure or intolerance to a minimum 3 month trial or contraindication to ONE of the following:
  - certolizumab
  - upadacitinib

### **AND**

**4** - Therapy must not be used in combination with other biologic disease modifying antirheumatic drug (DMARD) (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

AND

5 - Medication will be self-administered

**AND** 

6 - Prescribed by or in consultation with a Rheumatologist

| Product Name: Cosentyx  |                                    |  |
|---|------------------------------------|--|
| Diagnosis   | Enthesitis-related arthritis (ERA) |  |
| Approval Length   | 12/31/2039                         |  |
| Guideline Type Prior Authorization - All plans except IL and MN Plans |                                    |  |

| Product<br>Name               | Generic Name   | GPI            | Brand/Generic |
|-------------------------------|--|----------------|---------------|
| COSENTYX<br>SENSOREADY<br>PEN | SECUKINUMAB SUBCUTANEOUS SOLN AUTO-<br>INJECTOR 150 MG/ML      | 9025057500D520 | Brand         |
| COSENTYX<br>SENSOREADY<br>PEN | SECUKINUMAB SUBCUTANEOUS AUTO-INJ 150<br>MG/ML (300 MG DOSE)   | 9025057500D530 | Brand         |
| COSENTYX<br>UNOREADY          | SECUKINUMAB SUBCUTANEOUS SOLN AUTO-<br>INJECTOR 300 MG/2ML     | 9025057500D550 | Brand         |
| COSENTYX                      | SECUKINUMAB SUBCUTANEOUS SOLN<br>PREFILLED SYRINGE 75 MG/0.5ML | 9025057500E510 | Brand         |
| COSENTYX                      | SECUKINUMAB SUBCUTANEOUS SOLN<br>PREFILLED SYRINGE 150 MG/ML   | 9025057500E520 | Brand         |
| COSENTYX                      | SECUKINUMAB SUBCUTANEOUS PREF SYR 150<br>MG/ML (300 MG DOSE)   | 9025057500E530 | Brand         |

# **Approval Criteria**

1 - Diagnosis of Enthesitis-related arthritis (ERA)

AND

| <b>2</b> - Trial and failure, contraindication or intolerance to at least one NSAID (e.g., naproxen, nabumetone, diclofenac, etc.)  |
|---|
| AND   |
| <b>3</b> - Trial and failure, contraindication or intolerance to one DMARD (e.g., sulfasalazine, methotrexate)  |
| AND   |
| 4 - Member is greater than 4 years old  |
| AND   |
| <b>3</b> - Therapy must not be used in combination with other biologic disease modifying anti-rheumatic drug (DMARD) (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.) |
| AND   |
| 4 - Medication will be self-administered  |
| AND   |
| 7 - Prescribed by or in consultation with a Rheumatologist  |
|   |
|   |

| Product Name: Cosentyx |         |                                       |                |               |
|------------------------|---------|---------------------------------------|----------------|---------------|
| Diagnosis Er           |         | Enthesitis-related arthritis (ERA)    |                |               |
| Approval Length        |         | 12 month(s)                           |                |               |
| Therapy Stage          |         | Initial Authorization                 |                |               |
| Guideline Type         |         | Prior Authorization - IL and MN Plans |                |               |
| Product<br>Name        | Generic | Name                                  | GPI            | Brand/Generic |
| COSENTYX               | SECUKIN | UMAB SUBCUTANEOUS SOLN AUTO-          | 9025057500D520 | Brand         |

| SENSOREADY<br>PEN             | INJECTOR 150 MG/ML   |                |       |
|-------------------------------|--|----------------|-------|
| COSENTYX<br>SENSOREADY<br>PEN | SECUKINUMAB SUBCUTANEOUS AUTO-INJ 150<br>MG/ML (300 MG DOSE)   | 9025057500D530 | Brand |
| COSENTYX<br>UNOREADY          | SECUKINUMAB SUBCUTANEOUS SOLN AUTO-<br>INJECTOR 300 MG/2ML     | 9025057500D550 | Brand |
| COSENTYX                      | SECUKINUMAB SUBCUTANEOUS SOLN<br>PREFILLED SYRINGE 75 MG/0.5ML | 9025057500E510 | Brand |
| COSENTYX                      | SECUKINUMAB SUBCUTANEOUS SOLN<br>PREFILLED SYRINGE 150 MG/ML   | 9025057500E520 | Brand |
| COSENTYX                      | SECUKINUMAB SUBCUTANEOUS PREF SYR 150<br>MG/ML (300 MG DOSE)   | 9025057500E530 | Brand |

1 - Diagnosis of Enthesitis-related arthritis (ERA)

### **AND**

**2** - Trial and failure, contraindication or intolerance to at least one NSAID (e.g., naproxen, nabumetone, diclofenac, etc.)

### **AND**

**3** - Trial and failure, contraindication or intolerance to one DMARD (e.g., sulfasalazine, methotrexate)

### **AND**

4 - Member is greater than 4 years old

### **AND**

**5** - Therapy must not be used in combination with other biologic disease modifying antirheumatic drug (DMARD) (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.) AND

6 - Medication will be self-administered

### AND

**7** - Prescribed by or in consultation with a Rheumatologist

| Product Name: Cosentyx |                                       |  |  |
|------------------------|---------------------------------------|--|--|
| Diagnosis              | All Indications Listed Above          |  |  |
| Approval Length        | 12 month(s)                           |  |  |
| Therapy Stage          | Reauthorization                       |  |  |
| Guideline Type         | Prior Authorization - IL and MN Plans |  |  |

| Product<br>Name               | Generic Name   | GPI            | Brand/Generic |
|-------------------------------|--|----------------|---------------|
| COSENTYX<br>SENSOREADY<br>PEN | SECUKINUMAB SUBCUTANEOUS SOLN AUTO-<br>INJECTOR 150 MG/ML      | 9025057500D520 | Brand         |
| COSENTYX<br>SENSOREADY<br>PEN | SECUKINUMAB SUBCUTANEOUS AUTO-INJ 150<br>MG/ML (300 MG DOSE)   | 9025057500D530 | Brand         |
| COSENTYX<br>UNOREADY          | SECUKINUMAB SUBCUTANEOUS SOLN AUTO-<br>INJECTOR 300 MG/2ML     | 9025057500D550 | Brand         |
| COSENTYX                      | SECUKINUMAB SUBCUTANEOUS SOLN<br>PREFILLED SYRINGE 75 MG/0.5ML | 9025057500E510 | Brand         |
| COSENTYX                      | SECUKINUMAB SUBCUTANEOUS SOLN<br>PREFILLED SYRINGE 150 MG/ML   | 9025057500E520 | Brand         |
| COSENTYX                      | SECUKINUMAB SUBCUTANEOUS PREF SYR 150<br>MG/ML (300 MG DOSE)   | 9025057500E530 | Brand         |

### **Approval Criteria**

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months member demonstrates a positive clinical response to therapy as evidenced by improvements in functional status related to therapeutic response

| Product Name: Cosentyx |                                      |  |
|------------------------|--------------------------------------|--|
| Diagnosis              | Plaque psoriasis, AS, PSA, ERA       |  |
| Approval Length        | 12 month(s)                          |  |
| Guideline Type         | Quantity Exception - IL and MN Plans |  |

| Product<br>Name               | Generic Name   | GPI            | Brand/Generic |
|-------------------------------|--|----------------|---------------|
| COSENTYX<br>SENSOREADY<br>PEN | SECUKINUMAB SUBCUTANEOUS SOLN AUTO-<br>INJECTOR 150 MG/ML      | 9025057500D520 | Brand         |
| COSENTYX<br>SENSOREADY<br>PEN | SECUKINUMAB SUBCUTANEOUS AUTO-INJ 150<br>MG/ML (300 MG DOSE)   | 9025057500D530 | Brand         |
| COSENTYX<br>UNOREADY          | SECUKINUMAB SUBCUTANEOUS SOLN AUTO-<br>INJECTOR 300 MG/2ML     | 9025057500D550 | Brand         |
| COSENTYX                      | SECUKINUMAB SUBCUTANEOUS SOLN<br>PREFILLED SYRINGE 75 MG/0.5ML | 9025057500E510 | Brand         |
| COSENTYX                      | SECUKINUMAB SUBCUTANEOUS SOLN<br>PREFILLED SYRINGE 150 MG/ML   | 9025057500E520 | Brand         |
| COSENTYX                      | SECUKINUMAB SUBCUTANEOUS PREF SYR 150<br>MG/ML (300 MG DOSE)   | 9025057500E530 | Brand         |

1 - FDA labeled regimen (based on weight or lack of response to lower doses)

### OR

**2** - Trial and failure of a 3-month course of standard dosing and the prescriber provides published literature supporting the requested regimen for the person's diagnosis

| Product Name: Cosentyx                   |  |  |
|--|--|--|
| Diagnosis Plaque psoriasis, AS, PSA, ERA |  |  |
| Approval Length                          | h 12/31/2039   |  |
| Guideline Type                           | ideline Type Quantity Exception – All Plans except IL and MN Plans |  |
|  |  |  |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
|                 | SECUKINUMAB SUBCUTANEOUS SOLN AUTO-<br>INJECTOR 150 MG/ML | 9025057500D520 | Brand         |

| PEN                           |  |                |       |
|-------------------------------|--|----------------|-------|
| COSENTYX<br>SENSOREADY<br>PEN | SECUKINUMAB SUBCUTANEOUS AUTO-INJ 150<br>MG/ML (300 MG DOSE)   | 9025057500D530 | Brand |
| COSENTYX<br>UNOREADY          | SECUKINUMAB SUBCUTANEOUS SOLN AUTO-<br>INJECTOR 300 MG/2ML     | 9025057500D550 | Brand |
| COSENTYX                      | SECUKINUMAB SUBCUTANEOUS SOLN<br>PREFILLED SYRINGE 75 MG/0.5ML | 9025057500E510 | Brand |
| COSENTYX                      | SECUKINUMAB SUBCUTANEOUS SOLN<br>PREFILLED SYRINGE 150 MG/ML   | 9025057500E520 | Brand |
| COSENTYX                      | SECUKINUMAB SUBCUTANEOUS PREF SYR 150<br>MG/ML (300 MG DOSE)   | 9025057500E530 | Brand |

1 - FDA labeled regimen (based on weight or lack of response to lower doses)

OR

**2** - Trial and failure of a 3-month course of standard dosing and the prescriber provides published literature supporting the requested regimen for the person's diagnosis

# 2. Revision History

| Date      | Notes       |
|-----------|-------------|
| 12/7/2023 | New Program |

| Cystic Fibrosis Transmembrane Receptor (CFTR) Modifier   |  |  |
|--|--|--|
| (3) beliefungsvermidigen. Veder in bestellt med vider i den det bede his person in med artisant. |  |  |

# **Prior Authorization Guideline**

| Guideline ID          | GL-137861   |  |
|-----------------------|---|--|
| <b>Guideline Name</b> | Cystic Fibrosis Transmembrane Receptor (CFTR) Modifiers |  |
| Formulary             | Quartz  |  |

# Guideline Note:

| Effective Date:    | 1/1/2024 |
|--------------------|----------|
| P&T Approval Date: |          |
| P&T Revision Date: |          |

# 1. Criteria

| Product Name: Kalydeco, Orkambi, Symdeko, Trikafta |                       |
|--|-----------------------|
| Approval Length 12 month(s)                        |                       |
| Therapy Stage                                      | Initial Authorization |
| Guideline Type                                     | Prior Authorization   |

| Product<br>Name | Generic Name   | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| TRIKAFTA        | ELEXACAF-TEZACAF-IVACAF 80-40-60 MG& IVACAF 59.5MG THPK GRAN   | 4530990340B120 | Brand         |
| TRIKAFTA        | ELEXACAF-TEZACAF-IVACAF 100-50-75 MG& IVACAF<br>75MG THPK GRAN | 4530990340B140 | Brand         |
| TRIKAFTA        | ELEXACAF-TEZACAF-IVACAF 50-25-37.5 MG & IVACAFTOR 75 MG TBPK   | 4530990340B720 | Brand         |

| TRIKAFTA | ELEXACAF-TEZACAF-IVACAF 100-50-75 MG<br>&IVACAFTOR 150 MG TBPK | 4530990340B740 | Brand |
|----------|--|----------------|-------|
| KALYDECO | IVACAFTOR TAB 150 MG   | 45302030000320 | Brand |
| KALYDECO | IVACAFTOR PACKET 13.4 MG                                       | 45302030003005 | Brand |
| KALYDECO | IVACAFTOR PACKET 25 MG   | 45302030003010 | Brand |
| KALYDECO | IVACAFTOR PACKET 50 MG   | 45302030003020 | Brand |
| KALYDECO | IVACAFTOR PACKET 75 MG   | 45302030003030 | Brand |
| ORKAMBI  | LUMACAFTOR-IVACAFTOR TAB 100-125 MG                            | 45309902300310 | Brand |
| ORKAMBI  | LUMACAFTOR-IVACAFTOR TAB 200-125 MG                            | 45309902300320 | Brand |
| ORKAMBI  | LUMACAFTOR-IVACAFTOR GRANULES PACKET 75-94<br>MG               | 45309902303005 | Brand |
| ORKAMBI  | LUMACAFTOR-IVACAFTOR GRANULES PACKET 100-<br>125 MG            | 45309902303010 | Brand |
| ORKAMBI  | LUMACAFTOR-IVACAFTOR GRANULES PACKET 150-<br>188 MG            | 45309902303020 | Brand |
| SYMDEKO  | TEZACAFTOR-IVACAFTOR 50-75 MG & IVACAFTOR 75 MG TAB TBPK       | 4530990280B710 | Brand |
| SYMDEKO  | TEZACAFTOR-IVACAFTOR 100-150 MG & IVACAFTOR 150 MG TAB TBPK    | 4530990280B720 | Brand |

- 1 Submission of medical records (e.g., chart notes) documenting ALL of the following:
- **1.1** Diagnosis of cystic fibrosis (CF)

### **AND**

- **1.2** Patient has at least one of the following mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene:
  - Homozygous F508del CFTR mutation
  - Heterozygous F508del CFTR mutation
  - Heterozygous CFTR mutation that does not include F508del (Mutation is responsive to the drug as noted in the product labeling)

### **AND**

1.3 Patient has chronic sinopulmonary, gastrointestinal or nutritional abnormalities related to

| cystic fibrosis (CF) requiring medical treatment  |
|---|
| AND   |
| 2 - Prescribed by or in consultation with one of the following:   |
| <ul> <li>Pulmonologist</li> <li>Specialist in the care of cystic fibrosis (CF)</li> </ul>   |
| AND   |
| 3 - ONE of the following:   |
| 3.1 For members with homozygous F508del CFTR mutation, one of the following:  |
| 3.1.1 For Trikafta requests ONLY: Member is 2 years of age or older   |
| OR  |
| 3.1.2 For Orkambi requests ONLY, one of the following::   |
| 3.1.2.1 Member is between 1 and 2 years of age  |
| OR  |
| 3.1.2.2 Both of the following:  |
| <ul> <li>Member is 2 years of age or older</li> <li>Submission of medical records (e.g., chart notes) documenting trial and failure to a minimum 6-month trial, contraindication, or intolerance to Trikafta</li> </ul> |
| OR  |
| <b>3.1.3</b> For Symdeko requests ONLY, all of the following:   |
| <ul> <li>Member is 6 years of age or older</li> <li>Submission of medical records (e.g., chart notes) documenting trial and failure to a minimum 6-month trial, contraindication, or intolerance to Trikafta</li> </ul> |

Submission of medical records (e.g., chart notes) documenting trial and failure to a

minimum 6-month trial, contraindication, or intolerance to Orkambi OR **3.2** For members with heterozygous F508del CFTR mutation, one of the following: 3.2.1 For Trikafta requests ONLY: Member is 2 years of age or older OR 3.2.2 For Kalydeco requests ONLY, member is 1 months of age or older OR **3.2.3** For Symdeko requests ONLY, both of the following: Member is 6 years of age or older Submission of medical records (e.g., chart notes) documenting trial and failure to a minimum 6-month trial, contraindication, or intolerance to Trikafta OR 3.3 For members with heterozygous CFTR mutation that does not include F508del (Mutation is responsive to the drug as noted in the product labeling), one of the following: 3.3.1 For Kalydeco requests ONLY, member is 1 months of age or older **OR** 3.3.2 For Trikafta requests ONLY, member is 2 years of age or older OR

Submission of medical records (e.g., chart notes) documenting trial and failure to a

**3.3.3** For Symdeko requests ONLY, both of the following:

Member is 6 years of age or older

minimum 6-month trial, contraindication, or intolerance to Trikafta

| Product Name: Kalydeco, Orkambi, Symdeko, Trikafta |                     |
|--|---------------------|
| Approval Length 12 month(s)                        |                     |
| Therapy Stage                                      | Reauthorization     |
| Guideline Type                                     | Prior Authorization |

| Product<br>Name | Generic Name   | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| TRIKAFTA        | ELEXACAF-TEZACAF-IVACAF 80-40-60 MG& IVACAF 59.5MG THPK GRAN   | 4530990340B120 | Brand         |
| TRIKAFTA        | ELEXACAF-TEZACAF-IVACAF 100-50-75 MG& IVACAF<br>75MG THPK GRAN | 4530990340B140 | Brand         |
| TRIKAFTA        | ELEXACAF-TEZACAF-IVACAF 50-25-37.5 MG & IVACAFTOR 75 MG TBPK   | 4530990340B720 | Brand         |
| TRIKAFTA        | ELEXACAF-TEZACAF-IVACAF 100-50-75 MG<br>&IVACAFTOR 150 MG TBPK | 4530990340B740 | Brand         |
| KALYDECO        | IVACAFTOR TAB 150 MG   | 45302030000320 | Brand         |
| KALYDECO        | IVACAFTOR PACKET 13.4 MG                                       | 45302030003005 | Brand         |
| KALYDECO        | IVACAFTOR PACKET 25 MG   | 45302030003010 | Brand         |
| KALYDECO        | IVACAFTOR PACKET 50 MG   | 45302030003020 | Brand         |
| KALYDECO        | IVACAFTOR PACKET 75 MG   | 45302030003030 | Brand         |
| ORKAMBI         | LUMACAFTOR-IVACAFTOR TAB 100-125 MG                            | 45309902300310 | Brand         |
| ORKAMBI         | LUMACAFTOR-IVACAFTOR TAB 200-125 MG                            | 45309902300320 | Brand         |
| ORKAMBI         | LUMACAFTOR-IVACAFTOR GRANULES PACKET 75-94<br>MG               | 45309902303005 | Brand         |
| ORKAMBI         | LUMACAFTOR-IVACAFTOR GRANULES PACKET 100-<br>125 MG            | 45309902303010 | Brand         |
| ORKAMBI         | LUMACAFTOR-IVACAFTOR GRANULES PACKET 150-<br>188 MG            | 45309902303020 | Brand         |
| SYMDEKO         | TEZACAFTOR-IVACAFTOR 50-75 MG & IVACAFTOR 75 MG TAB TBPK       | 4530990280B710 | Brand         |
| SYMDEKO         | TEZACAFTOR-IVACAFTOR 100-150 MG & IVACAFTOR 150 MG TAB TBPK    | 4530990280B720 | Brand         |

# Approval Criteria

**1** - Submission of medical records (e.g., chart notes) from the previous 12 months

demonstrating positive clinical response to therapy by one of the following:

- FEV1 stabilization or improvement from baseline
- Reduction in the number of pulmonary exacerbations that require antibiotics in the past year
- Improvement in BMI from baseline
- Member-specific description of benefit

#### **AND**

- **2** Submission of medical records (e.g., chart notes) documenting patient has at least one of the following mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene:
  - Homozygous F508del CFTR mutation
  - Heterozygous F508del CFTR mutation
  - Heterozygous CFTR mutation that does not include F508del (Mutation is responsive to the drug as noted in the product labeling)

#### **AND**

- **3** ONE of the following:
- **3.1** For members with homozygous F508del CFTR mutation, one of the following:
- 3.1.1 For Trikafta requests ONLY: Member is 2 years of age or older

OR

- **3.1.2** For Orkambi requests ONLY, one of the following:
- 3.1.2.1 Member is between 1 and 2 years of age

OR

- **3.1.2.2** Both of the following:
  - Member is 2 years of age or older
  - Submission of medical records (e.g., chart notes) documenting trial and failure to a minimum 6-month trial, contraindication, or intolerance to Trikafta

OR

- **3.1.3** For Symdeko requests ONLY, all of the following:
  - Member is 6 years of age or older
  - Submission of medical records (e.g., chart notes) documenting trial and failure to a minimum 6-month trial, contraindication, or intolerance to Trikafta
  - Submission of medical records (e.g., chart notes) documenting trial and failure to a minimum 6-month trial, contraindication, or intolerance to Orkambi

OR

- **3.2** For members with heterozygous F508del CFTR mutation, one of the following:
- **3.2.1** For Trikafta requests ONLY: Member is 2 years of age or older

OR

3.2.2 For Kalydeco requests ONLY, member is 1 months of age or older

OR

- **3.2.3** For Symdeko requests ONLY, both of the following:
  - Member is 6 years of age or older
  - Submission of medical records (e.g., chart notes) documenting trial and failure to a minimum 6-month trial, contraindication, or intolerance to Trikafta

OR

- **3.3** For members with heterozygous CFTR mutation that does not include F508del (Mutation is responsive to the drug as noted in the product labeling), one of the following:
  - **3.3.1** For Kalydeco requests ONLY, member is 1 months of age or older

OR

3.3.2 For Trikafta requests ONLY, member is 2 years of age or older

OR

- **3.3.3** For Symdeko requests ONLY, both of the following:
  - Member is 6 years of age or older
  - Submission of medical records (e.g., chart notes) documenting trial and failure to a minimum 6-month trial, contraindication, or intolerance to Trikafta

# 2. Revision History

| Date       | Notes       |
|------------|-------------|
| 12/15/2023 | New Program |

| [  | Diacomit (Stiripentol)  |  |     |  |  |
|----|---|--|-----|--|--|
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# **Prior Authorization Guideline**

| Guideline ID          | GL-136422              |
|-----------------------|------------------------|
| <b>Guideline Name</b> | Diacomit (Stiripentol) |
| Formulary             | Quartz                 |

# **Guideline Note:**

| Effective Date: |
|-----------------|
|-----------------|

# 1. Criteria

| Product Name: Diacomit |  |  |
|------------------------|--|--|
| Approval Length        | 12 month(s)                              |  |
| Therapy Stage          | Initial Authorization                    |  |
| Guideline Type         | Prior Authorization-IL and MN Plans Only |  |

| Product<br>Name | Generic Name              | GPI            | Brand/Generic |
|-----------------|---------------------------|----------------|---------------|
| DIACOMIT        | STIRIPENTOL CAP 250 MG    | 72600070000120 | Brand         |
| DIACOMIT        | STIRIPENTOL CAP 500 MG    | 72600070000130 | Brand         |
| DIACOMIT        | STIRIPENTOL PACKET 250 MG | 72600070003020 | Brand         |
| DIACOMIT        | STIRIPENTOL PACKET 500 MG | 72600070003030 | Brand         |

1 - Diagnosis of Dravet Syndrome

### **AND**

2 - Prescribed by, or in consultation with, a neurologist

### **AND**

3 - Age greater than or equal to 2 years

### **AND**

4 - Used in combination with clobazam and valproate

| Product Name: Diacomit |  |
|------------------------|--|
| Approval Length        | 12 month(s)                              |
| Therapy Stage          | Reauthorization                          |
| Guideline Type         | Prior Authorization-IL and MN Plans Only |

| Product<br>Name | Generic Name              | GPI            | Brand/Generic |
|-----------------|---------------------------|----------------|---------------|
| DIACOMIT        | STIRIPENTOL CAP 250 MG    | 72600070000120 | Brand         |
| DIACOMIT        | STIRIPENTOL CAP 500 MG    | 72600070000130 | Brand         |
| DIACOMIT        | STIRIPENTOL PACKET 250 MG | 72600070003020 | Brand         |
| DIACOMIT        | STIRIPENTOL PACKET 500 MG | 72600070003030 | Brand         |

## **Approval Criteria**

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug

### Product Name: Diacomit

| Approval Length | 12/31/2039                                     |
|-----------------|--|
| Guideline Type  | Prior Authorization-All plans except IL and MN |

| Product<br>Name | Generic Name              | GPI            | Brand/Generic |
|-----------------|---------------------------|----------------|---------------|
| DIACOMIT        | STIRIPENTOL CAP 250 MG    | 72600070000120 | Brand         |
| DIACOMIT        | STIRIPENTOL CAP 500 MG    | 72600070000130 | Brand         |
| DIACOMIT        | STIRIPENTOL PACKET 250 MG | 72600070003020 | Brand         |
| DIACOMIT        | STIRIPENTOL PACKET 500 MG | 72600070003030 | Brand         |

1 - Diagnosis of Dravet Syndrome

**AND** 

2 - Prescribed by, or in consultation with, a neurologist

**AND** 

3 - Age greater than or equal to 2 years

**AND** 

4 - Used in combination with clobazam and valproate

# 2. Revision History

| Date      | Notes       |
|-----------|-------------|
| 12/8/2023 | New program |

| Dificid (Fidaxomicin)                 |   |  |  |  |
|---------------------------------------|---|--|--|--|
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|                                       |   |  |  |  |

# **Prior Authorization Guideline**

| Guideline ID          | GL-129944             |  |
|-----------------------|-----------------------|--|
| <b>Guideline Name</b> | Dificid (Fidaxomicin) |  |
| Formulary             | Quartz                |  |

# **Guideline Note:**

| Effective Date: |
|-----------------|
|-----------------|

# 1. Criteria

| Product Name: Dificid |                                   |  |
|-----------------------|-----------------------------------|--|
| Approval Length       | 12 month(s) with a fill count = 1 |  |
| Guideline Type        | Prior Authorization               |  |
|                       |                                   |  |

| Product<br>Name | Generic Name                  | GPI            | Brand/Generic |
|-----------------|-------------------------------|----------------|---------------|
| DIFICID         | FIDAXOMICIN TAB 200 MG        | 03530025000320 | Brand         |
| DIFICID         | FIDAXOMICIN FOR SUSP 40 MG/ML | 03530025001920 | Brand         |

# **Approval Criteria**

- **1** All of the following:
- **1.1** Outpatient initiation of treatment

| AND   |
|---|
| <b>1.2</b> Relapse or recurrence after a greater than or equal to 10 days treatment course with vancomycin                        |
| AND   |
| 1.3 One of the following:   |
| <b>1.3.1</b> Submission of medical records (i.e., PCR positive, toxin assay, or colonoscopy) of recurrent C difficile infection   |
| OR  |
| <b>1.3.2</b> Submission of medical records (e.g., chart notes) documenting low levels of neutralizing antibodies to C. difficile  |
| OR  |
| 2 - Both of the following:  |
| 2.1 Continuation of hospital therapy  |
| AND   |
| 2.2 Member has been receiving as an inpatient during hospitalization and needs to complete the course of therapy as an outpatient |
| OR  |
| <b>3</b> - (Illinois plans only) – the requested drug is being used for the long-term treatment of tickborne disease              |
| OR  |

- **4** (Minnesota plans only) Both of the following:

  - Member has stage four metastatic cancer Requested drug is being used to treat a cancer-related C. difficile infection

# 2. Revision History

| Date       | Notes                   |
|------------|-------------------------|
| 10/25/2023 | 2024 New Implementation |

| Dojolvi (Triheptanoin)   |  |  |  |  |
|--|--|--|--|--|
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# **Prior Authorization Guideline**

| Guideline ID          | GL-131134              |
|-----------------------|------------------------|
| <b>Guideline Name</b> | Dojolvi (Triheptanoin) |
| Formulary             | Quartz                 |

# **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

# 1. Criteria

| Product Name: Dojolvi |                                 |
|-----------------------|---------------------------------|
| Approval Length       | 12 month(s)                     |
| Therapy Stage         | Initial Authorization           |
| Guideline Type        | Prior Authorization - ALL Plans |

| Product<br>Name | Generic Name                  | GPI            | Brand/Generic |
|-----------------|-------------------------------|----------------|---------------|
| DOJOLVI         | TRIHEPTANOIN ORAL LIQUID 100% | 80200080000920 | Brand         |

# **Approval Criteria**

**1** - Diagnosis of long-chain fatty acid oxidation disorder

#### AND

- 2 Disease confirmed by one of the following:
  - elevation of acylcarnitine
  - enzyme activity assay below lower limit of normal
  - genetic testing showing mutation associated with long-chain fatty acid oxidation disorders

### **AND**

**3** - Trial and failure or contraindication to over-the-counter medium-chain fatty acid products for management of long-chain fatty acid oxidation disorder, including submission of medical records (e.g., chart notes) documenting specific adherence intervention deployed by a health care provider

### **AND**

**4** - Prescribed by or in consultation with a metabolic disease provider who specializes in management of fatty acid oxidation disorders

| *Member new to the plan (as evidenced by coverage effective date of I ess than or equal to 90 days) who initiated therapy using a manufactur er-sponsored free drug program, provider samples, and/or vouchers wil I go through initial criteria, otherwise for continuation of therapy for new |
|---|
| to plan, reauthorization criteria applies   |

| Product Name: Dojolvi |                                 |
|-----------------------|---------------------------------|
| Approval Length       | 12 month(s)                     |
| Therapy Stage         | Reauthorization                 |
| Guideline Type        | Prior Authorization - ALL Plans |

| Product Generic Name Name |                               | GPI            | Brand/Generic |  |
|---------------------------|-------------------------------|----------------|---------------|--|
| DOJOLVI                   | TRIHEPTANOIN ORAL LIQUID 100% | 80200080000920 | Brand         |  |

### **Approval Criteria**

1 - Diagnosis of long-chain fatty acid oxidation disorder

#### **AND**

- 2 Disease confirmed by one of the following:
  - elevation of acylcarnitine
  - enzyme activity assay below lower limit of normal
  - genetic testing showing mutation associated with long-chain fatty acid oxidation disorders

#### **AND**

**3** - Trial and failure or contraindication to over-the-counter medium-chain fatty acid products for management of long-chain fatty acid oxidation disorder, including submission of medical records (e.g., chart notes) documenting specific adherence intervention deployed by a health care provider

### **AND**

**4** - Prescribed by or in consultation with a metabolic disease provider who specializes in management of fatty acid oxidation disorders

#### AND

**5** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member has shown improvement with requested drug (e.g., improved cardiac symptoms/function, decreased hospitalizations or urgent care visits, decreased hypoglycemic episodes, etc.)

| Notes | *Member new to the plan (as evidenced by coverage effective date of I ess than or equal to 90 days) who initiated therapy using a manufactur er-sponsored free drug program, provider samples, and/or vouchers wil I go through initial criteria, otherwise for continuation of therapy for new |
|-------|---|
|       | to plan, reauthorization criteria applies   |

# 2. Revision History

| Date | Notes |
|------|-------|
|      |       |

| 8/20/2023 | 2024 New Implementation |
|-----------|-------------------------|
|           |                         |

| Dry Eye Disease |  |   |  |  |  |
|-----------------|--|---|--|--|--|
| The bins        | l'ingressent le diploje. Trefé ny hae kao most, seane, e è | obbel. Verily that the life points to the sometific and invation. |  |  |  |
|                 |  |   |  |  |  |

# **Prior Authorization Guideline**

| Guideline ID          | GL-127812       |
|-----------------------|-----------------|
| <b>Guideline Name</b> | Dry Eye Disease |
| Formulary             | Quartz          |

# **Guideline Note:**

| Effective Date: |
|-----------------|
|-----------------|

# 1. Criteria

| Product Name: Cequa, Tyrvaya, Xiidra          |                       |
|---|-----------------------|
| Approval Length 12 month(s)                   |                       |
| Therapy Stage                                 | Initial Authorization |
| Guideline Type Step Therapy - IL and MN Plans |                       |

| Product<br>Name | Generic Name                                | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| CEQUA           | CYCLOSPORINE (OPHTH) SOLN 0.09% (PF)        | 86720020002040 | Brand         |
| XIIDRA          | LIFITEGRAST OPHTH SOLN 5%                   | 86734050002020 | Brand         |
| TYRVAYA         | VARENICLINE TARTRATE NASAL SOLN 0.03 MG/ACT | 86280080202020 | Brand         |

# **Approval Criteria**

# **1** - Trial and failure of cyclosporine 0.05% eye drops

| Product Name: Cequa, Tyrvaya, Xiidra |                                |
|--------------------------------------|--------------------------------|
| Approval Length                      | 12 month(s)                    |
| Therapy Stage                        | Reauthorization                |
| Guideline Type                       | Step Therapy - IL and MN Plans |

| Product<br>Name | Generic Name                                | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| CEQUA           | CYCLOSPORINE (OPHTH) SOLN 0.09% (PF)        | 86720020002040 | Brand         |
| XIIDRA          | LIFITEGRAST OPHTH SOLN 5%                   | 86734050002020 | Brand         |
| TYRVAYA         | VARENICLINE TARTRATE NASAL SOLN 0.03 MG/ACT | 86280080202020 | Brand         |

# **Approval Criteria**

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug

| Product Name: Cequa, Tyrvaya, Xiidra |   |
|--------------------------------------|---|
| Approval Length 12/31/2039           |   |
| Guideline Type                       | Step Therapy - All plans except IL and MN Plans |

| Product<br>Name | Generic Name                                | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| CEQUA           | CYCLOSPORINE (OPHTH) SOLN 0.09% (PF)        | 86720020002040 | Brand         |
| XIIDRA          | LIFITEGRAST OPHTH SOLN 5%                   | 86734050002020 | Brand         |
| TYRVAYA         | VARENICLINE TARTRATE NASAL SOLN 0.03 MG/ACT | 86280080202020 | Brand         |

# **Approval Criteria**

1 - Trial and failure of cyclosporine 0.05% eye drops

# 2. Revision History

| Date      | Notes       |
|-----------|-------------|
| 8/21/2023 | New Program |

| Dupixent (dupilumab)   |  |  |  |  |
|--|--|--|--|--|
| The State of the S |  |  |  |  |

# **Prior Authorization Guideline**

| Guideline ID          | GL-134628            |
|-----------------------|----------------------|
| <b>Guideline Name</b> | Dupixent (dupilumab) |
| Formulary             | Quartz               |

# **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

# Note:

Member new to the plan (as evidenced by coverage effective date of less than or equal to 90 days) who initiated therapy using a manufacturer-sponsored free drug program, provider samples, and/or vouchers will go through initial criteria, otherwise for continuation of therapy for new to plan, reauthorization criteria applies.

# 1. Criteria

| Product Name: Dupixent      |              |                                       |                |               |  |
|-----------------------------|--------------|---------------------------------------|----------------|---------------|--|
| Diagnosis Atopic Dermatitis |              |                                       |                |               |  |
| Approval Length 12 month(s) |              |                                       |                |               |  |
| Therapy Stage               |              | Initial Authorization                 |                |               |  |
| Guideline Type              |              | Prior Authorization - IL and MN Plans |                |               |  |
| Product<br>Name             | Generic Name |                                       | GPI            | Brand/Generic |  |
| DUPIXENT                    | DUPILUMAB    | SUBCUTANEOUS SOLN PEN-INJECTOR        | 9027302000D215 | Brand         |  |

|          | 200 MG/1.14ML  |                |       |
|----------|--|----------------|-------|
| DUPIXENT | DUPILUMAB SUBCUTANEOUS SOLN PEN-INJECTOR 300 MG/2ML            | 9027302000D220 | Brand |
| DUPIXENT | DUPILUMAB SUBCUTANEOUS SOLN PREFILLED<br>SYRINGE 100 MG/0.67ML | 9027302000E510 | Brand |
| DUPIXENT | DUPILUMAB SUBCUTANEOUS SOLN PREFILLED<br>SYRINGE 200 MG/1.14ML | 9027302000E515 | Brand |
| DUPIXENT | DUPILUMAB SUBCUTANEOUS SOLN PREFILLED<br>SYRINGE 300 MG/2ML    | 9027302000E520 | Brand |

**1** - Diagnosis of moderate to severe atopic dermatitis based on body surface area (greater than 10%), extent of disability, extent of pruritus, or impact on sleep, quality of life, current use of systemic immunomodulators)

**AND** 

2 - Drug must be self-administered

### **AND**

**3** - Prescribed by, or in consultation with, a specialist experienced with the treatment of moderate to severe atopic dermatitis (e.g., Dermatologist, Pediatric Dermatologist, Allergist, Immunologist)

#### **AND**

- **4** Trial and failure, contraindication, or intolerance with at least TWO of the following:
- **4.1** Topical corticosteroid (e.g., clobetasol, betamethasone, triamcinolone)

OR

**4.2** Topical calcineurin inhibitor (e.g., pimecrolimus, tacrolimus)

OR

**4.3** Topical phosphodiesterase 4 (PDE-4) inhibitor (e.g., Crisaborole)

OR

**4.4** Topical janus kinase (JAK) inhibitor (e.g., ruxolitinib)

OR

# 4.5 Phototherapy\*

|  | *If clinic-based phototherapy- record of phototherapy episodes provide d. Adherence defined as 3 times per week for one month or if necessar y, modified regimen based on required adjustments for tolerability. If ho |
|--|--|
|  | me-based phototherapy- provision of data log recording use and dose adjustments as needed for tolerability   |

| Product Name: Dupixent      |  |  |
|-----------------------------|--|--|
| Diagnosis Atopic Dermatitis |  |  |
| Approval Length             | 12/39/2039   |  |
| Guideline Type              | Prior Authorization - All Plans except IL and MN Plans |  |

| Product<br>Name | Generic Name   | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| DUPIXENT        | DUPILUMAB SUBCUTANEOUS SOLN PEN-INJECTOR 200 MG/1.14ML         | 9027302000D215 | Brand         |
| DUPIXENT        | DUPILUMAB SUBCUTANEOUS SOLN PEN-INJECTOR 300 MG/2ML            | 9027302000D220 | Brand         |
| DUPIXENT        | DUPILUMAB SUBCUTANEOUS SOLN PREFILLED<br>SYRINGE 100 MG/0.67ML | 9027302000E510 | Brand         |
| DUPIXENT        | DUPILUMAB SUBCUTANEOUS SOLN PREFILLED<br>SYRINGE 200 MG/1.14ML | 9027302000E515 | Brand         |
| DUPIXENT        | DUPILUMAB SUBCUTANEOUS SOLN PREFILLED<br>SYRINGE 300 MG/2ML    | 9027302000E520 | Brand         |

# **Approval Criteria**

**1** - Diagnosis of moderate to severe atopic dermatitis based on body surface area (greater than 10%), extent of disability, extent of pruritus, or impact on sleep, quality of life, current use of systemic immunomodulators)

|                                 | AND  |  |  |
|---------------------------------|--|--|--|
| 2 - Drug must be self-adm       | inistered  |  |  |
|                                 | AND  |  |  |
|                                 | nsultation with, a specialist experienced with the treatment of dermatitis (e.g., Dermatologist, Pediatric Dermatologist, Allergist,       |  |  |
|                                 | AND  |  |  |
| 4 - Trial and failure, contra   | aindication, or intolerance with at least TWO of the following:  |  |  |
| 4.1 Topical corticosteroic      | d (e.g., clobetasol, betamethasone, triamcinolone)   |  |  |
|                                 | OR   |  |  |
| 4.2 Topical calcineurin in      | hibitor (e.g., pimecrolimus, tacrolimus)   |  |  |
|                                 | OR   |  |  |
| 4.3 Topical phosphodies         | terase 4 (PDE-4) inhibitor (e.g., Crisaborole)   |  |  |
|                                 | OR   |  |  |
| <b>4.4</b> Topical janus kinase | <b>4.4</b> Topical janus kinase (JAK) inhibitor (e.g., ruxolitinib)  |  |  |
|                                 | OR   |  |  |
| <b>4.5</b> Phototherapy*        |  |  |  |
|                                 | f clinic-based phototherapy- record of phototherapy episodes provide<br>Adherence defined as 3 times per week for one month or if necessar |  |  |

| y, modified regimen based on required adjustments for tolerability. If ho me-based phototherapy- provision of data log recording use and dose |
|---|
| adjustments as needed for tolerability  |

| Product Name: Dupixent |                                       |  |
|------------------------|---------------------------------------|--|
| Diagnosis              | Severe Asthma                         |  |
| Approval Length        | 12 month(s)                           |  |
| Therapy Stage          | Initial Authorization                 |  |
| Guideline Type         | Prior Authorization - IL and MN Plans |  |

| Product<br>Name | Generic Name   | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| DUPIXENT        | DUPILUMAB SUBCUTANEOUS SOLN PEN-INJECTOR 200 MG/1.14ML         | 9027302000D215 | Brand         |
| DUPIXENT        | DUPILUMAB SUBCUTANEOUS SOLN PEN-INJECTOR 300 MG/2ML            | 9027302000D220 | Brand         |
| DUPIXENT        | DUPILUMAB SUBCUTANEOUS SOLN PREFILLED<br>SYRINGE 100 MG/0.67ML | 9027302000E510 | Brand         |
| DUPIXENT        | DUPILUMAB SUBCUTANEOUS SOLN PREFILLED<br>SYRINGE 200 MG/1.14ML | 9027302000E515 | Brand         |
| DUPIXENT        | DUPILUMAB SUBCUTANEOUS SOLN PREFILLED<br>SYRINGE 300 MG/2ML    | 9027302000E520 | Brand         |

- 1 Both of the following
- **1.1** Diagnosis of eosinophilic asthma

### **AND**

- **1.2** Submission of medical records (e.g., chart notes) of one of the following:
  - Blood eosinophil count of greater than or equal to 150 cells/mm3 (other causes of eosinophilia such as hypereosinophilic syndromes, neoplastic disease, or parasitic disease must be ruled out)
  - Oral corticosteroid dependent asthma

### **AND**

2 - Drug must be self-administered

#### AND

**3** - Prescribed by, or in consultation with, an asthma specialist (e.g., Allergist, Immunologist, Pulmonologist)

### **AND**

- **4** One of the following:
- **4.1** Symptoms are not well controlled or poorly controlled despite an adherent (adherent treatment is defined as a medication possession ratio (MPR) greater than or equal to 70% based on the previous 120 days of prescription claims) greater than or equal to 3-month trial of medium to high- dose inhaled corticosteroids in combination with a long-acting bronchodilator or leukotriene modifier

#### OR

**4.2** Patient has intolerance to medium to high dose inhaled corticosteroids in combination with a long-acting bronchodilator or leukotriene modifier (see background for exceptions)

| Product Name: Dupixent  |  |  |
|-------------------------|--|--|
| Diagnosis Severe Asthma |  |  |
| Approval Length         | 12/31/2039                                       |  |
| Guideline Type          | Prior Authorization - All plans except IL and MN |  |

| Product<br>Name | Generic Name   | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| DUPIXENT        | DUPILUMAB SUBCUTANEOUS SOLN PEN-INJECTOR 200 MG/1.14ML         | 9027302000D215 | Brand         |
| DUPIXENT        | DUPILUMAB SUBCUTANEOUS SOLN PEN-INJECTOR 300 MG/2ML            | 9027302000D220 | Brand         |
| DUPIXENT        | DUPILUMAB SUBCUTANEOUS SOLN PREFILLED<br>SYRINGE 100 MG/0.67ML | 9027302000E510 | Brand         |
| DUPIXENT        | DUPILUMAB SUBCUTANEOUS SOLN PREFILLED<br>SYRINGE 200 MG/1.14ML | 9027302000E515 | Brand         |
| DUPIXENT        | DUPILUMAB SUBCUTANEOUS SOLN PREFILLED                          | 9027302000E520 | Brand         |

| OVERNOE acc 110 (c) !!   |                   |  |  |  |
|--|-------------------|--|--|--|
| SYRINGE 300 MG/2ML   |                   |  |  |  |
|  |                   |  |  |  |
| Approval Criteria  |                   |  |  |  |
| 1 - Both of the following  |                   |  |  |  |
| 1.1 Diagnosis of eosinophilic asthma   |                   |  |  |  |
| AND  |                   |  |  |  |
| 1.2 Submission of medical records (e.g., chart notes) of one   | of the following: |  |  |  |
| <ul> <li>Blood eosinophil count of greater than or equal to 150 cells/mm3 (other causes of eosinophilia such as hypereosinophilic syndromes, neoplastic disease, or parasitic disease must be ruled out)</li> <li>Oral corticosteroid dependent asthma</li> </ul>  |                   |  |  |  |
| AND  |                   |  |  |  |
| 2 - Drug must be self-administered   |                   |  |  |  |
| AND  |                   |  |  |  |
| <b>3</b> - Prescribed by, or in consultation with, an asthma specialist (e.g., Allergist, Immunologist, Pulmonologist)   |                   |  |  |  |
| AND  |                   |  |  |  |
| 4 - One of the following:  |                   |  |  |  |
| <b>4.1</b> Symptoms are not well controlled or poorly controlled despite an adherent (adherent treatment is defined as a medication possession ratio (MPR) greater than or equal to 70% based on the previous 120 days of prescription claims) greater than or equal to 3-month trial of medium to high- dose inhaled corticosteroids in combination with a long-acting bronchodilator or leukotriene modifier |                   |  |  |  |
| OR   |                   |  |  |  |

**4.2** Patient has intolerance to medium to high dose inhaled corticosteroids in combination with a long-acting bronchodilator or leukotriene modifier (see background for exceptions)

| Product Name: Dupixent |   |  |
|------------------------|---|--|
| Diagnosis              | Nasal Polyps                              |  |
| Approval Length        | 12 month(s)                               |  |
| Therapy Stage          | Initial Authorization                     |  |
| Guideline Type         | Prior Authorization - IL or MN Plans Only |  |

| Product<br>Name  | Generic Name   | GPI            | Brand/Generic |  |
|--|--|----------------|---------------|--|
| DUPIXENT   | DUPILUMAB SUBCUTANEOUS SOLN PEN-INJECTOR 200 MG/1.14ML         | 9027302000D215 | Brand         |  |
| DUPIXENT   | DUPILUMAB SUBCUTANEOUS SOLN PEN-INJECTOR 300 MG/2ML            | 9027302000D220 | Brand         |  |
| DUPIXENT DUPILUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 100 MG/0.67ML |  | 9027302000E510 | Brand         |  |
| DUPIXENT   | DUPILUMAB SUBCUTANEOUS SOLN PREFILLED<br>SYRINGE 200 MG/1.14ML | 9027302000E515 | Brand         |  |
| DUPIXENT   | DUPILUMAB SUBCUTANEOUS SOLN PREFILLED<br>SYRINGE 300 MG/2ML    | 9027302000E520 | Brand         |  |

### **Approval Criteria**

- 1 Diagnosis of chronic rhinosinusitis with nasal polyposis with ALL of the following:
  - At least eight weeks of moderate to severe nasal congestion/blockage/obstruction or diminished sense of smell or rhinorrhea
  - Documented nasal polyps by direct exam, endoscopy, or sinus CT scan (ex: nasal polyp score five out of eight)
  - No chronic or acute infection requiring systemic treatment within two weeks before therapy initiation

**AND** 

2 - Drug must be self-administered

**AND** 

**3** - Prescribed by, or in consultation with, a specialist experienced in the treatment of nasal polyps (ex: Otolaryngologist, Allergist)

#### **AND**

- **4** Trial and failure, contraindication, or intolerance to one of the following:
  - Oral corticosteroids for nasal polyps
  - Prior surgery for nasal polyps greater than six months ago
  - IM corticosteroid injections for polyps with one previous steroid nasal spray
  - To greater than 2 nasal steroid sprays (i.e., failed two nasal sprays)

#### **AND**

**5** - Requested drug will be used in combination with a nasal corticosteroid medication

### **AND**

**6** - Requested drug will not be used in combination with other biologics (e.g., benralizumab, mepolizumab, omalizumab, etc.)

| Product Name: Dupixent |  |  |
|------------------------|--|--|
| Diagnosis              | Nasal Polyps                                     |  |
| Approval Length        | 12/31/2039                                       |  |
| Guideline Type         | Prior Authorization - All plans except IL and MN |  |

| Product<br>Name   | Generic Name   | GPI            | Brand/Generic |
|---|--|----------------|---------------|
| DUPIXENT  | DUPILUMAB SUBCUTANEOUS SOLN PEN-INJECTOR<br>200 MG/1.14ML      | 9027302000D215 | Brand         |
| DUPIXENT  | DUPILUMAB SUBCUTANEOUS SOLN PEN-INJECTOR 300 MG/2ML            | 9027302000D220 | Brand         |
| DUPIXENT  | DUPILUMAB SUBCUTANEOUS SOLN PREFILLED<br>SYRINGE 100 MG/0.67ML | 9027302000E510 | Brand         |
| DUPIXENT  | DUPILUMAB SUBCUTANEOUS SOLN PREFILLED<br>SYRINGE 200 MG/1.14ML | 9027302000E515 | Brand         |
| DUPIXENT DUPILUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 300 MG/2ML |  | 9027302000E520 | Brand         |

- **1** Diagnosis of chronic rhinosinusitis with nasal polyposis with ALL of the following:
  - At least eight weeks of moderate to severe nasal congestion/blockage/obstruction or diminished sense of smell or rhinorrhea
  - Documented nasal polyps by direct exam, endoscopy, or sinus CT scan (ex: nasal polyp score five out of eight)
  - No chronic or acute infection requiring systemic treatment within two weeks before therapy initiation

#### **AND**

2 - Drug must be self-administered

#### AND

**3** - Prescribed by, or in consultation with, a specialist experienced in the treatment of nasal polyps (ex: Otolaryngologist, Allergist)

#### **AND**

- **4** Trial and failure, contraindication, or intolerance to one of the following:
  - Oral corticosteroids for nasal polyps
  - Prior surgery for nasal polyps greater than six months ago
  - IM corticosteroid injections for polyps with one previous steroid nasal spray
  - To greater than 2 nasal steroid sprays (i.e., failed two nasal sprays)

#### AND

**5** - Requested drug will be used in combination with a nasal corticosteroid medication

#### AND

6 - Requested drug will not be used in combination with other biologics (e.g., benralizumab,

mepolizumab, omalizumab, etc.)

| Product Name: Dupixent |                                       |  |
|------------------------|---------------------------------------|--|
| Diagnosis              | Eosinophilic Esophagitis              |  |
| Approval Length        | 12 month(s)                           |  |
| Therapy Stage          | Initial Authorization                 |  |
| Guideline Type         | Prior Authorization - IL and MN Plans |  |

| Product Generic Name   |   | GPI            | Brand/Generic |
|--|---|----------------|---------------|
| DUPIXENT   | DUPILUMAB SUBCUTANEOUS SOLN PEN-INJECTOR 200 MG/1.14ML      | 9027302000D215 | Brand         |
| DUPIXENT   | DUPILUMAB SUBCUTANEOUS SOLN PEN-INJECTOR 300 MG/2ML         | 9027302000D220 | Brand         |
| DUPIXENT DUPILUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 100 MG/0.67ML  DUPIXENT DUPILUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 200 MG/1.14ML |   | 9027302000E510 | Brand         |
|  |   | 9027302000E515 | Brand         |
| DUPIXENT   | DUPILUMAB SUBCUTANEOUS SOLN PREFILLED<br>SYRINGE 300 MG/2ML | 9027302000E520 | Brand         |

# **Approval Criteria**

1 - Diagnosis of eosinophilic esophagitis confirmed by biopsy

**AND** 

2 - Drug must be self-administered

**AND** 

**3** - Prescribed by, or in consultation with, a specialist experienced in the treatment of eosinophilic esophagitis (ex: Allergist, Gastroenterologist, Immunologist)

**AND** 

4 - Member is 12 years of age or older

#### **AND**

**5** - Trial and failure, intolerance, or contraindication to dietary therapy (e.g. elemental or amino acid-based formulary diet or empiric elimination diet that removes common triggers such as milk, wheat, soy, eggs, nuts, and seafood)

### **AND**

**6** - Trial and failure, intolerance, or contraindication to proton pump inhibitors (e.g., omeprazole, pantoprazole, lansoprazole)

#### AND

**7** - Requested drug will not be used in combination with other biologics (e.g., benralizumab, mepolizumab, omalizumab, etc.)

| Product Name: Dupixent |  |  |
|------------------------|--|--|
| Diagnosis              | Eosinophilic Esophagitis                         |  |
| Approval Length        | 12/31/2039                                       |  |
| Guideline Type         | Prior Authorization - All plans except IL and MN |  |

| Product<br>Name |  |                | Brand/Generic |  |
|-----------------|--|----------------|---------------|--|
| DUPIXENT        | DUPILUMAB SUBCUTANEOUS SOLN PEN-INJECTOR<br>200 MG/1.14ML      | 9027302000D215 | Brand         |  |
| DUPIXENT        | DUPILUMAB SUBCUTANEOUS SOLN PEN-INJECTOR 300 MG/2ML            | 9027302000D220 | Brand         |  |
| DUPIXENT        | DUPILUMAB SUBCUTANEOUS SOLN PREFILLED<br>SYRINGE 100 MG/0.67ML | 9027302000E510 | Brand         |  |
| DUPIXENT        | DUPILUMAB SUBCUTANEOUS SOLN PREFILLED<br>SYRINGE 200 MG/1.14ML | 9027302000E515 | Brand         |  |
| DUPIXENT        | DUPILUMAB SUBCUTANEOUS SOLN PREFILLED<br>SYRINGE 300 MG/2ML    | 9027302000E520 | Brand         |  |

# **Approval Criteria**

| 1 - Diagnosis of eosinophilic esophagitis confirmed by biopsy  |
|--|
| AND  |
| 2 - Drug must be self-administered   |
| AND  |
| <b>3</b> - Prescribed by, or in consultation with, a specialist experienced in the treatment of eosinophilic esophagitis (ex: Allergist, Gastroenterologist, Immunologist)   |
| AND  |
| 4 - Member is 12 years of age or older   |
| AND  |
| <b>5</b> - Trial and failure, intolerance, or contraindication to dietary therapy (e.g. elemental or amino acid-based formulary diet or empiric elimination diet that removes common triggers such as milk, wheat, soy, eggs, nuts, and seafood) |
| AND  |
| <b>6</b> - Trial and failure, intolerance, or contraindication to proton pump inhibitors (e.g., omeprazol pantoprazole, lansoprazole)  |
| AND  |
| 7 - Requested drug will not be used in combination with other biologics (e.g., benralizumab, mepolizumab, omalizumab, etc.)  |
|  |
| Product Name: Dupixent   |
| Diagnosis Prurigo nodularis (PN)   |

12 month(s)

Approval Length

| Therapy Stage  | Initial Authorization                 |
|----------------|---------------------------------------|
| Guideline Type | Prior Authorization - IL and MN Plans |

| Product<br>Name |  |                | Brand/Generic |  |
|-----------------|--|----------------|---------------|--|
| DUPIXENT        | DUPILUMAB SUBCUTANEOUS SOLN PEN-INJECTOR<br>200 MG/1.14ML      | 9027302000D215 | Brand         |  |
| DUPIXENT        | DUPILUMAB SUBCUTANEOUS SOLN PEN-INJECTOR 300 MG/2ML            | 9027302000D220 | Brand         |  |
| DUPIXENT        | DUPILUMAB SUBCUTANEOUS SOLN PREFILLED<br>SYRINGE 100 MG/0.67ML | 9027302000E510 | Brand         |  |
| DUPIXENT        | DUPILUMAB SUBCUTANEOUS SOLN PREFILLED<br>SYRINGE 200 MG/1.14ML | 9027302000E515 | Brand         |  |
| DUPIXENT        | DUPILUMAB SUBCUTANEOUS SOLN PREFILLED<br>SYRINGE 300 MG/2ML    | 9027302000E520 | Brand         |  |

| 1 | - Diagnosis of | f chronic | prurigo | nodularis ( | (PN | ) with | all of | the | following | 1: |
|---|----------------|-----------|---------|-------------|-----|--------|--------|-----|-----------|----|
|   |                |           |         |             |     |        |        |     |           |    |

- At least 3 months of symptoms
- At least 20 PN lesions in total
- Severe or very severe itch (WI-NRS score ≥ 7)

**AND** 

2 - Drug must be self-administered

**AND** 

**3** - Prescribed by, or in consultation with, a Dermatologist

**AND** 

4 - Member is 18 years of age or older

**AND** 

- 5 Trial and failure of an optimized regimen of one of the following:
  - Phototherapy\*
  - Moderate to high potency topical corticosteroids, intralesional corticosteroids, systemic corticosteroids
  - Systemic immunosuppressive agents (e.g., cyclosporine, methotrexate, azathioprine)
  - Immunomodulator agents (e.g., thalidomide, lenalidomide)
  - Anticonvulsants (e.g., pregabalin, gabapentin)

| Notes | *If clinic-based phototherapy- record of phototherapy episodes provide d. Adherence defined as 3 times per week for one month or if necessar y, modified regimen based on required adjustments for tolerability. If ho me-based phototherapy- provision of data log recording use and dose adjustments as need for tolerability |
|-------|---|
|       |   |

| Product Name: Dupixent  |                        |  |
|---|------------------------|--|
| Diagnosis   | Prurigo nodularis (PN) |  |
| Approval Length   | 12/31/2039             |  |
| Guideline Type Prior Authorization - All plans except IL and MN |                        |  |

| Product<br>Name | Generic Name   | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| DUPIXENT        | DUPILUMAB SUBCUTANEOUS SOLN PEN-INJECTOR 200 MG/1.14ML         | 9027302000D215 | Brand         |
| DUPIXENT        | DUPILUMAB SUBCUTANEOUS SOLN PEN-INJECTOR 300 MG/2ML            | 9027302000D220 | Brand         |
| DUPIXENT        | DUPILUMAB SUBCUTANEOUS SOLN PREFILLED<br>SYRINGE 100 MG/0.67ML | 9027302000E510 | Brand         |
| DUPIXENT        | DUPILUMAB SUBCUTANEOUS SOLN PREFILLED<br>SYRINGE 200 MG/1.14ML | 9027302000E515 | Brand         |
| DUPIXENT        | DUPILUMAB SUBCUTANEOUS SOLN PREFILLED<br>SYRINGE 300 MG/2ML    | 9027302000E520 | Brand         |

- 1 Diagnosis of chronic prurigo nodularis (PN) with all of the following:
  - At least 3 months of symptoms
  - At least 20 PN lesions in total
  - Severe or very severe itch (WI-NRS score ≥ 7)

# AND

2 - Drug must be self-administered

### **AND**

**3** - Prescribed by, or in consultation with, a Dermatologist

### AND

4 - Member is 18 years of age or older

### AND

- **5** Trial and failure of an optimized regimen of one of the following:
  - Phototherapy\*
  - Moderate to high potency topical corticosteroids, intralesional corticosteroids, systemic corticosteroids
  - Systemic immunosuppressive agents (e.g., cyclosporine, methotrexate, azathioprine)
  - Immunomodulator agents (e.g., thalidomide, lenalidomide)
  - Anticonvulsants (e.g., pregabalin, gabapentin)

| Product Name: Dupixent                               |  |  |  |
|--|--|--|--|
| Diagnosis All indications                            |  |  |  |
| Approval Length 12 month(s)                          |  |  |  |
| Therapy Stage Reauthorization                        |  |  |  |
| Guideline Type Prior Authorization - IL and MN Plans |  |  |  |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| DUPIXENT        | DUPILUMAB SUBCUTANEOUS SOLN PEN-INJECTOR 200 MG/1.14ML      | 9027302000D215 | Brand         |
| DUPIXENT        | DUPILUMAB SUBCUTANEOUS SOLN PEN-INJECTOR 300 MG/2ML         | 9027302000D220 | Brand         |
| DUPIXENT        | DUPILUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 100 MG/0.67ML | 9027302000E510 | Brand         |

| DUPIXENT | DUPILUMAB SUBCUTANEOUS SOLN PREFILLED<br>SYRINGE 200 MG/1.14ML | 9027302000E515 | Brand |
|----------|--|----------------|-------|
| DUPIXENT | DUPILUMAB SUBCUTANEOUS SOLN PREFILLED<br>SYRINGE 300 MG/2ML    | 9027302000E520 | Brand |

- **1** Prescriber submits medical records (e.g., chart notes) of documentation from the previous 12 months of a response to therapy for the treated diagnosis such as one of the following:
  - Decreased frequency of use of, or ability to lower the chronic daily dose, of oral corticosteroids to treat/prevent exacerbations
  - Decreased frequency of use of unscheduled emergency department/urgent care visits for exacerbations
  - Reduction in reported symptoms such as chest tightness, coughing, shortness of breath, or nocturnal awakenings, itching, nasal congestion, etc.
  - Sustained (at least six months) improvement in Asthma Control Test (ACT) scores
  - Improvement in body surface area affected
  - Improvement in nasal polyposis score
  - Reduction in dysphagic episodes

AND

2 - Drug must be self-administered

# 2. Background

# **Benefit/Coverage/Program Information**

### **Severe Asthma**

Exceptions to high dose inhaled corticosteroids in combination with a long-acting bronchodilator or leukotriene modifier. Exceptions based on adverse effects from high dose ICS or comorbid conditions increasing long-term risks of adverse effects from high dose ICS or oral corticosteroids include:

- Cataracts in patients > 40 years of age
- Glaucoma
- Recurrent Thrush
- Dysphonia
- Growth inhibition, after evaluation by Endocrine Consult

• Diagnosis of osteoporosis, treatment resistant to FDA approved osteoporosis treatment

# 3. Revision History

| Date      | Notes       |
|-----------|-------------|
| 12/4/2023 | New Program |

| Empaveli (Pegcetacoplan)   |  |  |  |  |
|--|--|--|--|--|
| The best of the process of the proce |  |  |  |  |

# **Prior Authorization Guideline**

| Guideline ID   | GL-129123                |  |
|----------------|--------------------------|--|
| Guideline Name | Empaveli (Pegcetacoplan) |  |
| Formulary      | Quartz                   |  |

# **Guideline Note:**

| Effective Date: |
|-----------------|
|-----------------|

# 1. Criteria

| Product Name: Empaveli             |                       |  |
|------------------------------------|-----------------------|--|
| Approval Length 12 month(s)        |                       |  |
| Therapy Stage                      | Initial Authorization |  |
| Guideline Type Prior Authorization |                       |  |

| Product<br>Name | Generic Name   | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| EMPAVELI        | PEGCETACOPLAN SUBCUTANEOUS SOLN 1080<br>MG/20ML (54 MG/ML) | 85804065002020 | Brand         |

# **Approval Criteria**

1 - Confirmed diagnosis of PNH by flow cytometry

# AND 2 - Prescribed by, or in consultation with, a Hematologist or Oncologist. **AND** 3 - Low hemoglobin (≤ 9 mg/dL with symptoms of anemia), elevated lactate dehydrogenase level (LDH ≥ 1.5 X ULN) and/or number of transfusions in last year **AND** 4 - Documentation of the clinical manifestations of disease (e.g., major vascular event, transfusion dependence, renal insufficiency, disabling fatigue and/or other end organ manifestations). AND 5 - Documentation of receipt of Advisory Committee on Immunization Practices (ACIP) recommended vaccinations at least two weeks prior to therapy initiation as outlined in drug REMS program. AND 6 - Age greater than or equal to 18 AND 7 - Drug is not being used in combination with another complement inhibitor\* **Notes** \*Combination of pegcetacoplan with another agent may be considered for circumstances where all three individual

or ravulizumab) or there are signs of ongoing

hemolysis (pegcetacoplan).

complement inhibitors failed to adequately control anemia (eculizumab

| Product Name: Empaveli      |                     |  |
|-----------------------------|---------------------|--|
| Approval Length 12 month(s) |                     |  |
| Therapy Stage               | Reauthorization     |  |
| Guideline Type              | Prior Authorization |  |

| Product<br>Name | Generic Name   | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| EMPAVELI        | PEGCETACOPLAN SUBCUTANEOUS SOLN 1080<br>MG/20ML (54 MG/ML) | 85804065002020 | Brand         |

1 - Confirmed diagnosis of PNH by flow cytometry

### **AND**

2 - Prescribed by, or in consultation with, a Hematologist or Oncologist.

### **AND**

**3** - Low hemoglobin ( $\leq$  9 mg/dL with symptoms of anemia), elevated lactate dehydrogenase level (LDH  $\geq$  1.5 X ULN) and/or number of transfusions in last year.

### AND

**4** - Documentation of the clinical manifestations of disease (e.g., major vascular event, transfusion dependence, renal insufficiency, disabling fatigue and/or other end organ manifestations).

#### **AND**

**5** - Documentation of receipt of Advisory Committee on Immunization Practices (ACIP) recommended vaccinations at least two weeks prior to therapy initiation as outlined in drug REMS program.

|  | AND   |  |
|--|---|--|
|  |   |  |
| 6 - Age greater than or  | equal to 18   |  |
|  |   |  |
|  | AND   |  |
|  |   |  |
| 7 - Drug is not being us   | ed in combination with another complement inhibitor*                  |  |
|  |   |  |
|  | AND   |  |
|  |   |  |
| <b>8</b> - Clinical documentation from the past 12 months of improvement or clinical stability, (e.g., |   |  |
| improvement in hemogl  | obin, lactate dehydrogenase level, haptoglobin level and/or number of |  |
| transfusions in the last   | year).  |  |
| Notes  | *Combination of pegcetacoplan with another agent may be considered    |  |

for circumstances where all three individual

or ravulizumab) or there are signs of ongoing

hemolysis (pegcetacoplan).

complement inhibitors failed to adequately control anemia (eculizumab

| Product Name: Empaveli        |              |                             |                |               |
|-------------------------------|--------------|-----------------------------|----------------|---------------|
| Approval Lo                   | ength        | n 2 doses/week              |                |               |
| Guideline Type Quantity Limit |              |                             |                |               |
| Product<br>Name               | Generic Name |                             | GPI            | Brand/Generic |
| EMPAVELI                      | PEGCETACO    | PLAN SUBCUTANEOUS SOLN 1080 | 85804065002020 | Brand         |

# **Approval Criteria**

**1** - Documentation of continued hemolysis (LDH levels  $\geq$  2X ULM) despite an adequate 2-month trial of twice weekly dosing and the prescriber provided an evidence-based rationale for using the requested dose.

# 2. Revision History

| Date      | Notes       |
|-----------|-------------|
| 9/11/2023 | New Program |

| Enbrel (etanercept)  |  |
|--|--|
| (S) have required included. This has proper executed a data with definite present an executive residual. |  |

# **Prior Authorization Guideline**

| Guideline ID          | GL-134998           |
|-----------------------|---------------------|
| <b>Guideline Name</b> | Enbrel (etanercept) |
| Formulary             | Quartz              |

# **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

# Note:

Member new to the plan (as evidenced by coverage effective date of less than or equal to 90 days) who initiated therapy using a manufacturer-sponsored free drug program, provider samples, and/or vouchers will go through initial criteria, otherwise for continuation of therapy for new to plan, reauthorization criteria applies.

# 1. Criteria

| Product Name: Enbrel  |   |                 |                |               |
|---|---|-----------------|----------------|---------------|
| Diagnosis   | agnosis Plaque Psoriasis                                    |                 |                |               |
| Approval Le   | ength   | ngth 12/31/2039 |                |               |
| Guideline Type Prior Authorization – All Plans except IL and MN Plans |   |                 |                |               |
| Product<br>Name   | Generic Name  |                 | GPI            | Brand/Generic |
| ENBREL<br>SURECLICK   | ETANERCEPT SUBCUTANEOUS SOLUTION AUTO-<br>INJECTOR 50 MG/ML |                 | 6629003000D530 | Brand         |

| ENBREL<br>MINI | ETANERCEPT SUBCUTANEOUS SOLUTION<br>CARTRIDGE 50 MG/ML     | 6629003000E230 | Brand |
|----------------|--|----------------|-------|
| ENBREL         | ETANERCEPT SUBCUTANEOUS SOLN PREFILLED SYRINGE 25 MG/0.5ML | 6629003000E525 | Brand |
| ENBREL         | ETANERCEPT SUBCUTANEOUS SOLN PREFILLED SYRINGE 50 MG/ML    | 6629003000E530 | Brand |
| ENBREL         | ETANERCEPT SUBCUTANEOUS INJ 25 MG/0.5ML                    | 66290030002015 | Brand |

1 - Diagnosis of moderate to severe plaque psoriasis

#### AND

- 2 One of the following:
  - Significant functional disability
  - Body surface area (BSA) involvement of greater than or equal to 3%
  - Debilitating palmer/plantar psoriasis or other vulnerable areas that are difficult to treat (e.g. nails, scalp, genitals, or intertriginous areas)

#### **AND**

3 - Prescribed by or in consultation with a dermatologist

#### AND

**4** - Trial and failure, contraindication, or intolerance to topical treatment (e.g. topical corticosteroids, calcipotriene, retinoids)

### **AND**

**5** - Not used in combination with other biologic disease modifying anti-rheumatic drugs (DMARDs) (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

### **AND**

### 6 - Medication will be self-administered

| Product Name: Enbrel |                                       |  |
|----------------------|---------------------------------------|--|
| Diagnosis            | Plaque Psoriasis                      |  |
| Approval Length      | 12 month(s)                           |  |
| Therapy Stage        | Initial Authorization                 |  |
| Guideline Type       | Prior Authorization – IL and MN Plans |  |

| Product<br>Name     | Generic Name   | GPI            | Brand/Generic |
|---------------------|--|----------------|---------------|
| ENBREL<br>SURECLICK | ETANERCEPT SUBCUTANEOUS SOLUTION AUTO-INJECTOR 50 MG/ML    | 6629003000D530 | Brand         |
| ENBREL<br>MINI      | ETANERCEPT SUBCUTANEOUS SOLUTION CARTRIDGE 50 MG/ML        | 6629003000E230 | Brand         |
| ENBREL              | ETANERCEPT SUBCUTANEOUS SOLN PREFILLED SYRINGE 25 MG/0.5ML | 6629003000E525 | Brand         |
| ENBREL              | ETANERCEPT SUBCUTANEOUS SOLN PREFILLED SYRINGE 50 MG/ML    | 6629003000E530 | Brand         |
| ENBREL              | ETANERCEPT SUBCUTANEOUS INJ 25 MG/0.5ML                    | 66290030002015 | Brand         |

# **Approval Criteria**

1 - Diagnosis of moderate to severe plaque psoriasis

### **AND**

- 2 One of the following:
  - Significant functional disability
  - Body surface area (BSA) involvement of greater than or equal to 3%
  - Debilitating palmer/plantar psoriasis or other vulnerable areas that are difficult to treat (e.g. nails, scalp, genitals, or intertriginous areas)

### **AND**

3 - Prescribed by or in consultation with a dermatologist

### AND

**4** - Trial and failure, contraindication, or intolerance to topical treatment (e.g. topical corticosteroids, calcipotriene, retinoids)

### **AND**

**5** - Not used in combination with other biologic disease modifying anti-rheumatic drugs (DMARDs) (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

### **AND**

6 - Medication will be self-administered

| Product Name: Enbrel |  |
|----------------------|--|
| Diagnosis            | Psoriatic Arthritis (PsA)                              |
| Approval Length      | 12/31/2039   |
| Guideline Type       | Prior Authorization – All Plans except IL and MN Plans |

| Product<br>Name     | Generic Name  | GPI            | Brand/Generic |
|---------------------|---|----------------|---------------|
| ENBREL<br>SURECLICK | ETANERCEPT SUBCUTANEOUS SOLUTION AUTO-INJECTOR 50 MG/ML       | 6629003000D530 | Brand         |
| ENBREL<br>MINI      | ETANERCEPT SUBCUTANEOUS SOLUTION<br>CARTRIDGE 50 MG/ML        | 6629003000E230 | Brand         |
| ENBREL              | ETANERCEPT SUBCUTANEOUS SOLN PREFILLED<br>SYRINGE 25 MG/0.5ML | 6629003000E525 | Brand         |
| ENBREL              | ETANERCEPT SUBCUTANEOUS SOLN PREFILLED SYRINGE 50 MG/ML       | 6629003000E530 | Brand         |
| ENBREL              | ETANERCEPT SUBCUTANEOUS INJ 25 MG/0.5ML                       | 66290030002015 | Brand         |

# **Approval Criteria**

1 - Diagnosis of moderate to severely active psoriatic arthritis (PsA)

### AND

2 - Prescribed by or in consultation with a dermatologist or rheumatologist

### **AND**

- ${f 3}$  Submission of medical records (e.g., chart notes) documenting at least ONE of the following:
  - · actively inflamed joints
  - axial disease
  - active skin, nail, or scalp psoriasis involvement
  - dactylitis
  - enthesitis

### **AND**

**4** - Not used in combination with other biologic DMARDs (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

### **AND**

5 - Medication will be self-administered

| Product Name: Enbrel |                                       |
|----------------------|---------------------------------------|
| Diagnosis            | Psoriatic Arthritis (PsA)             |
| Approval Length      | 12 month(s)                           |
| Therapy Stage        | Initial Authorization                 |
| Guideline Type       | Prior Authorization – IL and MN Plans |

| Product<br>Name     | Generic Name  | GPI            | Brand/Generic |
|---------------------|---|----------------|---------------|
| ENBREL<br>SURECLICK | ETANERCEPT SUBCUTANEOUS SOLUTION AUTO-INJECTOR 50 MG/ML       | 6629003000D530 | Brand         |
| ENBREL<br>MINI      | ETANERCEPT SUBCUTANEOUS SOLUTION<br>CARTRIDGE 50 MG/ML        | 6629003000E230 | Brand         |
| ENBREL              | ETANERCEPT SUBCUTANEOUS SOLN PREFILLED<br>SYRINGE 25 MG/0.5ML | 6629003000E525 | Brand         |

| ENBREL | ETANERCEPT SUBCUTANEOUS SOLN PREFILLED<br>SYRINGE 50 MG/ML | 6629003000E530 | Brand |
|--------|--|----------------|-------|
| ENBREL | ETANERCEPT SUBCUTANEOUS INJ 25 MG/0.5ML                    | 66290030002015 | Brand |

1 - Diagnosis of moderate to severely active psoriatic arthritis (PsA)

### **AND**

2 - Prescribed by or in consultation with a dermatologist or rheumatologist

### **AND**

- **3** Submission of medical records (e.g., chart notes) documenting at least ONE of the following:
  - actively inflamed joints
  - axial disease
  - active skin, nail, or scalp psoriasis involvement
  - dactylitis
  - enthesitis

### **AND**

**4** - Not used in combination with other biologic DMARDs (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

#### **AND**

5 - Medication will be self-administered

| Product Name: Enbrel |  |
|----------------------|--|
| _                    | Juvenile Idiopathic Arthritis (JIA), Moderate to Severely Active Rheumatoid Arthritis (RA) |
| Approval Length      | 12/31/2039   |

| Guideline I         | Guideline Type Prior Authorization – All Plans except IL and MIN Plans |  |      |                |       |
|---------------------|--|--|------|----------------|-------|
| Product<br>Name     | Generic Name   |  | GPI  | Brand/Generic  |       |
| ENBREL<br>SURECLICK | ETANERCEP<br>INJECTOR 5  | T SUBCUTANEOUS SOLUTION AU<br>0 MG/ML  | ITO- | 6629003000D530 | Brand |
| ENBREL<br>MINI      | ETANERCEP<br>CARTRIDGE   | T SUBCUTANEOUS SOLUTION<br>50 MG/ML    |      | 6629003000E230 | Brand |
| ENBREL              | ETANERCEP<br>SYRINGE 25  | T SUBCUTANEOUS SOLN PREFIL<br>MG/0.5ML | LED  | 6629003000E525 | Brand |
| ENBREL              | ETANERCEP<br>SYRINGE 50  | T SUBCUTANEOUS SOLN PREFIL<br>MG/ML    | LED  | 6629003000E530 | Brand |
| ENBREL              | ETANERCEP  | T SUBCUTANEOUS INJ 25 MG/0.5           | ML   | 66290030002015 | Brand |

- **1** Diagnosis of one of the following:
  - Moderate to severely active rheumatoid arthritis (RA)
  - Juvenile idiopathic arthritis (JIA)

#### **AND**

- **2** Submission of medical records (e.g., chart notes) documenting a 3-month trial and failure, intolerance, or contraindication to ONE of the following:
  - methotrexate (MTX)\*
  - leflunomide
  - hydroxychloroquine
  - sulfasalazine

#### **AND**

3 - Medication will be self-administered (not in clinic or provider office)

#### **AND**

4 - Prescribed by or in consultation with a rheumatologist

|   | AND   |
|---|---|
| 5 - Not used in combina apremilast and TNF an | ation with other biologic DMARDs (i.e., TNF antagonist and IL-12/23, tagonist, etc.)  |
| Notes   | * Absolute contraindications to methotrexate are pregnancy, nursing, al coholism, alcoholic liver disease or other chronic liver disease, immuno deficiency syndromes, bone marrow hyperplasia, leukopenia, thromboc ytopenia or significant anemia, or hypersensitivity to methotrexate. |

| Product Name: Enbrel |  |  |
|----------------------|--|--|
| Diagnosis            | Juvenile Idiopathic Arthritis (JIA), Moderate to Severely Active Rheumatoid Arthritis (RA) |  |
| Approval Length      | 12 month(s)  |  |
| Therapy Stage        | Initial Authorization  |  |
| Guideline Type       | Prior Authorization – IL and MN Plans  |  |

| Product<br>Name     | Generic Name  | GPI            | Brand/Generic |
|---------------------|---|----------------|---------------|
| ENBREL<br>SURECLICK | ETANERCEPT SUBCUTANEOUS SOLUTION AUTO-INJECTOR 50 MG/ML       | 6629003000D530 | Brand         |
| ENBREL<br>MINI      | ETANERCEPT SUBCUTANEOUS SOLUTION<br>CARTRIDGE 50 MG/ML        | 6629003000E230 | Brand         |
| ENBREL              | ETANERCEPT SUBCUTANEOUS SOLN PREFILLED<br>SYRINGE 25 MG/0.5ML | 6629003000E525 | Brand         |
| ENBREL              | ETANERCEPT SUBCUTANEOUS SOLN PREFILLED<br>SYRINGE 50 MG/ML    | 6629003000E530 | Brand         |
| ENBREL              | ETANERCEPT SUBCUTANEOUS INJ 25 MG/0.5ML                       | 66290030002015 | Brand         |

- 1 Diagnosis of one of the following:
  - Moderate to severely active rheumatoid arthritis (RA) Juvenile idiopathic arthritis (JIA)

#### **AND**

**2** - Submission of medical records (e.g., chart notes) documenting a 3-month trial and failure, intolerance, or contraindication to ONE of the following:

- methotrexate (MTX)\*
- leflunomide
- hydroxychloroquine
- sulfasalazine

#### **AND**

3 - Medication will be self-administered (not in clinic or provider office)

#### **AND**

**4** - Prescribed by or in consultation with a rheumatologist

## **AND**

**5** - Not used in combination with other biologic DMARDs (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

| N | otes | * Absolute contraindications to methotrexate are pregnancy, nursing, al  |
|---|------|--|
|   |      | coholism, alcoholic liver disease or other chronic liver disease, immuno |
|   |      | deficiency syndromes, bone marrow hyperplasia, leukopenia, thromboc      |
|   |      | ytopenia or significant anemia, or hypersensitivity to methotrexate.     |

| Product Name: Enbrel                  |  |  |
|---------------------------------------|--|--|
| Diagnosis Ankylosing Spondylitis (AS) |  |  |
| Approval Length                       | 12/31/2039   |  |
| Guideline Type                        | Prior Authorization – All Plans except IL and MN Plans |  |

| Product<br>Name     | Generic Name  | GPI            | Brand/Generic |
|---------------------|---|----------------|---------------|
| ENBREL<br>SURECLICK | ETANERCEPT SUBCUTANEOUS SOLUTION AUTO-INJECTOR 50 MG/ML       | 6629003000D530 | Brand         |
| ENBREL<br>MINI      | ETANERCEPT SUBCUTANEOUS SOLUTION<br>CARTRIDGE 50 MG/ML        | 6629003000E230 | Brand         |
| ENBREL              | ETANERCEPT SUBCUTANEOUS SOLN PREFILLED<br>SYRINGE 25 MG/0.5ML | 6629003000E525 | Brand         |
| ENBREL              | ETANERCEPT SUBCUTANEOUS SOLN PREFILLED<br>SYRINGE 50 MG/ML    | 6629003000E530 | Brand         |

| ENBREL | ETANERCEPT SUBCUTANEOUS INJ 25 MG/0.5ML | 66290030002015 | Brand |
|--------|---|----------------|-------|
|--------|---|----------------|-------|

1 - Diagnosis of ankylosing spondylitis (AS)

#### **AND**

2 - Prescribed by or in consultation with a rheumatologist

#### **AND**

**3** - Minimum duration of a 1-month trial and failure, contraindication, or intolerance of scheduled prescription doses of TWO different NSAIDs (e.g., naproxen, nabumetone, diclofenac)

#### **AND**

**4** - Not used in combination with other biologic DMARDs (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

#### **AND**

5 - Medication will be self-administered

| Product Name: Enbrel                  |                                      |     |               |
|---------------------------------------|--------------------------------------|-----|---------------|
| Diagnosis Ankylosing Spondylitis (AS) |                                      |     |               |
| Approval Length 12 month(s)           |                                      |     |               |
| Therapy Stage                         | Initial Authorization                |     |               |
| Guideline Type                        | Prior Authorization – IL and MN Plar | ıs  |               |
| Product Congric Name CPI              |                                      | CDI | Brand/Conorio |

| Product<br>Name     | Generic Name  | GPI            | Brand/Generic |
|---------------------|---|----------------|---------------|
| ENBREL<br>SURECLICK | ETANERCEPT SUBCUTANEOUS SOLUTION AUTO-INJECTOR 50 MG/ML | 6629003000D530 | Brand         |

| ENBREL<br>MINI | ETANERCEPT SUBCUTANEOUS SOLUTION CARTRIDGE 50 MG/ML           | 6629003000E230 | Brand |
|----------------|---|----------------|-------|
| ENBREL         | ETANERCEPT SUBCUTANEOUS SOLN PREFILLED<br>SYRINGE 25 MG/0.5ML | 6629003000E525 | Brand |
| ENBREL         | ETANERCEPT SUBCUTANEOUS SOLN PREFILLED<br>SYRINGE 50 MG/ML    | 6629003000E530 | Brand |
| ENBREL         | ETANERCEPT SUBCUTANEOUS INJ 25 MG/0.5ML                       | 66290030002015 | Brand |

1 - Diagnosis of ankylosing spondylitis (AS)

## **AND**

2 - Prescribed by or in consultation with a rheumatologist

#### **AND**

**3** - Minimum duration of a 1-month trial and failure, contraindication, or intolerance of scheduled prescription doses of TWO different NSAIDs (e.g., naproxen, nabumetone, diclofenac)

#### **AND**

**4** - Not used in combination with other biologic DMARDs (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

#### **AND**

5 - Medication will be self-administered

| Product Name: Enbrel |                                       |  |
|----------------------|---------------------------------------|--|
| Diagnosis            | All Indications                       |  |
| Approval Length      | 12 month(s)                           |  |
| Therapy Stage        | Reauthorization                       |  |
| Guideline Type       | Prior Authorization – IL and MN Plans |  |

| Product<br>Name     | Generic Name  | GPI            | Brand/Generic |
|---------------------|---|----------------|---------------|
| ENBREL<br>SURECLICK | ETANERCEPT SUBCUTANEOUS SOLUTION AUTO-INJECTOR 50 MG/ML       | 6629003000D530 | Brand         |
| ENBREL<br>MINI      | ETANERCEPT SUBCUTANEOUS SOLUTION<br>CARTRIDGE 50 MG/ML        | 6629003000E230 | Brand         |
| ENBREL              | ETANERCEPT SUBCUTANEOUS SOLN PREFILLED<br>SYRINGE 25 MG/0.5ML | 6629003000E525 | Brand         |
| ENBREL              | ETANERCEPT SUBCUTANEOUS SOLN PREFILLED<br>SYRINGE 50 MG/ML    | 6629003000E530 | Brand         |
| ENBREL              | ETANERCEPT SUBCUTANEOUS INJ 25 MG/0.5ML                       | 66290030002015 | Brand         |

**1** - Prescriber provides clinical documentation from the previous 12 months of the member's response to therapy including individual improvements in functional status related to therapeutic response

| Date      | Notes                   |
|-----------|-------------------------|
| 12/4/2023 | 2024 New Implementation |

| Ensp                              | Enspryng (Satralizumab)                          |   |  |  |  |
|-----------------------------------|--|---|--|--|--|
| The bits of lange connect literal | diphysi. Trofir may han han mossi, marani, ar di | dani. Veriy mad be lek polaku bir avverelle ani kuale |  |  |  |

| Guideline ID   | GL-131918               |
|----------------|-------------------------|
| Guideline Name | Enspryng (Satralizumab) |
| Formulary      | Quartz                  |

# **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

# 1. Criteria

| Product Name: (Enspryng            |                       |  |
|------------------------------------|-----------------------|--|
| Approval Length                    | 12 month(s)           |  |
| Therapy Stage                      | Initial Authorization |  |
| Guideline Type Prior Authorization |                       |  |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| ENSPRYNG        | SATRALIZUMAB-MWGE SUBCUTANEOUS SOLN PREF<br>SYRINGE 120 MG/ML | 9940507040E520 | Brand         |

## **Approval Criteria**

**1** - Diagnosis of neuromyelitis optica spectrum disorder (NMOSD) confirmed by positive serologic test for antiaquaporin-4 (AQP4) receptor antibody

#### **AND**

2 - Prescribed by, or in consultation with, a Neurologist or other specialist in NMOSD treatment

#### **AND**

3 - History of at least one NMOSD relapse in the last 12 months

#### **AND**

**4** - Trial and failure, contraindication or intolerance to an adequate trial of at least one of the following: rituximab, mycophenolate or azathioprine

#### **AND**

**5** - Will not be used in combination with other biologic treatments for NMOSD (i.e. rituximab, inebilizumab, eculizumab)

| Product Name: (Enspryng |                     |
|-------------------------|---------------------|
| Approval Length         | 12 month(s)         |
| Therapy Stage           | Reauthorization     |
| Guideline Type          | Prior Authorization |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| ENSPRYNG        | SATRALIZUMAB-MWGE SUBCUTANEOUS SOLN PREF<br>SYRINGE 120 MG/ML | 9940507040E520 | Brand         |

## **Approval Criteria**

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug and there is stable disease or improvement in symptoms.

| Date       | Notes       |
|------------|-------------|
| 10/31/2023 | New program |

| Enzyme Inhibitors for Gaucher Dise |  |  |
|------------------------------------|--|--|
|                                    | The handlest ground subgroups. The best read, so made, a made and parts to prints to so would not have |  |
|                                    |  |  |
|                                    |  |  |

| Guideline ID          | GL-129253                             |
|-----------------------|---------------------------------------|
| <b>Guideline Name</b> | Enzyme Inhibitors for Gaucher Disease |
| Formulary             | Quartz                                |

# **Guideline Note:**

| Effective Date: |
|-----------------|
|-----------------|

# 1. Criteria

| Product Name: Generic Miglustat                      |                       |
|--|-----------------------|
| Approval Length                                      | 12 month(s)           |
| Therapy Stage  | Initial Authorization |
| Guideline Type Prior Authorization - IL and MN Plans |                       |

| Product<br>Name | Generic Name         | GPI            | Brand/Generic |
|-----------------|----------------------|----------------|---------------|
| MIGLUSTAT       | MIGLUSTAT CAP 100 MG | 82700070000120 | Generic       |

# **Approval Criteria**

1 - Diagnosis of type-1 Gaucher disease

#### AND

2 - Trial and failure, intolerance, or contraindication to enzyme replacement therapy

| Product Name: Generic Miglustat                      |                 |
|--|-----------------|
| Approval Length                                      | 12 month(s)     |
| Therapy Stage  | Reauthorization |
| Guideline Type Prior Authorization - IL and MN Plans |                 |

| Product<br>Name | Generic Name         | GPI            | Brand/Generic |
|-----------------|----------------------|----------------|---------------|
| MIGLUSTAT       | MIGLUSTAT CAP 100 MG | 82700070000120 | Generic       |

## **Approval Criteria**

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug

| Product Name: Cerdelga                               |                       |
|--|-----------------------|
| Approval Length                                      | 12 month(s)           |
| Therapy Stage  | Initial Authorization |
| Guideline Type Prior Authorization - IL and MN Plans |                       |

| Product<br>Name | Generic Name                                       | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| CERDELGA        | ELIGLUSTAT TARTRATE CAP 84 MG (BASE<br>EQUIVALENT) | 82700040600120 | Brand         |

## **Approval Criteria**

1 - Diagnosis of type-1 Gaucher disease

#### **AND**

2 - Trial and failure, intolerance, or contraindication to enzyme replacement therapy

#### AND

**3** - Have been determined to be CYP2D6 extensive, intermediate, or poor metabolizers by an FDA-approved test

| Product Name: Cerdelga                               |                 |
|--|-----------------|
| Approval Length                                      | 12 month(s)     |
| Therapy Stage  | Reauthorization |
| Guideline Type Prior Authorization - IL and MN Plans |                 |

| Product<br>Name | Generic Name                                    | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| CERDELGA        | ELIGLUSTAT TARTRATE CAP 84 MG (BASE EQUIVALENT) | 82700040600120 | Brand         |

## **Approval Criteria**

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug

| Product Name: Generic Miglustat                                 |  |
|---|--|
| Approval Length 12/31/2039                                      |  |
| Guideline Type Prior Authorization - All plans except IL and MN |  |

| Product<br>Name | Generic Name         | GPI            | Brand/Generic |
|-----------------|----------------------|----------------|---------------|
| MIGLUSTAT       | MIGLUSTAT CAP 100 MG | 82700070000120 | Generic       |

## **Approval Criteria**

1 - Diagnosis of type-1 Gaucher disease

#### AND

2 - Trial and failure, intolerance, or contraindication to enzyme replacement therapy

| Product Name: Cerdelga  |  |
|---|--|
| Approval Length 12/31/2039                                      |  |
| Guideline Type Prior Authorization - All plans except IL and MN |  |

| Product<br>Name | Generic Name                                    | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| CERDELGA        | ELIGLUSTAT TARTRATE CAP 84 MG (BASE EQUIVALENT) | 82700040600120 | Brand         |

## **Approval Criteria**

1 - Diagnosis of type-1 Gaucher disease

#### **AND**

2 - Trial and failure, intolerance, or contraindication to enzyme replacement therapy

#### **AND**

**3** - Have been determined to be CYP2D6 extensive, intermediate, or poor metabolizers by an FDA-approved test

| Date       | Notes       |
|------------|-------------|
| 10/25/2023 | New program |

| Erythropoiesis-Stimulating Agents  |  |  |
|--|--|--|
| (2) Indicates proceedings. In this to have a common or common to the state of processing and the state of the |  |  |
|  |  |  |

| Guideline ID          | GL-129740                         |
|-----------------------|-----------------------------------|
| <b>Guideline Name</b> | Erythropoiesis-Stimulating Agents |
| Formulary             | Quartz                            |

# **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

# 1. Criteria

| Product Name: Aranesp, Mircera, Retacrit |  |                     |     |               |
|--|--|---------------------|-----|---------------|
| Approval Length 12 month(s)              |  |                     |     |               |
| Guideline Type                           |  | Prior Authorization |     |               |
| Product Generic Name                     |  | me                  | CDI | Brand/Generic |

| Product<br>Name            | Generic Name   | GPI            | Brand/Generic |
|----------------------------|--|----------------|---------------|
| ARANESP<br>ALBUMIN<br>FREE | DARBEPOETIN ALFA SOLN PREFILLED SYRINGE 10<br>MCG/0.4ML  | 02401013102310 |               |
| ARANESP<br>ALBUMIN<br>FREE | DARBEPOETIN ALFA SOLN PREFILLED SYRINGE 25<br>MCG/0.42ML | 8240101510E528 | Brand         |
| ARANESP<br>ALBUMIN<br>FREE | DARBEPOETIN ALFA SOLN PREFILLED SYRINGE 40 MCG/0.4ML     | 8240101510E543 | Brand         |
| ARANESP<br>ALBUMIN         | DARBEPOETIN ALFA SOLN PREFILLED SYRINGE 60<br>MCG/0.3ML  | 8240101510E552 | Brand         |

| FREE                       |  |                |         |
|----------------------------|--|----------------|---------|
| ARANESP<br>ALBUMIN<br>FREE | DARBEPOETIN ALFA SOLN PREFILLED SYRINGE 100 8240101510E560 Brand MCG/0.5ML |                | Brand   |
| ARANESP<br>ALBUMIN<br>FREE | DARBEPOETIN ALFA SOLN PREFILLED SYRINGE 150<br>MCG/0.3ML                   | 8240101510E575 | Brand   |
| ARANESP<br>ALBUMIN<br>FREE | DARBEPOETIN ALFA SOLN PREFILLED SYRINGE 200<br>MCG/0.4ML                   | 8240101510E582 | Brand   |
| ARANESP<br>ALBUMIN<br>FREE | DARBEPOETIN ALFA SOLN PREFILLED SYRINGE 300 MCG/0.6ML                      | 8240101510E588 | Brand   |
| ARANESP<br>ALBUMIN<br>FREE | DARBEPOETIN ALFA SOLN PREFILLED SYRINGE 500<br>MCG/ML                      | 8240101510E590 | Brand   |
| ARANESP<br>ALBUMIN<br>FREE | DARBEPOETIN ALFA SOLN INJ 25 MCG/ML  | 82401015102010 | Brand   |
| ARANESP<br>ALBUMIN<br>FREE | DARBEPOETIN ALFA SOLN INJ 40 MCG/ML  | 82401015102020 | Brand   |
| ARANESP<br>ALBUMIN<br>FREE | DARBEPOETIN ALFA SOLN INJ 60 MCG/ML  | 82401015102030 | Brand   |
| ARANESP<br>ALBUMIN<br>FREE | 02401010102040   |                | Brand   |
| ARANESP<br>ALBUMIN<br>FREE | DARBEPOETIN ALFA SOLN INJ 200 MCG/ML                                       | 82401015102060 | Brand   |
| RETACRIT                   | EPOETIN ALFA-EPBX INJ 2000 UNIT/ML   | 82401020042010 | Generic |
| RETACRIT                   | EPOETIN ALFA-EPBX INJ 3000 UNIT/ML   | 82401020042015 | Generic |
| RETACRIT                   | EPOETIN ALFA-EPBX INJ 4000 UNIT/ML   | 82401020042020 | Generic |
| RETACRIT                   | EPOETIN ALFA-EPBX INJ 10000 UNIT/ML  | 82401020042040 | Generic |
| RETACRIT                   | EPOETIN ALFA-EPBX INJ 20000 UNIT/ML  | 82401020042050 | Generic |
| RETACRIT                   | EPOETIN ALFA-EPBX INJ 40000 UNIT/ML  | 82401020042060 | Brand   |
| MIRCERA                    | METHOXY PEG-EPOETIN BETA SOLN PREFILLED SYR 30 MCG/0.3ML                   | 8240104010E510 | Brand   |
| MIRCERA                    | METHOXY PEG-EPOETIN BETA SOLN PREFILLED SYR 50 MCG/0.3ML                   | 8240104010E515 | Brand   |
| MIRCERA                    | METHOXY PEG-EPOETIN BETA SOLN PREFILLED SYR 75 MCG/0.3ML                   | 8240104010E520 | Brand   |
| MIRCERA                    | METHOXY PEG-EPOETIN BETA SOLN PREFILLED SYR 100 MCG/0.3ML                  | 8240104010E525 | Brand   |

| MIRCERA | METHOXY PEG-EPOETIN BETA SOLN PREFILLED SYR 120 MCG/0.3ML | 8240104010E530 | Brand |
|---------|---|----------------|-------|
| MIRCERA | METHOXY PEG-EPOETIN BETA SOLN PREFILLED SYR 150 MCG/0.3ML | 8240104010E535 | Brand |
| MIRCERA | METHOXY PEG-EPOETIN BETA SOLN PREFILLED SYR 200 MCG/0.3ML | 8240104010E545 | Brand |

- 1 Diagnosis of one of the following:
  - Non-myeloid cancer RECEIVING chemotherapy or within 8 weeks of receiving chemotherapy where the anemia is due to the effect of chemotherapy
  - HIV infection, for zidovudine-related anemia
  - Severe autoimmune hemolytic anemia
  - Myelodysplastic syndrome
  - Anemia associated with treatment regimens for Hepatitis C if ribavirin dose reduction does not provide adequate response
  - Chronic renal failure with or without dialysis
  - Post-transplant anemia
  - Religious beliefs prohibiting blood transfusions

#### **AND**

2 - Member or family member is self-administering the medication

#### **AND**

- 3 Submission of medical records (e.g., chart notes) documenting one of the following:
  - Hemoglobin (Hgb) < 10 g/dL</li>
  - Hematocrit (HCT) < 30%

| Date      | Notes                   |
|-----------|-------------------------|
| 8/21/2023 | 2024 New Implementation |

| Eucris                                    | Eucrisa (crisaborole)   |  |  |  |  |
|---|---|--|--|--|--|
| The bit and image current the elliptiques | . The Servey have been record, sonarrail, or dislatel, Verily | that the link points in the conscribe and invalen. |  |  |  |
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|   |   |  |  |  |  |

| Guideline ID          | GL-127846             |
|-----------------------|-----------------------|
| <b>Guideline Name</b> | Eucrisa (crisaborole) |
| Formulary             | Quartz                |

# **Guideline Note:**

| Effective Date: |
|-----------------|
|-----------------|

# 1. Criteria

| Product Name: Eucrisa |                                |
|-----------------------|--------------------------------|
| Approval Length       | 12 month(s)                    |
| Therapy Stage         | Initial Authorization          |
| Guideline Type        | Step Therapy - IL and MN Plans |

| Product<br>Name | Generic Name        | GPI            | Brand/Generic |
|-----------------|---------------------|----------------|---------------|
| EUCRISA         | CRISABOROLE OINT 2% | 90230025004220 | Brand         |

# **Approval Criteria**

- **1** Trial and failure of one of the following:
- **1.1** Topical steroid (see background for examples)

#### OR

**1.2** Topical calcineurin inhibitor (e.g., tacrolimus, pimecrolimus)

| Product Name: Eucrisa |                                |
|-----------------------|--------------------------------|
| Approval Length       | 12 month(s)                    |
| Therapy Stage         | Reauthorization                |
| Guideline Type        | Step Therapy - IL and MN Plans |

| Product<br>Name | Generic Name        | GPI            | Brand/Generic |
|-----------------|---------------------|----------------|---------------|
| EUCRISA         | CRISABOROLE OINT 2% | 90230025004220 | Brand         |

# **Approval Criteria**

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug

| Product Name: Eucrisa      |   |
|----------------------------|---|
| Approval Length 12/31/2039 |   |
| Guideline Type             | Step Therapy - All plans except IL and MN Plans |

| Product<br>Name | Generic Name        | GPI            | Brand/Generic |
|-----------------|---------------------|----------------|---------------|
| EUCRISA         | CRISABOROLE OINT 2% | 90230025004220 | Brand         |

## **Approval Criteria**

- 1 Trial and failure of one of the following:
- **1.1** Topical steroid (see background for examples)

OR

**1.2** Topical calcineurin inhibitor (e.g., tacrolimus, pimecrolimus)

## 2. Background

#### Benefit/Coverage/Program Information

#### **Examples of topical steroids**

alclometasone dipropionate 0.05% cream/ointment, betamethasone dipropionate 0.05% cream/ointment/lotion/gel/spray/pump, betamethasone valerate 0.1% ointment/cream/lotion, betamethasone valerate 0.12% foam, betamethasone/propylene glycol 0.05% cream/lotion/ointment, clobetasol propionate 0.025% cream, clobetasol propionate 0.05% ointment/cream/solution/gel/foam/lotion/spray, clobetasol propionate emollient 0.05% cream/foam, clocortolone pivalate 0.1% cream, desonide 0.05% ointment/lotion/cream/foam/gel, desoximetasone 0.05% gel/cream/ointment, desoximetasone 0.25% cream/ointment/spray, diflorasone diacetate 0.05% ointment/cream, diflorasone diacetate emollient 0.05% cream, fluocinolone acetonide 0.01% solution/cream/oil, fluocinolone acetonide 0.025% ointment/cream, fluocinonide 0.05% cream/ointment/solution/gel, fluocinonide 0.1% cream, fluocinonide emollient 0.05% cream, flurandrenolide 0.025% cream, flurandrenolide 0.05% cream/lotion/ointment, fluticasone propionate 0.005% ointment. fluticasone propionate 0.05% cream/lotion/, halcinonide 0.1% cream/ointment, halobetasol propionate 0.01% lotion, halobetasol propionate 0.05% cream/ointment/lotion/foam, hydrocortisone 1% cream/ointment, hydrocortisone 2% lotion, hydrocortisone 2.5% cream/ointment/solution/lotion, hydrocortisone butyrate 0.1% solution/cream/ointment/lotion, hydrocortisone butyrate emollient 0.1% cream, hydrocortisone probutate 0.1% cream, hydrocortisone valerate 0.2% ointment/cream, mometasone furoate 0.1% cream/ointment/solution, hydrocortisone acetate/aloe vera 2% lotion, prednicarbate 0.1% ointment/cream, triamcinolone acetonide 0.025% cream/ointment/lotion, triamcinolone acetonide 0.05% ointment, triamcinolone acetonide 0.1% cream/ointment/lotion, triamcinolone acetonide 0.147mg/g aerosol, triamcinolone acetonide 0.5% cream/ointment

| Date      | Notes        |
|-----------|--------------|
| 8/25/2023 | New Programs |

| Evrysdi (ri  | sdiplam  | )      |  |
|--|--|--------|--|
| The Shind Image current for displayed. The Sir may have have necessary | mares), or distant. Worly that the link position that committle an | riado. |  |
|  |  |        |  |

| Guideline ID          | GL-131441           |
|-----------------------|---------------------|
| <b>Guideline Name</b> | Evrysdi (risdiplam) |
| Formulary             | Quartz              |

## **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

## Note:

\*Member new to the plan (as evidenced by coverage effective date of less than or equal to 90 days) who initiated therapy using a manufacturer-sponsored free drug program, provider samples, and/or vouchers will go through initial criteria, otherwise for continuation of therapy for new to plan, reauthorization criteria applies

## 1. Criteria

| Product Name: Evrysdi               |              |                     |                |               |
|-------------------------------------|--------------|---------------------|----------------|---------------|
| Approval Length                     |              | 12 month(s)         |                |               |
| Therapy Stage Initial Authorization |              |                     |                |               |
| Guideline Type                      |              | Prior Authorization |                |               |
| Product<br>Name                     | Generic Name |                     | GPI            | Brand/Generic |
| EVRYSDI RISDIPLAM F                 |              | FOR SOLN 0.75 MG/ML | 74706560002120 | Brand         |
|                                     |              |                     |                |               |

**1** - Diagnosis of spinal muscle atrophy (SMA)

#### AND

**2** - Submission of medical records (e.g., chart notes) documenting gene mutation analysis with bi-allelic SMN1 mutations (5q-autosomal recessive point mutation/deletion) phenotype 1,2 or 3.

#### AND

**3** - Prescribed by or in consultation with a Neurologist or other clinician with expertise in management and treatment of neuromuscular disorders

#### **AND**

**4** - Member does not have advanced SMA (e.g., permanent ventilatory dependence, tracheostomy, complete limb paralysis, etc.)

#### **AND**

**5** - For members less than or equal to 2 yeas of age established on nusinersen, will not continue nusinersen (Spinraza) post onasemnogene infusion

#### **AND**

**6** - For members less than or equal to 2 yeas of age established on risdiplam, will not continue risdiplam (Evrysdi) post- onasemnogene infusion

| Product Name: Evrysdi              |                 |
|------------------------------------|-----------------|
| Approval Length 12 month(s)        |                 |
| Therapy Stage                      | Reauthorization |
| Guideline Type Prior Authorization |                 |

| Product<br>Name | Generic Name                  | GPI            | Brand/Generic |
|-----------------|-------------------------------|----------------|---------------|
| EVRYSDI         | RISDIPLAM FOR SOLN 0.75 MG/ML | 74706560002120 | Brand         |

1 - Diagnosis of spinal muscle atrophy (SMA)

#### **AND**

**2** - Submission of medical records (e.g., chart notes) documenting gene mutation analysis with bi-allelic SMN1 mutations (5q-autosomal recessive point mutation/deletion) phenotype 1,2 or 3.

#### **AND**

**3** - Prescribed by or in consultation with a Neurologist or other clinician with expertise in management and treatment of neuromuscular disorders

#### **AND**

**4** - Member does not have advanced SMA (e.g., permanent ventilatory dependence, tracheostomy, complete limb paralysis, etc.)

#### **AND**

**5** - For members less than or equal to 2 yeas of age established on nusinersen, will not continue nusinersen (Spinraza) post onasemnogene infusion

#### **AND**

**6** - For members less than or equal to 2 yeas of age established on risdiplam, will not continue risdiplam (Evrysdi) post- onasemnogene infusion

#### **AND**

7 - Member is established on therapy

#### **AND**

- 8 Submission of medical records (e.g., chart notes) documenting both of the following:
- **8.1** Clinically significant improvement in SMA-related symptoms as evidence by an improvement, stabilization or decreased decline since previous approval

#### **AND**

8.2 Specific scale used based on age and motor function and comparison to baseline

| Date      | Notes                   |
|-----------|-------------------------|
| 10/8/2023 | 2024 New Implementation |

| Fasenra (benralizumab)  |  |  |  |  |
|---|--|--|--|--|
| The black they want to replace The bary has not consider and or about the first before the security and trades. |  |  |  |  |
|   |  |  |  |  |

| Guideline ID          | GL-132802              |
|-----------------------|------------------------|
| <b>Guideline Name</b> | Fasenra (benralizumab) |
| Formulary             | Quartz                 |

## **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

## Note:

Member new to the plan (as evidenced by coverage effective date of less than or equal to 90 days) who initiated therapy using a manufacturer-sponsored free drug program, provider samples, and/or vouchers will go through initial criteria, otherwise for continuation of therapy for new to plan, reauthorization criteria applies

## 1. Criteria

| Product Name: Fasenra               |  |                                       |       |               |
|-------------------------------------|--|---------------------------------------|-------|---------------|
| Approval Length 12 month(s)         |  |                                       |       |               |
| Therapy Stage Initial Authorization |  |                                       |       |               |
| Guideline Type                      |  | Prior Authorization - IL and MN Plans |       |               |
| Product<br>Name                     | t Generic Name GPI   |                                       | GPI   | Brand/Generic |
| FASENRA<br>PEN                      | BENRALIZUMAB SUBCUTANEOUS SOLN AUTO-<br>INJECTOR 30 MG/ML  4460402000D520  Bra |                                       | Brand |               |

| Approval Criteria   |
|---|
| 1 - Requested medication will be self-administered  |
| AND   |
| <b>2</b> - Prescribed by or in consultation with one of the following:  |
| <ul> <li>Allergist</li> <li>Immunologist</li> <li>Pulmonologist</li> </ul>  |
| AND   |
| 3 - Member is 12 years of age or older  |
| AND   |
| 4 - All of the following:   |
| <ul> <li>Diagnosis of eosinophilic asthma</li> <li>Blood eosinophil count of ≥ 150 cells/mm3</li> <li>All other causes of eosinophilia such as hypereosinophilic syndromes, neoplastic disease, or parasitic disease have been ruled out</li> </ul>   |
| AND   |
| 5 - One of the following:   |
| <b>5.1</b> Symptoms are not well controlled or poorly controlled (refer to Table 1 in background section) despite an adherent ‡ ≥ 3-month trial of medium to high-dose inhaled corticosteroids in combination with a long-acting bronchodilator, long-acting muscarinic antagonist, or leukotriene modifier |
| OR  |

**5.2** Intolerance to medium to high dose inhaled corticosteroids in combination with a long-acting bronchodilator or leukotriene modifier. Exceptions based on adverse effects from medium to high dose ICS or comorbid conditions increasing long-term risks of adverse effects from high dose ICS or oral corticosteroids including at least ONE of the following:

- Cataracts in patients > 40 years of age
- Glaucoma
- Recurrent thrush
- Dysphonia
- Growth inhibition, after evaluation by Endocrine Consult
- Diagnosis of osteoporosis, treatment resistant to FDA approved osteoporosis treatment

| Notes | ‡Adherent treatment is defined as a medication possession ratio (MPR ) ≥ 70% based on the previous 120 days of prescription claims.  |
|-------|--|
|       | NOTE: II-5 inhibitor drugs in combination with omalizumab will be consi dered on a case-by-case basis if each individual agent with combination high dose ICS/LABA did not control symptoms. Tezepelumab, in combination with other biologics, has not been studied and coverage is not allowed except in extenuating circumstances (applies to both eosinophilic or non-eosinophilic asthma populations). |
|       | *Continuation of therapy/coverage criteria will not be applied to person s who were not previously approved for coverage whose therapy was i nitiated using a manufacturer-sponsored free drug program, provider s amples, and/or vouchers.  |

| Product Name: Fasenra                                |                 |
|--|-----------------|
| Approval Length 12 month(s)                          |                 |
| Therapy Stage  | Reauthorization |
| Guideline Type Prior Authorization - IL and MN Plans |                 |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| FASENRA<br>PEN  | BENRALIZUMAB SUBCUTANEOUS SOLN AUTO-<br>INJECTOR 30 MG/ML | 4460402000D520 | Brand         |

#### **Approval Criteria**

- **1** Submission of medical records (e.g., chart notes) documenting positive clinical response to therapy within the previous 12 months defined by one of the following:
  - Decreased frequency of use of, or ability to lower the chronic daily dose, of oral

- corticosteroids to treat/prevent exacerbations
- Decreased frequency of use of unscheduled emergency department/urgent care visits for exacerbations
- Reduction in reported symptoms such as chest tightness, coughing, shortness of breath, nocturnal awakenings, nasal congestion, obstruction, etc.
- Sustained (at least six months) improvement in Asthma Control Test (ACT) scores

| Notes | NOTE: Continuation of case-by case-approved IgE inhibitor and IL-5 in hibitor, or tezepelumab combination therapy will only be considered if ICS/LABA therapy was also continued AND there was reduction in oral steroid dose, exacerbations, or hospitalizations. |
|-------|--|
|       | *Continuation of therapy/coverage criteria will not be applied to person s who were not previously approved for coverage whose therapy was i nitiated using a manufacturer-sponsored free drug program, provider s amples, and/or vouchers.                        |

| Product Name: Fasenra      |  |  |
|----------------------------|--|--|
| Approval Length 12/31/2039 |  |  |
| Guideline Type             | Prior Authorization - All Plans Except IL and MN Plans |  |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
|                 | BENRALIZUMAB SUBCUTANEOUS SOLN AUTO-<br>INJECTOR 30 MG/ML | 4460402000D520 | Brand         |

1 - Requested medication will be self-administered

#### AND

- 2 Prescribed by or in consultation with one of the following:
  - Allergist
  - Immunologist
  - Pulmonologist

#### **AND**

**3** - Member is 12 years of age or older

#### **AND**

- 4 All of the following:
  - Diagnosis of eosinophilic asthma
  - Blood eosinophil count of ≥ 150 cells/mm3
  - All other causes of eosinophilia such as hypereosinophilic syndromes, neoplastic disease, or parasitic disease have been ruled out

#### **AND**

- **5** One of the following:
- **5.1** Symptoms are not well controlled or poorly controlled (refer to Table 1 in background section) despite an adherent ‡ ≥ 3-month trial of medium to high-dose inhaled corticosteroids in combination with a long-acting bronchodilator, long-acting muscarinic antagonist, or leukotriene modifier

#### OR

- **5.2** Intolerance to medium to high dose inhaled corticosteroids in combination with a longacting bronchodilator or leukotriene modifier. Exceptions based on adverse effects from medium to high dose ICS or comorbid conditions increasing long-term risks of adverse effects from high dose ICS or oral corticosteroids including at least ONE of the following:
  - Cataracts in patients > 40 years of age
  - Glaucoma
  - Recurrent thrush
  - Dysphonia
  - Growth inhibition, after evaluation by Endocrine Consult
  - Diagnosis of osteoporosis, treatment resistant to FDA approved osteoporosis treatment

# \*Adherent treatment is defined as a medication possession ratio (MPR ) ≥ 70% based on the previous 120 days of prescription claims. NOTE: II-5 inhibitor drugs in combination with omalizumab will be consi dered on a case-by-case basis if each individual agent with combination high dose ICS/LABA did not control symptoms. Tezepelumab, in combination with other biologics, has not been studied and coverage is not allowed except in e xtenuating circumstances (applies to both

| eosinophilic or non-eosinophilic asthma populations).   |
|---|
| *Continuation of therapy/coverage criteria will not be applied to person s who were not previously approved for coverage whose therapy was i nitiated using a manufacturer-sponsored free drug program, provider s amples, and/or youchers. |

# 2. Background

# Benefit/Coverage/Program Information

**Table 1. Outcome Measure values for uncontrolled asthma** 

| Measure   | Not Well Controlled               | Very Poorly<br>Controlled        |
|---|-----------------------------------|----------------------------------|
| Baseline symptoms (outside of exacerbation)       | > 2 days/week                     | Throughout the day               |
| Nighttime awakening                               | 1-3 times/week                    | ≥ 4 times/week                   |
| Interference with normal activity                 | Some limitation                   | Extremely limited                |
| Short acting beta agonist use for symptom control | > 2 days/week                     | Several times per day            |
| FEV1  | 60-80% predicted or personal best | < 60% predicted or personal best |
| Asthma<br>exacerbations<br>requiring oral         | Yes                               | Yes                              |
| steroids ≥ 2 times in<br>the past year            |                                   |                                  |
| Asthma Control Test<br>(ACT)                      | 16-19                             | ≤ 15                             |

| Date      | Notes                   |
|-----------|-------------------------|
| 11/1/2023 | 2024 New Implementation |

| Febuxostat  |
|---|
| (2) The Marketings are not happying. The Box 1 has been record, second, a sided both parties for promoting of hardes. |
|   |
|   |

| Guideline ID   | GL-128129 |  |
|----------------|-----------|--|
| Guideline Name | ebuxostat |  |
| Formulary      | Quartz    |  |

# **Guideline Note:**

| Effective Date: |
|-----------------|
|-----------------|

# 1. Criteria

| Product Name: Generic Febuxostat |                                |  |  |
|----------------------------------|--------------------------------|--|--|
| Approval Length 12 month(s)      |                                |  |  |
| Therapy Stage                    | Initial Authorization          |  |  |
| Guideline Type                   | Step Therapy - IL and MN Plans |  |  |

| Product<br>Name | Generic Name         | GPI            | Brand/Generic |
|-----------------|----------------------|----------------|---------------|
| FEBUXOSTAT      | FEBUXOSTAT TAB 40 MG | 68000030000320 | Generic       |
| FEBUXOSTAT      | FEBUXOSTAT TAB 80 MG | 68000030000330 | Generic       |

# **Approval Criteria**

1 - Submission of medical records (e.g., chart notes) documenting a trial and failure of 3

months of allopurinol 300 mg

| Product Name: Generic Febuxostat |                                |  |  |  |
|----------------------------------|--------------------------------|--|--|--|
| Approval Length                  | pproval Length 12 month(s)     |  |  |  |
| Therapy Stage                    | Reauthorization                |  |  |  |
| Guideline Type                   | Step Therapy - IL and MN Plans |  |  |  |

| Product<br>Name | Generic Name         | GPI            | Brand/Generic |
|-----------------|----------------------|----------------|---------------|
| FEBUXOSTAT      | FEBUXOSTAT TAB 40 MG | 68000030000320 | Generic       |
| FEBUXOSTAT      | FEBUXOSTAT TAB 80 MG | 68000030000330 | Generic       |

## **Approval Criteria**

**1** - Submission of medical notes (e.g. chart notes) from the past 12 months that member is continuing therapy with the requested drug

| Product Name: Generic Febuxostat                         |  |
|--|--|
| Approval Length 12/31/2039                               |  |
| Guideline Type Step Therapy - All plans except IL and MN |  |

| Product<br>Name | Generic Name         | GPI            | Brand/Generic |
|-----------------|----------------------|----------------|---------------|
| FEBUXOSTAT      | FEBUXOSTAT TAB 40 MG | 68000030000320 | Generic       |
| FEBUXOSTAT      | FEBUXOSTAT TAB 80 MG | 68000030000330 | Generic       |

## **Approval Criteria**

**1** - Submission of medical records (e.g., chart notes) documenting a trial and failure of 3 months of allopurinol 300 mg

| Date      | Notes       |
|-----------|-------------|
| 8/21/2023 | New Program |

| Fetzima (levomilnacipran)   |  |  |  |  |
|---|--|--|--|--|
| (i) The billion frequency to the first to be the transfer most, count, a state and factor in process to constitution. |  |  |  |  |
|   |  |  |  |  |

| Guideline ID          | GL-127842                 |
|-----------------------|---------------------------|
| <b>Guideline Name</b> | Fetzima (levomilnacipran) |
| Formulary             | Quartz                    |

# **Guideline Note:**

| Effective Date: |
|-----------------|
|-----------------|

# 1. Criteria

| Product Name: Fetzima                         |                       |
|---|-----------------------|
| Approval Length 12 month(s)                   |                       |
| Therapy Stage                                 | Initial Authorization |
| Guideline Type Step Therapy - IL and MN Plans |                       |

| Product<br>Name              | Generic Name   | GPI            | Brand/Generic |
|------------------------------|--|----------------|---------------|
| FETZIMA<br>TITRATION<br>PACK | LEVOMILNACIPRAN HCL CAP ER 24HR 20 & 40 MG<br>THERAPY PACK | 5818005010B620 | Brand         |
| FETZIMA                      | LEVOMILNACIPRAN HCL CAP ER 24HR 20 MG (BASE EQUIVALENT)    | 58180050107020 | Brand         |
| FETZIMA                      | LEVOMILNACIPRAN HCL CAP ER 24HR 40 MG (BASE EQUIVALENT)    | 58180050107040 | Brand         |
| FETZIMA                      | LEVOMILNACIPRAN HCL CAP ER 24HR 80 MG (BASE EQUIVALENT)    | 58180050107060 | Brand         |

|  | LEVOMILNACIPRAN HCL CAP ER 24HR 120 MG (BASE EQUIVALENT) | 58180050107080 | Brand |
|--|--|----------------|-------|
|--|--|----------------|-------|

- 1 Trial and failure of at least one preferred serotonin reuptake inhibitor (SSRI):
  - citalopram
  - escitalopram
  - sertraline
  - paroxetine
  - fluoxetine

#### **AND**

- **2** Trial and failure of at least one preferred Serotonin Norepinephrine Reuptake inhibitor (SNRI):
  - venlafaxine
  - duloxetine

| Product Name: Fetzima                         |  |
|---|--|
| Approval Length 12 month(s)                   |  |
| Therapy Stage Reauthorization                 |  |
| Guideline Type Step Therapy - IL and MN Plans |  |

| Product<br>Name              | Generic Name   | GPI            | Brand/Generic |
|------------------------------|--|----------------|---------------|
| FETZIMA<br>TITRATION<br>PACK | LEVOMILNACIPRAN HCL CAP ER 24HR 20 & 40 MG<br>THERAPY PACK | 5818005010B620 | Brand         |
| FETZIMA                      | LEVOMILNACIPRAN HCL CAP ER 24HR 20 MG (BASE EQUIVALENT)    | 58180050107020 | Brand         |
| FETZIMA                      | LEVOMILNACIPRAN HCL CAP ER 24HR 40 MG (BASE EQUIVALENT)    | 58180050107040 | Brand         |
| FETZIMA                      | LEVOMILNACIPRAN HCL CAP ER 24HR 80 MG (BASE EQUIVALENT)    | 58180050107060 | Brand         |
| FETZIMA                      | LEVOMILNACIPRAN HCL CAP ER 24HR 120 MG (BASE EQUIVALENT)   | 58180050107080 | Brand         |

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug

| Product Name: Fetzima  |  |
|--|--|
| Approval Length 12/31/2039                                     |  |
| Guideline Type Step Therapy - All plans except IL and MN Plans |  |

| Product<br>Name              | Generic Name   | GPI            | Brand/Generic |
|------------------------------|--|----------------|---------------|
| FETZIMA<br>TITRATION<br>PACK | LEVOMILNACIPRAN HCL CAP ER 24HR 20 & 40 MG<br>THERAPY PACK | 5818005010B620 | Brand         |
| FETZIMA                      | LEVOMILNACIPRAN HCL CAP ER 24HR 20 MG (BASE EQUIVALENT)    | 58180050107020 | Brand         |
| FETZIMA                      | LEVOMILNACIPRAN HCL CAP ER 24HR 40 MG (BASE EQUIVALENT)    | 58180050107040 | Brand         |
| FETZIMA                      | LEVOMILNACIPRAN HCL CAP ER 24HR 80 MG (BASE EQUIVALENT)    | 58180050107060 | Brand         |
| FETZIMA                      | LEVOMILNACIPRAN HCL CAP ER 24HR 120 MG (BASE EQUIVALENT)   | 58180050107080 | Brand         |

## **Approval Criteria**

- 1 Trial and failure of at least one preferred serotonin reuptake inhibitor (SSRI):
  - citalopram
  - escitalopram
  - sertraline
  - paroxetine
  - fluoxetine

#### **AND**

- **2** Trial and failure of at least one preferred Serotonin Norepinephrine Reuptake inhibitor (SNRI):
  - venlafaxine

duloxetine

| Date      | Notes       |
|-----------|-------------|
| 8/21/2023 | New Program |

| Fintepla (Fenfluramine)  |
|--|
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| Guideline ID          | GL-129617               |
|-----------------------|-------------------------|
| <b>Guideline Name</b> | Fintepla (Fenfluramine) |
| Formulary             | Quartz                  |

## **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

## 1. Criteria

| Product Name: Fintepla                               |                       |
|--|-----------------------|
| Approval Length 12 month(s)                          |                       |
| Therapy Stage  | Initial Authorization |
| Guideline Type Prior Authorization - IL and MN Plans |                       |

| Product<br>Name | Generic Name                         | GPI            | Brand/Generic |
|-----------------|--------------------------------------|----------------|---------------|
| FINTEPLA        | FENFLURAMINE HCL ORAL SOLN 2.2 MG/ML | 72600028102020 | Brand         |

## **Approval Criteria**

1 - Diagnosis of seizures associated with Dravet syndrome or Lennox-Gastaut syndrome

2 - Prescribed by, or in consultation with, a Neurologist

#### **AND**

**3** - Previous trial and failure, contraindication or intolerance to an adequate trial of cannabidiol and at least one of the following: topiramate, valproic acid, clobazam or clobazam in combination with stiripentol.

| Product Na                                    | Product Name: Fintepla |                                       |       |               |
|---|------------------------|---------------------------------------|-------|---------------|
| Approval Length                               |                        | 12 month(s)                           |       |               |
| Therapy Stage                                 |                        | Reauthorization                       |       |               |
| Guideline Type                                |                        | Prior Authorization - IL and MN Plans |       |               |
| Product Generic Na<br>Name                    |                        | me                                    | GPI   | Brand/Generic |
| FINTEPLA FENFLURAMINE HCL ORAL SOLN 2.2 MG/ML |                        | 72600028102020                        | Brand |               |

### **Approval Criteria**

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug.

| Product Name: Fintepla |   |  |                |               |
|------------------------|---|--|----------------|---------------|
| Approval Length        |   | 12/31/2039                                       |                |               |
| Guideline Type         |   | Prior Authorization - All plans except IL and MN |                |               |
| Product Generic Name   |   | me   | GPI            | Brand/Generic |
| FINTEPLA               | FINTEPLA FENFLURAMINE HCL ORAL SOLN 2.2 MG/ML |  | 72600028102020 | Brand         |

### **Approval Criteria**

1 - Diagnosis of seizures associated with Dravet syndrome or Lennox-Gastaut syndrome

2 - Prescribed by, or in consultation with, a Neurologist

### **AND**

**3** - Previous trial and failure, contraindication or intolerance to an adequate trial of cannabidiol and at least one of the following: topiramate, valproic acid, clobazam or clobazam in combination with stiripentol.

| Date      | Notes       |
|-----------|-------------|
| 10/6/2023 | New Program |

| Firdapse, Ruzurgi (amifampridine)  |  |
|--|--|
| (2) Indicating water-indicate. In this to channel water a loss of the first in provide contribution and contribution of the co |  |
|  |  |

| Guideline ID          | GL-127692                         |
|-----------------------|-----------------------------------|
| <b>Guideline Name</b> | Firdapse, Ruzurgi (amifampridine) |
| Formulary             | Quartz                            |

## **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

## 1. Criteria

| Product Name: Firdapse      |                       |
|-----------------------------|-----------------------|
| Approval Length 12 month(s) |                       |
| Therapy Stage               | Initial Authorization |
| Guideline Type              | Prior Authorization   |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| FIRDAPSE        | AMIFAMPRIDINE PHOSPHATE TAB 10 MG (BASE EQUIVALENT) | 76000012100320 | Brand         |

## **Approval Criteria**

**1** - All of the following:

**1.1** Diagnosis of Lambert-Eaton myasthenic syndrome (LEMS)

#### **AND**

**1.2** Diagnosis confirmed by neurophysiology studies or a positive anti-P/Q type voltage-gated calcium channel antibody test

#### **AND**

1.3 Prescribed by or in consult with an expert in the treatment of neuromuscular disorders

### OR

**2** - Member is new to the plan (as evidenced by coverage effective date of less than or equal to 90 days), the prescriber must provide submission of medical records (e.g. chart notes) from the previous 12 months regarding the member's response to therapy with improvement or stabilization in muscle weakness compared to baseline

| Product Name: Firdapse |                     |
|------------------------|---------------------|
| Approval Length        | 12 month(s)         |
| Therapy Stage          | Reauthorization     |
| Guideline Type         | Prior Authorization |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| FIRDAPSE        | AMIFAMPRIDINE PHOSPHATE TAB 10 MG (BASE EQUIVALENT) | 76000012100320 | Brand         |

### **Approval Criteria**

**1** - Submission of medical records (e.g. chart notes) from the previous 12 months of therapy indicating improvement or stabilization in muscle weakness compared to baseline.

| Date      | Notes       |
|-----------|-------------|
| 11/3/2023 | New Program |

| Fycompa (perampanel)   |
|--|
| The State of they are set to display in Trolling I have been considerable and the State of the S |
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|  |

| Guideline ID          | GL-127845            |  |
|-----------------------|----------------------|--|
| <b>Guideline Name</b> | Fycompa (perampanel) |  |
| Formulary             | Quartz               |  |

# **Guideline Note:**

| Effective Date: |
|-----------------|
|-----------------|

## 1. Criteria

| Product Name: Fycompa       |                                |
|-----------------------------|--------------------------------|
| Approval Length 12 month(s) |                                |
| Therapy Stage               | Initial Authorization          |
| Guideline Type              | Step Therapy - IL and MN Plans |

| Product<br>Name | Generic Name         | GPI            | Brand/Generic |
|-----------------|----------------------|----------------|---------------|
| FYCOMPA         | PERAMPANEL TAB 2 MG  | 72550060000310 | Brand         |
| FYCOMPA         | PERAMPANEL TAB 4 MG  | 72550060000320 | Brand         |
| FYCOMPA         | PERAMPANEL TAB 6 MG  | 72550060000330 | Brand         |
| FYCOMPA         | PERAMPANEL TAB 8 MG  | 72550060000340 | Brand         |
| FYCOMPA         | PERAMPANEL TAB 10 MG | 72550060000350 | Brand         |
| FYCOMPA         | PERAMPANEL TAB 12 MG | 72550060000360 | Brand         |

| FYCOMPA | PERAMPANEL SUSP 0.5 MG/ML | 72550060001820 | Brand |
|---------|---------------------------|----------------|-------|

- 1 Trial and failure, contraindication, or intolerance to at least TWO preferred anticonvulsants:
  - lamotrigine
  - levetiracetam
  - carbamazepine
  - valproate
  - oxcarbazepine
  - gabapentin
  - pregabalin
  - topiramate
  - phenytoin
  - zonisamide
  - primidone

| Product Name: Fycompa |                                |
|-----------------------|--------------------------------|
| Approval Length       | 12 month(s)                    |
| Therapy Stage         | Reauthorization                |
| Guideline Type        | Step Therapy - IL and MN Plans |

| Product<br>Name | Generic Name              | GPI            | Brand/Generic |
|-----------------|---------------------------|----------------|---------------|
| FYCOMPA         | PERAMPANEL TAB 2 MG       | 72550060000310 | Brand         |
| FYCOMPA         | PERAMPANEL TAB 4 MG       | 72550060000320 | Brand         |
| FYCOMPA         | PERAMPANEL TAB 6 MG       | 72550060000330 | Brand         |
| FYCOMPA         | PERAMPANEL TAB 8 MG       | 72550060000340 | Brand         |
| FYCOMPA         | PERAMPANEL TAB 10 MG      | 72550060000350 | Brand         |
| FYCOMPA         | PERAMPANEL TAB 12 MG      | 72550060000360 | Brand         |
| FYCOMPA         | PERAMPANEL SUSP 0.5 MG/ML | 72550060001820 | Brand         |

### **Approval Criteria**

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug

| Product Name: Fycompa |   |
|-----------------------|---|
| Approval Length       | 12/31/2039                                      |
| Guideline Type        | Step Therapy - All plans except IL and MN Plans |

| Product<br>Name | Generic Name              | GPI            | Brand/Generic |
|-----------------|---------------------------|----------------|---------------|
| FYCOMPA         | PERAMPANEL TAB 2 MG       | 72550060000310 | Brand         |
| FYCOMPA         | PERAMPANEL TAB 4 MG       | 72550060000320 | Brand         |
| FYCOMPA         | PERAMPANEL TAB 6 MG       | 72550060000330 | Brand         |
| FYCOMPA         | PERAMPANEL TAB 8 MG       | 72550060000340 | Brand         |
| FYCOMPA         | PERAMPANEL TAB 10 MG      | 72550060000350 | Brand         |
| FYCOMPA         | PERAMPANEL TAB 12 MG      | 72550060000360 | Brand         |
| FYCOMPA         | PERAMPANEL SUSP 0.5 MG/ML | 72550060001820 | Brand         |

- 1 Trial and failure, contraindication, or intolerance to at least TWO preferred anticonvulsants:
  - lamotrigine
  - levetiracetam
  - carbamazepine
  - valproate
  - oxcarbazepine
  - gabapentin
  - pregabalin
  - topiramate

  - phenytoin zonisamide
  - primidone

| Date      | Notes       |
|-----------|-------------|
| 8/21/2023 | New Program |

| Galafold (Migalastat)                              |  |                       |  |  |
|--|--|-----------------------|--|--|
| The left of large connect has single-post. The fin | my han han moust, owners, or distance thely fined to be primite from cover | fix and in the second |  |  |

| Guideline ID          | GL-129103             |
|-----------------------|-----------------------|
| <b>Guideline Name</b> | Galafold (Migalastat) |
| Formulary             | Quartz                |

## **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

## 1. Criteria

| Product Name: Galafold |                                       |
|------------------------|---------------------------------------|
| Approval Length        | 12 month(s)                           |
| Therapy Stage          | Initial Authorization                 |
| Guideline Type         | Prior Authorization - IL and MN Plans |

| Product<br>Name | Generic Name                                | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| GALAFOLD        | MIGALASTAT HCL CAP 123 MG (BASE EQUIVALENT) | 30903650100120 | Brand         |

## **Approval Criteria**

1 - Diagnosis of Fabry disease

**2** - Submission of medical records (e.g., chart notes) of an amenable galactosidase alpha gene (GLA) variant as noted in the product labeling.

#### **AND**

3 - Member does not have severe renal impairment (eGFR

### **AND**

4 - Member is 16 years of age or older

#### **AND**

5 - Member will not be using migalastat in combination with enzyme replacement therapy

| Product Name: Galafold |                                       |  |
|------------------------|---------------------------------------|--|
| Approval Length        | 12 month(s)                           |  |
| Therapy Stage          | Reauthorization                       |  |
| Guideline Type         | Prior Authorization - IL and MN Plans |  |

| ı | Product<br>Name | Generic Name                                | GPI            | Brand/Generic |
|---|-----------------|---|----------------|---------------|
|   | GALAFOLD        | MIGALASTAT HCL CAP 123 MG (BASE EQUIVALENT) | 30903650100120 | Brand         |

### **Approval Criteria**

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug

| Product Name: Galafold |  |
|------------------------|--|
| Approval Length        | 12/31//2039                                      |
| Guideline Type         | Prior Authorization - All plans except IL and MN |

| Product<br>Name | Generic Name                                | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| GALAFOLD        | MIGALASTAT HCL CAP 123 MG (BASE EQUIVALENT) | 30903650100120 | Brand         |

1 - Diagnosis of Fabry disease

### **AND**

**2** - Submission of medical records (e.g., chart notes) of an amenable galactosidase alpha gene (GLA) variant as noted in the product labeling.

#### **AND**

3 - Member does not have severe renal impairment (eGFR

#### **AND**

4 - Member is 16 years of age or older

#### **AND**

5 - Member will not be using migalastat in combination with enzyme replacement therapy

| Date     | Notes       |
|----------|-------------|
| 9/7/2023 | New Program |

| Gattex   | Gattex (Teduglutide)   |             |  |  |
|--|--|-------------|--|--|
| The bital image current to displayers. The file may it | van kan mousi, vouwel, or diddel. Welly that he his points in the convertile | and leaders |  |  |
|  |  |             |  |  |

| Guideline ID          | GL-131937            |
|-----------------------|----------------------|
| <b>Guideline Name</b> | Gattex (Teduglutide) |
| Formulary             | Quartz               |

## **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

## 1. Criteria

| Product Name: Gattex |  |  |
|----------------------|--|--|
| Approval Length      | 12 month(s)                              |  |
| Therapy Stage        | Initial Authorization                    |  |
| Guideline Type       | Prior Authorization-IL and MN Plans Only |  |

| Product<br>Name | Generic Name                        | GPI            | Brand/Generic |
|-----------------|-------------------------------------|----------------|---------------|
| GATTEX          | TEDUGLUTIDE (RDNA) FOR INJ KIT 5 MG | 52533070006420 | Brand         |

## **Approval Criteria**

1 - Diagnosis of Short Bowel Syndrome

2 - Prescribed by, or in consultation with, a Gastroenterologist

### AND

**3** - Person dependent on parenteral support

| Product Name: Gattex |                               |  |
|----------------------|-------------------------------|--|
| Approval Length      | 12 month(s)                   |  |
| Therapy Stage        | Reauthorization               |  |
| Guideline Type       | Prior Authorization-All plans |  |

| Product<br>Name | Generic Name                        | GPI            | Brand/Generic |
|-----------------|-------------------------------------|----------------|---------------|
| GATTEX          | TEDUGLUTIDE (RDNA) FOR INJ KIT 5 MG | 52533070006420 | Brand         |

### **Approval Criteria**

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months a  $\geq$  20% reduction in parenteral support requirement from baseline.

| Product Name: Gattex |  |  |
|----------------------|--|--|
| Approval Length      | 6 month(s)                                     |  |
| Therapy Stage        | Initial Authorization                          |  |
| Guideline Type       | Prior Authorization-All plans except IL and MN |  |

| Product<br>Name | Generic Name                        | GPI            | Brand/Generic |
|-----------------|-------------------------------------|----------------|---------------|
| GATTEX          | TEDUGLUTIDE (RDNA) FOR INJ KIT 5 MG | 52533070006420 | Brand         |

### **Approval Criteria**

1 - Diagnosis of Short Bowel Syndrome

**2** - Prescribed by, or in consultation with, a Gastroenterologist

### AND

**3** - Person dependent on parenteral support

| Date       | Notes       |
|------------|-------------|
| 10/31/2023 | New program |

| Glucagon-like Peptide 1 (GLP-1) Ago  | nist |
|--|------|
| (g) beliefungs were helpful finde in som to some a some and so the finde in product or worth annual. |      |

| Guideline ID          | GL-137502                               |
|-----------------------|---|
| <b>Guideline Name</b> | Glucagon-like Peptide 1 (GLP-1) Agonist |
| Formulary             | Quartz                                  |

# **Guideline Note:**

| Effective Date: |
|-----------------|
|-----------------|

## 1. Criteria

| Product Name: Byetta, Bydureon, Trulicity                       |                      |  |                |               |
|---|----------------------|--|----------------|---------------|
| Approval Length 12/31/2039                                      |                      |  |                |               |
| Guideline Type Prior Authorization - All plans except IL and MN |                      |  |                |               |
| Product<br>Name   | Generic Na           | ame                                      | GPI            | Brand/Generic |
| BYETTA  | EXENATIDE            | SOLN PEN-INJECTOR 5 MCG/0.02ML           | 2717002000D220 | Brand         |
| BYETTA  | EXENATIDE            | SOLN PEN-INJECTOR 10 MCG/0.04ML          | 2717002000D240 | Brand         |
| BYDUREON<br>BCISE   | EXENATIDE INJECTOR 2 | EXTENDED RELEASE SUSP AUTO-<br>MG/0.85ML | 2717002000D420 | Brand         |
| TRULICITY   | DULAGLUTI            | DE SOLN PEN-INJECTOR 0.75 MG/0.5ML       | 2717001500D220 | Brand         |
| TRULICITY   | DULAGLUTI            | DE SOLN PEN-INJECTOR 1.5 MG/0.5ML        | 2717001500D230 | Brand         |
| TRULICITY   | DULAGLUTI            | DE SOLN PEN-INJECTOR 3 MG/0.5ML          | 2717001500D240 | Brand         |

| TRULICITY DULAGLUTIDE SOLN PEN-INJECTOR 4.5 MG/0.5M | 1L 2717001500D250 | Brand |
|---|-------------------|-------|
|---|-------------------|-------|

1 - Diagnosis of diabetes mellitus

| Product Name: Byetta, Bydureon, Trulicity |                                       |
|---|---------------------------------------|
| Approval Length                           | 12 month(s)                           |
| Therapy Stage                             | Initial Authorization                 |
| Guideline Type                            | Prior Authorization - IL and MN Plans |

| Product<br>Name   | Generic Name  | GPI            | Brand/Generic |
|-------------------|---|----------------|---------------|
| BYETTA            | EXENATIDE SOLN PEN-INJECTOR 5 MCG/0.02ML                      | 2717002000D220 | Brand         |
| BYETTA            | EXENATIDE SOLN PEN-INJECTOR 10 MCG/0.04ML                     | 2717002000D240 | Brand         |
| BYDUREON<br>BCISE | EXENATIDE EXTENDED RELEASE SUSP AUTO-<br>INJECTOR 2 MG/0.85ML | 2717002000D420 | Brand         |
| TRULICITY         | DULAGLUTIDE SOLN PEN-INJECTOR 0.75 MG/0.5ML                   | 2717001500D220 | Brand         |
| TRULICITY         | DULAGLUTIDE SOLN PEN-INJECTOR 1.5 MG/0.5ML                    | 2717001500D230 | Brand         |
| TRULICITY         | DULAGLUTIDE SOLN PEN-INJECTOR 3 MG/0.5ML                      | 2717001500D240 | Brand         |
| TRULICITY         | DULAGLUTIDE SOLN PEN-INJECTOR 4.5 MG/0.5ML                    | 2717001500D250 | Brand         |

### **Approval Criteria**

BYETTA

1 - Diagnosis of diabetes mellitus

| Product Name: Byetta, Bydureon, Trulicity |  |                                |                |               |
|---|--|--------------------------------|----------------|---------------|
| Approval Le                               | Approval Length 12 month(s)                          |                                |                |               |
| Therapy Sta                               | age  | Reauthorization                |                |               |
| Guideline T                               | Guideline Type Prior Authorization - IL and MN Plans |                                |                |               |
| Product<br>Name                           | Generic Na   | ame                            | GPI            | Brand/Generic |
| BYETTA                                    | EXENATIDE  | SOLN PEN-INJECTOR 5 MCG/0.02ML | 2717002000D220 | Brand         |

EXENATIDE SOLN PEN-INJECTOR 10 MCG/0.04ML

Brand

2717002000D240

| BYDUREON<br>BCISE | EXENATIDE EXTENDED RELEASE SUSP AUTO-<br>INJECTOR 2 MG/0.85ML | 2717002000D420 | Brand |
|-------------------|---|----------------|-------|
| TRULICITY         | DULAGLUTIDE SOLN PEN-INJECTOR 0.75 MG/0.5ML                   | 2717001500D220 | Brand |
| TRULICITY         | DULAGLUTIDE SOLN PEN-INJECTOR 1.5 MG/0.5ML                    | 2717001500D230 | Brand |
| TRULICITY         | DULAGLUTIDE SOLN PEN-INJECTOR 3 MG/0.5ML                      | 2717001500D240 | Brand |
| TRULICITY         | DULAGLUTIDE SOLN PEN-INJECTOR 4.5 MG/0.5ML                    | 2717001500D250 | Brand |

## **1** - Documentation of positive response to therapy

| Notes | *Continuation of therapy/coverage criteria will not be applied to person |
|-------|--|
|       | s who were not previously approved for coverage whose therapy was i      |
|       | nitiated using a manufacturer-sponsored free drug program, provider s    |
|       | amples, and/or vouchers.   |

| Date      | Notes       |
|-----------|-------------|
| 12/7/2023 | New program |

| GNRH Antagonist  |
|--|
| The ball day and briggin. Sels by facilities and creek of date bifs before paint to count or date. |
|  |
|  |

| Guideline ID          | GL-136601       |
|-----------------------|-----------------|
| <b>Guideline Name</b> | GNRH Antagonist |
| Formulary             | Quartz          |

## **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

## 1. Criteria

| Product Name: Myfembree   |           |  |
|---|-----------|--|
| Approval Length   | 2 year(s) |  |
| Guideline Type Prior Authorization - All plans except IL and MN Plans |           |  |
|   |           |  |

| Product<br>Name | Generic Name   | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| MYFEMBREE       | RELUGOLIX-ESTRADIOL-NORETHINDRONE<br>ACETATE TAB 40-1-0.5 MG | 24993503800320 | Brand         |

## **Approval Criteria**

- 1 One of the following:
- **1.1** All of the following:

| <b>1.1.1</b> Diagnosis of heavy menstrual bleeding (menstrual blood loss greater than 80 ml) due to uterine fibroids  |
|---|
| AND   |
| 1.1.2 Member is premenopausal   |
| AND   |
| 1.1.3 Trial and failure, intolerance, or contraindication to two of the following:  |
| <ul> <li>Combined oral contraceptives (e.g., Aubra, Gianvi)</li> <li>Levonorgestrel-releasing intrauterine device (IUD, e.g., Mirena)</li> <li>Tranexamic acid</li> </ul>   |
| OR  |
| 1.2 Both of the following:  |
| <b>1.2.1</b> Diagnosis of moderate to severe pain associated with endometriosis (other than dyspareunia)  |
| AND   |
| 1.2.2 Trial and failure (at least 3 months), intolerance, or contraindication to at least two different continuous hormonal contraceptives in combination with prescription-strength nonsteroidal anti-inflammatory (NSAID) drugs |
| AND   |
| 2 - Prescribed by, or in consultation with, an expert in the treatment of Obstetrics and/or Gynecology  |

| Product Name: Myfembree |                       |
|-------------------------|-----------------------|
| Approval Length         | 12 month(s)           |
| Therapy Stage           | Initial Authorization |

| Guideline Type  |              | Prior Authorization - IL and MN Plans        |                |               |
|-----------------|--------------|--|----------------|---------------|
| Product<br>Name | Generic Name |  | GPI            | Brand/Generic |
| MYFEMBREE       |              | X-ESTRADIOL-NORETHINDRONE<br>FAB 40-1-0.5 MG | 24993503800320 | Brand         |

- 1 One of the following:
- **1.1** All of the following:
- **1.1.1** Diagnosis of heavy menstrual bleeding (menstrual blood loss greater than 80 ml) due to uterine fibroids

**AND** 

**1.1.2** Member is premenopausal

#### **AND**

- **1.1.3** Trial and failure, intolerance, or contraindication to two of the following:
  - Combined oral contraceptives (e.g., Aubra, Gianvi)
  - Levonorgestrel-releasing intrauterine device (IUD, e.g., Mirena)
  - Tranexamic acid

OR

- **1.2** Both of the following:
- **1.2.1** Diagnosis of moderate to severe pain associated with endometriosis (other than dyspareunia)

**AND** 

**1.2.2** Trial and failure (at least 3 months), intolerance, or contraindication to at least two different continuous hormonal contraceptives in combination with prescription-strength

nonsteroidal anti-inflammatory (NSAID) drugs

### AND

**2** - Prescribed by, or in consultation with, an expert in the treatment of Obstetrics and/or Gynecology

| Product Name: Myfembree                              |                               |             |               |
|--|-------------------------------|-------------|---------------|
| Approval Len   | gth                           | 12 month(s) |               |
| Therapy Stag   | Therapy Stage Reauthorization |             |               |
| Guideline Type Prior Authorization - IL and MN Plans |                               |             |               |
| Due direct Con ania Name                             |                               | CDI         | Duand/Canania |

| Product<br>Name | Generic Name   | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| MYFEMBREE       | RELUGOLIX-ESTRADIOL-NORETHINDRONE<br>ACETATE TAB 40-1-0.5 MG | 24993503800320 | Brand         |

### **Approval Criteria**

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug

| Product Name: Orilissa |  |
|------------------------|--|
| Approval Length        | 12/31/2039   |
| Guideline Type         | Prior Authorization - All plans except IL and MN Plans |

| Product<br>Name | Generic Name                            | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| ORILISSA        | ELAGOLIX SODIUM TAB 150 MG (BASE EQUIV) | 30090030100320 | Brand         |
| ORILISSA        | ELAGOLIX SODIUM TAB 200 MG (BASE EQUIV) | 30090030100330 | Brand         |

### **Approval Criteria**

**1** - Diagnosis of moderate to severe pain associated with endometriosis (other than dyspareunia)

**2** - Prescribed by, or in consultation with, an expert in the treatment of Obstetrics and/or Gynecology

#### AND

**3** - Trial and failure (at least 3 months), intolerance, or contraindication to at least two different continuous hormonal contraceptives in combination with prescription-strength nonsteroidal anti-inflammatory (NSAID) drugs

| Product Name: Orilissa |                                       |
|------------------------|---------------------------------------|
| Approval Length        | 12 month(s)                           |
| Therapy Stage          | Initial Authorization                 |
| Guideline Type         | Prior Authorization - IL and MN Plans |

| Product<br>Name | Generic Name                            | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| ORILISSA        | ELAGOLIX SODIUM TAB 150 MG (BASE EQUIV) | 30090030100320 | Brand         |
| ORILISSA        | ELAGOLIX SODIUM TAB 200 MG (BASE EQUIV) | 30090030100330 | Brand         |

### **Approval Criteria**

**1** - Diagnosis of moderate to severe pain associated with endometriosis (other than dyspareunia)

#### AND

**2** - Prescribed by, or in consultation with, an expert in the treatment of Obstetrics and/or Gynecology

#### **AND**

**3** - Trial and failure (at least 3 months), intolerance, or contraindication to at least two different continuous hormonal contraceptives in combination with prescription-strength nonsteroidal anti-inflammatory (NSAID) drugs

| Product Name: Orilissa |                                       |  |
|------------------------|---------------------------------------|--|
| Approval Length        | 12 month(s)                           |  |
| Therapy Stage          | Reauthorization                       |  |
| Guideline Type         | Prior Authorization - IL and MN Plans |  |

| Product<br>Name | Generic Name                            | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| ORILISSA        | ELAGOLIX SODIUM TAB 150 MG (BASE EQUIV) | 30090030100320 | Brand         |
| ORILISSA        | ELAGOLIX SODIUM TAB 200 MG (BASE EQUIV) | 30090030100330 | Brand         |

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug

| Date       | Notes                   |
|------------|-------------------------|
| 11/20/2023 | 2024 New Implementation |

| Hemangeol (propranolo solution 4.28 mg/  |  |  |  |
|--|--|--|--|
| (3) Transferring and the larger Trails are seen as about the larger larg |  |  |  |

| Guideline ID          | GL-131417                                  |  |
|-----------------------|--|--|
| <b>Guideline Name</b> | Hemangeol (propranolo solution 4.28 mg/mL) |  |
| Formulary             | Quartz                                     |  |

## **Guideline Note:**

| Effective Date: | 1/1/2023 |
|-----------------|----------|
|-----------------|----------|

## 1. Criteria

| Product Name: Hemangeol            |  |  |
|------------------------------------|--|--|
| Approval Length 12 month(s)        |  |  |
| Guideline Type Prior Authorization |  |  |
|                                    |  |  |

| Product<br>Name | Generic Name   | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| HEMANGEOL       | PROPRANOLOL HCL ORAL SOLN 4.28 MG/ML (3.75 MG/ML BASE EQUIV) | 33100040102080 | Brand         |

## **Approval Criteria**

**1** - Diagnosis of proliferating infantile hemangioma requiring systemic therapy.

**2** - Therapeutic failure or intolerance to the preferred propranolol solution options at an equivalent dose.

### **AND**

**3** - The prescriber provides an evidence-based clinical rationale as to why the Hemangeol product would be expected to produce superior therapeutic results

| Date       | Notes       |
|------------|-------------|
| 10/24/2023 | New Program |

| Hemlibra (Emicizumab)   |              |  |  |  |
|---|--------------|--|--|--|
| The State Company and the Stagle of The Stagle Company Council, council, a stable level for the Stagle points for | and distance |  |  |  |

| Guideline ID          | GL-129926             |  |
|-----------------------|-----------------------|--|
| <b>Guideline Name</b> | Hemlibra (Emicizumab) |  |
| Formulary             | Quartz                |  |

# **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

## 1. Criteria

| Product Name: Hemlibra |  |  |                |       |
|------------------------|--|--|----------------|-------|
| Approval Length        |  | 12/31/2039   |                |       |
| Guideline Type         |  | Prior Authorization - All plans except IL and MN Plans |                |       |
| Product<br>Name        | Generic Name GPI Brand/Generic   |  |                |       |
| HEMLIBRA               | EMICIZUMAE<br>MG/ML  | 3-KXWH SUBCUTANEOUS SOLN 30                            | 85105030202010 | Brand |
| HEMLIBRA               | EMICIZUMAB-KXWH SUBCUTANEOUS SOLN 60 85105030202020 Brand MG/0.4ML (150 MG/ML) |  | Brand          |       |
| HEMLIBRA               | EMICIZUMAE<br>MG/0.7ML (1  | B-KXWH SUBCUTANEOUS SOLN 105<br>50 MG/ML)              | 85105030202030 | Brand |
| HEMLIBRA               | EMICIZUMAB-KXWH SUBCUTANEOUS SOLN 150 85105030202040 Brand MG/ML               |  | Brand          |       |
|                        |  |  |                | _     |

| Approval Criteria  |
|--|
| 1 - Diagnosis of congenital hemophilia A   |
|  |
| AND  |
| 2 - One of the following:  |
| 2.1 ALL of the following:  |
| 2.1.1 Hemophilia A with inhibitors to Factor VIII  |
|  |
| AND  |
| 2.1.2 Member requires prophylaxis to prevent or reduce bleeding episodes   |
|  |
| AND  |
| 2.4.2 One of the following:  |
| 2.1.3 One of the following:  |
| <ul> <li>Not used in combination with Immune Tolerance Induction (ITI) therapy</li> <li>Member is currently on a bypassing agent (NovoSeven, FEIBA)</li> </ul>   |
|  |
| OR   |
| 2.2 BOTH of the following:   |
| 2.2.1 Hemophilia A without inhibitors  |
|  |
| AND  |
| 2.2.2 One of the following:  |
| <ul> <li>Member requires prophylaxis to prevent or reduce bleeding episodes despite optimal dose/frequency of Factor VIII product</li> <li>Member is unable to administer prophylaxis based on individual patient factors (e.g., IV</li> </ul> |
| • Member is unable to administer propriyaxis based on individual patient factors (e.g., iv   |

access, home administration, etc.)

#### **AND**

3 - Member is followed by a plan approved bleeding disorders program

| Product Name: Hemlibra |  |
|------------------------|--|
| Approval Length        | 12 month(s)                            |
| Therapy Stage          | Initial Authorization                  |
| Guideline Type         | Prior Authorization - IL PPO/POS Plans |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| HEMLIBRA        | EMICIZUMAB-KXWH SUBCUTANEOUS SOLN 30<br>MG/ML                 | 85105030202010 | Brand         |
| HEMLIBRA        | EMICIZUMAB-KXWH SUBCUTANEOUS SOLN 60<br>MG/0.4ML (150 MG/ML)  | 85105030202020 | Brand         |
| HEMLIBRA        | EMICIZUMAB-KXWH SUBCUTANEOUS SOLN 105<br>MG/0.7ML (150 MG/ML) | 85105030202030 | Brand         |
| HEMLIBRA        | EMICIZUMAB-KXWH SUBCUTANEOUS SOLN 150<br>MG/ML                | 85105030202040 | Brand         |

### **Approval Criteria**

1 - Diagnosis of congenital hemophilia A

**AND** 

- 2 One of the following:
- **2.1** ALL of the following:
- 2.1.1 Hemophilia A with inhibitors to Factor VIII

### **AND**

2.1.2 Member requires prophylaxis to prevent or reduce bleeding episodes

### **2.1.3** One of the following:

- Not used in combination with Immune Tolerance Induction (ITI) therapy
- Member is currently on a bypassing agent (NovoSeven, FEIBA)

OR

### **2.2** BOTH of the following:

### 2.2.1 Hemophilia A without inhibitors

#### **AND**

### **2.2.2** One of the following:

- Member requires prophylaxis to prevent or reduce bleeding episodes despite optimal dose/frequency of Factor VIII product
- Member is unable to administer prophylaxis based on individual patient factors (e.g., IV access, home administration, etc.)

#### **AND**

3 - Member is followed by a specialist in bleeding disorders or a bleeding disorders program

| Product Name: Hemlibra |                                |   |   |
|------------------------|--------------------------------|---|---|
| Approval Length        | 12 month(s)                    |   |   |
| Therapy Stage          | Initial Authorization          |   |   |
| Guideline Type         | Prior Authorization - MN Plans |   |   |
|                        |                                | · | _ |

| Product<br>Name | Generic Name                                  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| HEMLIBRA        | EMICIZUMAB-KXWH SUBCUTANEOUS SOLN 30<br>MG/ML | 85105030202010 | Brand         |

| HEMLIBRA | EMICIZUMAB-KXWH SUBCUTANEOUS SOLN 60<br>MG/0.4ML (150 MG/ML)  | 85105030202020 | Brand |
|----------|---|----------------|-------|
| HEMLIBRA | EMICIZUMAB-KXWH SUBCUTANEOUS SOLN 105<br>MG/0.7ML (150 MG/ML) | 85105030202030 | Brand |
| HEMLIBRA | EMICIZUMAB-KXWH SUBCUTANEOUS SOLN 150<br>MG/ML                | 85105030202040 | Brand |

1 - Diagnosis of congenital hemophilia A

**AND** 

- 2 One of the following:
- **2.1** ALL of the following:
- 2.1.1 Hemophilia A with inhibitors to Factor VIII

AND

2.1.2 Member requires prophylaxis to prevent or reduce bleeding episodes

**AND** 

- **2.1.3** One of the following:
  - Not used in combination with Immune Tolerance Induction (ITI) therapy
  - Member is currently on a bypassing agent (NovoSeven, FEIBÁ)

OR

- **2.2** BOTH of the following:
- 2.2.1 Hemophilia A without inhibitors

**AND** 

### **2.2.2** One of the following:

- Member requires prophylaxis to prevent or reduce bleeding episodes despite optimal dose/frequency of Factor VIII product
- Member is unable to administer prophylaxis based on individual patient factors (e.g., IV access, home administration, etc.)

#### **AND**

**3** - Member is followed by a plan approved bleeding disorders program

| Product Name: Hemlibra |                                       |
|------------------------|---------------------------------------|
| Approval Length        | 12 month(s)                           |
| Therapy Stage          | Reauthorization                       |
| Guideline Type         | Prior Authorization - IL and MN Plans |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| HEMLIBRA        | EMICIZUMAB-KXWH SUBCUTANEOUS SOLN 30<br>MG/ML                 | 85105030202010 | Brand         |
| HEMLIBRA        | EMICIZUMAB-KXWH SUBCUTANEOUS SOLN 60<br>MG/0.4ML (150 MG/ML)  | 85105030202020 | Brand         |
| HEMLIBRA        | EMICIZUMAB-KXWH SUBCUTANEOUS SOLN 105<br>MG/0.7ML (150 MG/ML) | 85105030202030 | Brand         |
| HEMLIBRA        | EMICIZUMAB-KXWH SUBCUTANEOUS SOLN 150<br>MG/ML                | 85105030202040 | Brand         |

### **Approval Criteria**

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug

| Date      | Notes                   |
|-----------|-------------------------|
| 8/14/2023 | 2024 New Implementation |

| Hepatitis C Direct Acting Antivirals   |
|--|
| (in the contract of the contra |
|  |

| Guideline ID  | GL-129749 |
|---|-----------|
| Guideline Name Hepatitis C Direct Acting Antivirals |           |
| Formulary   | Quartz    |

# **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

## 1. Criteria

| Product Name: Brand Epclusa, Mavyret  |                                 |  |
|---|---------------------------------|--|
| Diagnosis Post-Transplant   |                                 |  |
| Approval Length 12 months with a fill count = 2-3 fills based on drug regimen reque |                                 |  |
| Guideline Type  | Prior Authorization – IL and MN |  |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| MAVYRET         | GLECAPREVIR-PIBRENTASVIR TAB 100-40 MG 12359902350320 Bra |                | Brand         |
| MAVYRET         | MAVYRET GLECAPREVIR-PIBRENTASVIR PELLET PACK 50-20 MG     |                | Brand         |
| EPCLUSA         | SOFOSBUVIR-VELPATASVIR TAB 200-50 MG                      | 12359902650320 | Brand         |
| EPCLUSA         | SOFOSBUVIR-VELPATASVIR PELLET PACK 200-50 MG              | 12359902653030 | Brand         |
| EPCLUSA         | SOFOSBUVIR-VELPATASVIR PELLET PACK 150-37.5<br>MG         | 12359902653020 | Brand         |

**1** - Member is scheduled to undergo, or is status-post heart, lung, kidney or liver transplant

### **AND**

- **2** Both of the following:
  - HCV antibody (+) donor
  - NAT (+) donor

### **AND**

### 3 - HCV-negative recipients

| to 12 weeks if cannot begin on Day 0 or any interruption in treatment)  ** Members new to the plan who are established on therapy will have  |       |  |
|--|-------|--|
| ent course. Coverage of the drug product will be extended to new mer bers who have already started therapy. Duration of therapy will be det rmined based on the person's indication and accepted treatment course in labeled and/or guideline supported regimens. Restrictions to specific | Notes | *Approval length: Mavyret = 12 weeks, Epclusa = 4 weeks (can extend to 12 weeks if cannot begin on Day 0 or any interruption in treatment)  ** Members new to the plan who are established on therapy will have c overage under their drug benefit for the remainder of the current treatment course. Coverage of the drug product will be extended to new members who have already started therapy. Duration of therapy will be determined based on the person's indication and accepted treatment course in labeled and/or guideline supported regimens. Restrictions to specific network pharmacies and participation in medication management pr |

| Product Name: Brand Epclusa, Mavyret |  |  |                |               |  |
|--------------------------------------|--|--|----------------|---------------|--|
| Diagnosis                            |  | Post-Transplant                                  |                |               |  |
| Approval Length                      |  | 2-3 fills based on drug regimen requested        |                |               |  |
| Guideline Type Prior                 |  | Prior Authorization – All Plans except IL and MN |                |               |  |
| Product<br>Name                      | Generic Name                                     |  | GPI            | Brand/Generic |  |
| MAVYRET                              | GLECAPREVIR-PIBRENTASVIR TAB 100-40 MG           |  | 12359902350320 | Brand         |  |
| MAVYRET                              | GLECAPREVIR-PIBRENTASVIR PELLET PACK 50-20<br>MG |  | 12359902353020 | Brand         |  |
| EPCLUSA                              | SOFOSBUVIR-VELPATASVIR TAB 200-50 MG             |  | 12359902650320 | Brand         |  |
| EPCLUSA                              | SOFOSBUVIR-VELPATASVIR PELLET PACK 200-50 MG     |  | 12359902653030 | Brand         |  |

| EPCLUSA | SOFOSBUVIR-VELPATASVIR PELLET PACK 150-37.5<br>MG | 12359902653020 | Brand |
|---------|---|----------------|-------|
|---------|---|----------------|-------|

**1** - Member is scheduled to undergo, or is status-post heart, lung, kidney or liver transplant

### AND

- 2 Both of the following:
  - HCV antibody (+) donorNAT (+) donor

### **AND**

### 3 - HCV-negative recipients

| Notes | *Approval length: Mavyret = 12 weeks, Epclusa = 4 weeks (can extend to 12 weeks if cannot begin on Day 0 or any interruption in treatment) ** Members new to the plan who are established on therapy will have c overage under their drug benefit for the remainder of the current treatm ent course. Coverage of the drug product will be extended to new mem bers who have already started therapy. Duration of therapy will be dete rmined based on the person's indication and accepted treatment cours e in labeled and/or guideline supported regimens. Restrictions to specific network pharmacies and participation in medication management programs may apply. |
|-------|--|

| Product Name: Non-Preferred Agents: Sovaldi, Viekira Pak, Zepatier |                |  |  |
|--|----------------|--|--|
| Diagnosis Chronic Hepatitis C Virus (HCV)                          |                |  |  |
| Approval Length  | th 12 month(s) |  |  |
| Guideline Type Prior Authorization - IL and MN Plans Only          |                |  |  |

| Product<br>Name | Generic Name                       | GPI            | Brand/Generic |
|-----------------|------------------------------------|----------------|---------------|
| ZEPATIER        | ELBASVIR-GRAZOPREVIR TAB 50-100 MG | 12359902300320 | Brand         |
| SOVALDI         | SOFOSBUVIR TAB 200 MG              | 12353080000310 | Brand         |
| SOVALDI         | SOFOSBUVIR TAB 400 MG              | 12353080000320 | Brand         |

| SOVALDI            | SOFOSBUVIR PELLET PACK 150 MG                               | 12353080003015 | Brand |
|--------------------|---|----------------|-------|
| SOVALDI            | SOFOSBUVIR PELLET PACK 200 MG                               | 12353080003020 | Brand |
| VIEKIRA<br>PAK TAB | OMBITAS-PARITAPRE-RITON & DASAB TAB PAK 12.5-75-50 & 250 MG | 1235990460B720 | Brand |

- **1** Both of the following:
  - Diagnosis of chronic hepatitis C infection
  - HCV infection > 6 months

#### **AND**

- 2 Submission of medical records (e.g., chart notes) documenting ALL of the following:
  - HCV genotype
  - Viral RNA levels measured within the past 3 months prior to initiating therapy
  - Age
  - Past treatment regimens used or documented treatment naïve status
  - Extent of liver disease: non-cirrhotic, compensated cirrhosis (Child-Pugh A), decompensated cirrhosis (ChildPugh B, C)
  - Current renal function
  - NS5A RAS (if indicated to direct treatment)
  - History of liver transplant
  - History of kidney transplant
  - HIV status and therapy

#### **AND**

- **3** One of the following:
- **3.1** Contraindication or intolerance to ALL of the following preferred agents:
  - Mavyret (glecaprevir/pibrentasvir)
  - Ledipasvir/sofosbuvir (Harvoni brand)
  - Sofosbuvir/velpatasvir (Epclusa brand)
  - Vosevi (sofosbuvir/velpatasvir/voxilaprevir)

OR

| <b>3.2</b> The requested non-preferred agent will be used in a patient population that cannot be treated with a preferred agent |   |  |
|---|---|--|
| Notes   | *Approval length: As indicated in package labeling or hcvguidelines.org (the shortest appropriate recommended duration will be approved)  ** Members new to the plan who are established on therapy will have c overage under their drug benefit for the remainder of the current treatm ent course. Coverage of the drug product will be extended to new mem bers who have already started therapy. Duration of therapy will be dete rmined based on the person's indication and accepted treatment cours e in labeled and/or guideline supported regimens. Restrictions to specific network pharmacies and participation in medication management programs may apply. |  |

| Product Name: Non-Preferred Agents: Sovaldi, Viekira Pak, Zepatier |  |           |  |
|--|--|-----------|--|
| Diagnosis  | Chronic Hepatitis C Virus (HCV)  |           |  |
| Approval Length  | *Approval length: As indicated in pac<br>(the shortest appropriate recommend |           |  |
| Guideline Type   | Prior Authorization - All plans except                                       | IL and MN |  |
| Dur to to Consider Name  |  | D         |  |

| Product<br>Name    | Generic Name  | GPI            | Brand/Generic |
|--------------------|---|----------------|---------------|
| ZEPATIER           | ELBASVIR-GRAZOPREVIR TAB 50-100 MG                          | 12359902300320 | Brand         |
| SOVALDI            | SOFOSBUVIR TAB 200 MG                                       | 12353080000310 | Brand         |
| SOVALDI            | SOFOSBUVIR TAB 400 MG                                       | 12353080000320 | Brand         |
| SOVALDI            | SOFOSBUVIR PELLET PACK 150 MG                               | 12353080003015 | Brand         |
| SOVALDI            | SOFOSBUVIR PELLET PACK 200 MG                               | 12353080003020 | Brand         |
| VIEKIRA<br>PAK TAB | OMBITAS-PARITAPRE-RITON & DASAB TAB PAK 12.5-75-50 & 250 MG | 1235990460B720 | Brand         |

- **1** Both of the following:
  - Diagnosis of chronic hepatitis C infection HCV infection > 6 months

## AND

- 2 Submission of medical records (e.g., chart notes) documenting ALL of the following:
  - HCV genotype
  - Viral RNA levels measured within the past 3 months prior to initiating therapy
  - Age
  - Past treatment regimens used or documented treatment naïve status
  - Extent of liver disease: non-cirrhotic, compensated cirrhosis (Child-Pugh A), decompensated cirrhosis (ChildPugh B, C)
  - Current renal function
  - NS5A RAS (if indicated to direct treatment)
  - History of liver transplant
  - History of kidney transplant
  - HIV status and therapy

#### **AND**

- **3** One of the following:
- **3.1** Contraindication or intolerance to ALL of the following preferred agents:
  - Mavyret (glecaprevir/pibrentasvir)
  - Ledipasvir/sofosbuvir (Harvoni brand)
  - Sofosbuvir/velpatasvir (Epclusa brand)
  - Vosevi (sofosbuvir/velpatasvir/voxilaprevir)

#### OR

**3.2** The requested non-preferred agent will be used in a patient population that cannot be treated with a preferred agent

|       | -   |
|-------|---|
| Notes | *Approval length: As indicated in package labeling or hcvguidelines.org (the shortest appropriate recommended duration will be approved)  ** Members new to the plan who are established on therapy will have c overage under their drug benefit for the remainder of the current treatm ent course. Coverage of the drug product will be extended to new mem bers who have already started therapy. Duration of therapy will be dete rmined based on the person's indication and accepted treatment cours e in labeled and/or guideline supported regimens. Restrictions to specific network pharmacies and participation in medication management programs may apply. |

| Product Name: Preferred Agents: Brand Epclusa, Brand Harvoni 90-400 mg, 45-200mg, Mavyret, Vosevi |                                 |
|---|---------------------------------|
| Diagnosis   | Chronic Hepatitis C Virus (HCV) |

| Approval Length | 12 month(s)                              |
|-----------------|--|
| Guideline Type  | Prior Authorization-IL and MN Plans Only |

| Product<br>Name | Generic Name   | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| MAVYRET         | GLECAPREVIR-PIBRENTASVIR TAB 100-40 MG                 | 12359902350320 | Brand         |
| MAVYRET         | GLECAPREVIR-PIBRENTASVIR PELLET PACK 50-20<br>MG       | 12359902353020 | Brand         |
| VOSEVI          | SOFOSBUVIR-VELPATASVIR-VOXILAPREVIR TAB 400-100-100 MG | 12359903800330 | Brand         |
| HARVONI         | LEDIPASVIR-SOFOSBUVIR TAB 90-400 MG                    | 12359902400320 | Generic       |
| EPCLUSA         | SOFOSBUVIR-VELPATASVIR TAB 200-50 MG                   | 12359902650320 | Brand         |
| EPCLUSA         | SOFOSBUVIR-VELPATASVIR PELLET PACK 200-50 MG           | 12359902653030 | Brand         |
| EPCLUSA         | SOFOSBUVIR-VELPATASVIR PELLET PACK 150-37.5<br>MG      | 12359902653020 | Brand         |
| HARVONI         | LEDIPASVIR-SOFOSBUVIR TAB 45-200 MG                    | 12359902400310 | Brand         |
| HARVONI         | LEDIPASVIR-SOFOSBUVIR PELLET PACK 33.75-150 MG         | 12359902403006 | Brand         |
| EPCLUSA         | SOFOSBUVIR-VELPATASVIR TAB 400-100 MG                  | 12359902650330 | Generic       |

- **1** Both of the following:
  - Diagnosis of chronic hepatitis C infection
  - HCV infection > 6 months

### **AND**

- 2 Submission of medical records (e.g., chart notes) documenting ALL of the following:
  - HCV genotype
  - Viral RNA levels measured within the past 3 months prior to initiating therapy
  - Age
  - Past treatment regimens used or documented treatment naïve status
  - Extent of liver disease: non-cirrhotic, compensated cirrhosis (Child-Pugh A), decompensated cirrhosis (ChildPugh B, C)
  - Current renal function
  - NS5A RAS (if indicated to direct treatment)
  - History of liver transplant
  - History of kidney transplant

| HIV status a | and therapy   |
|--------------|---|
| Notes        | *Approval length: As indicated in package labeling or hcvguidelines.org (the shortest appropriate recommended duration will be approved)  ** Members new to the plan who are established on therapy will have c overage under their drug benefit for the remainder of the current treatm ent course. Coverage of the drug product will be extended to new mem bers who have already started therapy. Duration of therapy will be dete rmined based on the person's indication and accepted treatment cours e in labeled and/or guideline supported regimens. Restrictions to specific network pharmacies and participation in medication management programs may apply. |

| Product Name: Preferred Agents: Brand Epclusa, Brand Harvoni 90-400 mg, 45-200mg, Mavyret, Vosevi |  |  |
|---|--|--|
| Diagnosis   | Chronic Hepatitis C Virus (HCV)  |  |
| Approval Length   | *Approval length: As indicated in package labeling or hcvguidelines.org (the shortest appropriate recommended duration will be approved) |  |
| Guideline Type Prior Authorization-All Plans except IL and MN                                     |  |  |

| Product<br>Name | Generic Name   | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| MAVYRET         | GLECAPREVIR-PIBRENTASVIR TAB 100-40 MG                 | 12359902350320 | Brand         |
| MAVYRET         | GLECAPREVIR-PIBRENTASVIR PELLET PACK 50-20<br>MG       | 12359902353020 | Brand         |
| VOSEVI          | SOFOSBUVIR-VELPATASVIR-VOXILAPREVIR TAB 400-100-100 MG | 12359903800330 | Brand         |
| HARVONI         | LEDIPASVIR-SOFOSBUVIR TAB 90-400 MG                    | 12359902400320 | Brand         |
| EPCLUSA         | SOFOSBUVIR-VELPATASVIR TAB 200-50 MG                   | 12359902650320 | Brand         |
| EPCLUSA         | SOFOSBUVIR-VELPATASVIR PELLET PACK 200-50 MG           | 12359902653030 | Brand         |
| EPCLUSA         | SOFOSBUVIR-VELPATASVIR PELLET PACK 150-37.5<br>MG      | 12359902653020 | Brand         |
| HARVONI         | LEDIPASVIR-SOFOSBUVIR TAB 45-200 MG                    | 12359902400310 | Brand         |
| HARVONI         | LEDIPASVIR-SOFOSBUVIR PELLET PACK 33.75-150<br>MG      | 12359902403006 | Brand         |
| EPCLUSA         | SOFOSBUVIR-VELPATASVIR TAB 400-100 MG                  | 12359902650330 | Generic       |

1 - Both of the following:

- Diagnosis of chronic hepatitis C infection
- HCV infection > 6 months

#### **AND**

- 2 Submission of medical records (e.g., chart notes) documenting ALL of the following:
  - HCV genotype
  - Viral RNA levels measured within the past 3 months prior to initiating therapy
  - Age
  - Past treatment regimens used or documented treatment naïve status
  - Extent of liver disease: non-cirrhotic, compensated cirrhosis (Child-Pugh A), decompensated cirrhosis (ChildPugh B, C)
  - Current renal function
  - NS5A RAS (if indicated to direct treatment)
  - History of liver transplant
  - History of kidney transplant
  - HIV status and therapy

| Notes | *Approval length: As indicated in package labeling or hcvguidelines.org (the shortest appropriate recommended duration will be approved)  ** Members new to the plan who are established on therapy will have c overage under their drug benefit for the remainder of the current treatm ent course. Coverage of the drug product will be extended to new mem bers who have already started therapy. Duration of therapy will be determined based on the person's indication and accepted treatment cours e in labeled and/or guideline supported regimens. Restrictions to specific network pharmacies and participation in medication management programs may apply. |
|-------|--|

# 2. Revision History

| Date       | Notes                   |
|------------|-------------------------|
| 10/27/2023 | 2024 New Implementation |

| Hereditary Angioedema (HAE) Medica  | itions |
|---|--------|
| S Indiagnosis shakes with the trade or colds and all the field of the |        |

# **Prior Authorization Guideline**

| Guideline ID          | GL-129772                               |  |
|-----------------------|---|--|
| <b>Guideline Name</b> | Hereditary Angioedema (HAE) Medications |  |
| Formulary             | Quartz                                  |  |

## **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

### Note:

Member is new to the plan (as evidenced by coverage effective date of less than or equal to 90 days) who are established on therapy, will have coverage under their drug benefit for the remainder of the current treatment course. Restrictions to specific network pharmacies and participation in medication management programs may apply.

### 1. Criteria

| Product Name: Berinert, generic icatibant, Ruconest                   |  |            |                |               |
|---|--|------------|----------------|---------------|
| Diagnosis Treatment of Acute Attacks                                  |  |            |                |               |
| Approval Le   | ength  | 12/31/2039 |                |               |
| Guideline Type Prior Authorization - All Plans Except IL and MN Plans |  |            |                |               |
| Product<br>Name   | Generic Name   |            | GPI            | Brand/Generic |
| BERINERT  | C1 ESTERASE INHIBITOR (HUMAN) FOR IV INJ KIT<br>500 UNIT |            | 85802022006420 | Brand         |

| RUCONEST         | C1 ESTERASE INHIBITOR (RECOMBINANT) FOR IV INJ 2100 UNIT  | 85802022102130 | Brand   |
|------------------|---|----------------|---------|
| 11.07.11.27.11.1 | ICATIBANT ACETATE SUBCUTANEOUS SOLN PREF<br>SYR 30 MG/3ML | 8582004010E520 | Generic |

1 - Diagnosis of Hereditary Angioedema (HAE)

AND

- **2** One of the following:
- 2.1 Low C4 AND low C1 inhibitor level or function

OR

- **2.2** Both of the following:
  - Normal C1 inhibitor level with a family history of HAE
  - High dose antihistamines did not control symptoms

#### **AND**

**3** - Prescribed by or in consultation with an allergist or other provider experienced in the treatment of HAE

### **AND**

**4** - All medications that may cause angioedema have been discontinued (e.g., ACE inhibitors, estrogens, ARBs)

#### **AND**

**5** - Requested medication will not be used in combination with other approved treatments for acute attacks

| Product Name: Cinryze |  |  |
|-----------------------|--|--|
| Diagnosis             | Long-Term Prevention/Prophylaxis                       |  |
| Approval Length       | 12/31/2039   |  |
| Guideline Type        | Prior Authorization - All Plans Except IL and MN Plans |  |

| Product<br>Name | Generic Name   | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| CINRYZE         | C1 ESTERASE INHIBITOR (HUMAN) FOR IV INJ 500<br>UNIT | 85802022002120 | Brand         |

1 - Diagnosis of Hereditary Angioedema (HAE)

**AND** 

- 2 One of the following:
  - History of ≥ 2 attacks per month
  - Symptoms are moderate to severe

**AND** 

- 3 One of the following:
- 3.1 Low C4 AND low C1 inhibitor level or function

OR

- **3.2** Both of the following:
  - Normal C1 inhibitor level with a family history of HAE
  - High dose antihistamines did not control symptoms

**AND** 

4 - Prescribed by or in consultation with an allergist or other provider experienced in the

treatment of HAE

#### **AND**

**5** - All medications that may cause angioedema have been discontinued (e.g., ACE inhibitors, estrogens, ARBs)

#### **AND**

**6** - Requested medication will not be used in combination with other approved HAE prevention treatments

#### AND

- **7** Trial and failure (defined as no reduction in frequency of attacks or severity of attacks), contraindication, or intolerance to BOTH of the following:
  - Haegarda
  - Takhzyro

### **AND**

- 8 One of the following:
  - Trial and failure (defined as no reduction in frequency of attacks or severity of attacks), contraindication, or intolerance to Orladeyo
  - Member is between 6 and 12 years of age

| Product Name: Berinert, generic icatibant, Ruconest |            |                                       |     |               |
|---|------------|---------------------------------------|-----|---------------|
| Diagnosis   |            | Treatment of Acute Attacks            |     |               |
| Approval Le   | ength      | 12 month(s)                           |     |               |
| Therapy Sta   | age        | Initial Authorization                 |     |               |
| Guideline T   | уре        | Prior Authorization - IL and MN Plans |     |               |
| Product<br>Name                                     | Generic Na | ame                                   | GPI | Brand/Generic |

| BERINERT             | C1 ESTERASE INHIBITOR (HUMAN) FOR IV INJ KIT<br>500 UNIT  | 85802022006420 | Brand   |
|----------------------|---|----------------|---------|
| RUCONEST             | C1 ESTERASE INHIBITOR (RECOMBINANT) FOR IV INJ 2100 UNIT  | 85802022102130 | Brand   |
| ICATIBANT<br>ACETATE | ICATIBANT ACETATE SUBCUTANEOUS SOLN PREF<br>SYR 30 MG/3ML | 8582004010E520 | Generic |

1 - Diagnosis of Hereditary Angioedema (HAE)

**AND** 

- **2** One of the following:
- **2.1** Low C4 AND low C1 inhibitor level or function

OR

- **2.2** Both of the following:
  - Normal C1 inhibitor level with a family history of HAE
  - High dose antihistamines did not control symptoms

### **AND**

**3** - Prescribed by or in consultation with an allergist or other provider experienced in the treatment of HAE

#### **AND**

**4** - All medications that may cause angioedema have been discontinued (e.g., ACE inhibitors, estrogens, ARBs)

AND

**5** - Requested medication will not be used in combination with other approved treatments for acute attacks

| Product Name: Cinryze |                                       |  |
|-----------------------|---------------------------------------|--|
| Diagnosis             | Long-Term Prevention/Prophylaxis      |  |
| Approval Length       | 12 month(s)                           |  |
| Therapy Stage         | Initial Authorization                 |  |
| Guideline Type        | Prior Authorization - IL and MN Plans |  |

| Product<br>Name | Generic Name   | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| CINRYZE         | C1 ESTERASE INHIBITOR (HUMAN) FOR IV INJ 500<br>UNIT | 85802022002120 | Brand         |

## **Approval Criteria**

1 - Diagnosis of Hereditary Angioedema (HAE)

AND

- **2** One of the following:
  - History of ≥ 2 attacks per month
  - Symptoms are moderate to severe

**AND** 

- **3** One of the following:
- 3.1 Low C4 AND low C1 inhibitor level or function

OR

- **3.2** Both of the following:
  - Normal C1 inhibitor level with a family history of HAE

• High dose antihistamines did not control symptoms

#### **AND**

**4** - Prescribed by or in consultation with an allergist or other provider experienced in the treatment of HAE

#### **AND**

**5** - All medications that may cause angioedema have been discontinued (e.g., ACE inhibitors, estrogens, ARBs)

#### **AND**

**6** - Requested medication will not be used in combination with other approved HAE prevention treatments

#### **AND**

- **7** Trial and failure (defined as no reduction in frequency of attacks or severity of attacks), contraindication, or intolerance to BOTH of the following:
  - Haegarda
  - Takhzyro

#### **AND**

- **8** One of the following:
  - Trial and failure (defined as no reduction in frequency of attacks or severity of attacks), contraindication, or intolerance to Orladeyo
  - Member is between 6 and 12 years of age

| Product Name: Berinert, generic icatibant, Ruconest, Cinryze |                              |
|--|------------------------------|
| Diagnosis  | All Indications Listed Above |

| Approval Length | 12 month(s)                           |
|-----------------|---------------------------------------|
| Therapy Stage   | Reauthorization                       |
| Guideline Type  | Prior Authorization - IL and MN Plans |

| Product<br>Name      | Generic Name  | GPI            | Brand/Generic |
|----------------------|---|----------------|---------------|
| BERINERT             | C1 ESTERASE INHIBITOR (HUMAN) FOR IV INJ KIT 500 UNIT     | 85802022006420 | Brand         |
| RUCONEST             | C1 ESTERASE INHIBITOR (RECOMBINANT) FOR IV INJ 2100 UNIT  | 85802022102130 | Brand         |
| ICATIBANT<br>ACETATE | ICATIBANT ACETATE SUBCUTANEOUS SOLN PREF<br>SYR 30 MG/3ML | 8582004010E520 | Generic       |
| CINRYZE              | C1 ESTERASE INHIBITOR (HUMAN) FOR IV INJ 500<br>UNIT      | 85802022002120 | Brand         |

1 - For members new to plan\* (as evidenced by coverage effective date of less than or equal to 90 days)\*\*: Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member has experienced positive clinical response to therapy with the requested drug

#### OR

**2** - For members requesting renewal (reauthorization): Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member has experienced positive clinical response to therapy with the requested drug

| Notes | *Member is new to the plan (as evidenced by coverage effective date of less than or equal to 90 days) who are established on therapy, will have coverage under their drug benefit for the remainder of the current treatment course. Restrictions to specific network pharmacies and participation in medication management programs may apply. |
|-------|---|
|       | **Member new to the plan (as evidenced by coverage effective date of less than or equal to 90 days) who initiated therapy using a manufactur er-sponsored free drug program, provider samples, and/or vouchers wil I go through initial criteria, otherwise for continuation of therapy for new to plan, reauthorization criteria applies       |

| Product Name: Haegarda, Orladeyo, Takhzyro |                                  |
|--|----------------------------------|
| Diagnosis                                  | Long-Term Prevention/Prophylaxis |

| Approval Length | 6 month(s)                                       |
|-----------------|--|
| Therapy Stage   | Initial Authorization                            |
| Guideline Type  | Prior Authorization - All Plans Except IL and MN |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| HAEGARDA        | C1 ESTERASE INHIBITOR (HUMAN) FOR<br>SUBCUTANEOUS INJ 2000 UNIT | 85802022002130 | Brand         |
| HAEGARDA        | C1 ESTERASE INHIBITOR (HUMAN) FOR SUBCUTANEOUS INJ 3000 UNIT    | 85802022002140 | Brand         |
| TAKHZYRO        | LANADELUMAB-FLYO SOLN PREF SYRINGE 150<br>MG/ML                 | 8584204020E510 | Brand         |
| TAKHZYRO        | LANADELUMAB-FLYO SOLN PREF SYRINGE 300<br>MG/2ML (150 MG/ML)    | 8584204020E520 | Brand         |
| TAKHZYRO        | LANADELUMAB-FLYO INJ 300 MG/2ML (150 MG/ML)                     | 85842040202020 | Brand         |
| ORLADEYO        | BEROTRALSTAT HCL CAP 110 MG                                     | 85840010200120 | Brand         |
| ORLADEYO        | BEROTRALSTAT HCL CAP 150 MG                                     | 85840010200130 | Brand         |

1 - Diagnosis of Hereditary Angioedema (HAE)

AND

- **2** One of the following:
  - History of ≥ 2 attacks per month
  - Symptoms are moderate to severe

**AND** 

- **3** One of the following:
  - **3.1** Low C4 AND low C1 inhibitor level or function

OR

**3.2** Both of the following:

- Normal C1 inhibitor level with a family history of HAE
- High dose antihistamines did not control symptoms

### **AND**

**4** - Prescribed by or in consultation with an allergist or other provider experienced in the treatment of HAE

#### **AND**

**5** - All medications that may cause angioedema have been discontinued (e.g., ACE inhibitors, estrogens, ARBs)

#### **AND**

**6** - Requested medication will not be used in combination with other approved HAE prevention treatments

| Product Name: Haegarda, Orladeyo, Takhzyro |  |
|--|--|
| Diagnosis Long Term Prevention/Prophylaxis |  |
| Approval Length                            | 6 month(s)                                       |
| Therapy Stage                              | Reauthorization                                  |
| Guideline Type                             | Prior Authorization - All Plans Except IL and MN |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| HAEGARDA        | C1 ESTERASE INHIBITOR (HUMAN) FOR<br>SUBCUTANEOUS INJ 2000 UNIT | 85802022002130 | Brand         |
| HAEGARDA        | C1 ESTERASE INHIBITOR (HUMAN) FOR<br>SUBCUTANEOUS INJ 3000 UNIT | 85802022002140 | Brand         |
| TAKHZYRO        | LANADELUMAB-FLYO SOLN PREF SYRINGE 150<br>MG/ML                 | 8584204020E510 | Brand         |
| TAKHZYRO        | LANADELUMAB-FLYO SOLN PREF SYRINGE 300<br>MG/2ML (150 MG/ML)    | 8584204020E520 | Brand         |
| TAKHZYRO        | LANADELUMAB-FLYO INJ 300 MG/2ML (150 MG/ML)                     | 85842040202020 | Brand         |
| ORLADEYO        | BEROTRALSTAT HCL CAP 110 MG                                     | 85840010200120 | Brand         |

| ORLADEYO BEROTRALSTAT HCL CAP 150 MG | 85840010200130 | Brand |
|--------------------------------------|----------------|-------|
|--------------------------------------|----------------|-------|

1 - For members new to plan\* (as evidenced by coverage effective date of less than or equal to 90 days)\*\*: Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member has experienced positive clinical response to therapy with the requested drug

#### **OR**

- 2 For members requesting renewal (reauthorization), ALL of the following:
- **2.1** Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member has experienced positive clinical response to therapy with the requested drug

#### **AND**

**2.2** For Takhzyro and Orladeyo requests ONLY: Submission of medical records (e.g., chart notes) supporting member has experienced no attacks during the preceding 12 months

### **AND**

**2.3** For Haegarda requests ONLY: Confirmation there are no weight changes warranting different quantity limits

| Notes | Member is new to the plan (as evidenced by coverage effective date of less than or equal to 90 days) who are established on therapy, will hav e coverage under their drug benefit for the remainder of the current tre atment course. Restrictions to specific network pharmacies and particip ation in medication management programs may apply. |
|-------|---|
|       | **Member new to the plan (as evidenced by coverage effective date of less than or equal to 90 days) who initiated therapy using a manufactur er-sponsored free drug program, provider samples, and/or vouchers wil I go through initial criteria, otherwise for continuation of therapy for new to plan, reauthorization criteria applies         |

Product Name: Haegarda, Orladeyo, Takhzyro

| Diagnosis       | Long-Term Prevention/Prophylaxis           |
|-----------------|--|
| Approval Length | 12 month(s)                                |
| Therapy Stage   | Initial Authorization                      |
| Guideline Type  | Prior Authorization - IL and MN Plans Only |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| HAEGARDA        | C1 ESTERASE INHIBITOR (HUMAN) FOR<br>SUBCUTANEOUS INJ 2000 UNIT | 85802022002130 | Brand         |
| HAEGARDA        | C1 ESTERASE INHIBITOR (HUMAN) FOR<br>SUBCUTANEOUS INJ 3000 UNIT | 85802022002140 | Brand         |
| TAKHZYRO        | LANADELUMAB-FLYO SOLN PREF SYRINGE 150<br>MG/ML                 | 8584204020E510 | Brand         |
| TAKHZYRO        | LANADELUMAB-FLYO SOLN PREF SYRINGE 300<br>MG/2ML (150 MG/ML)    | 8584204020E520 | Brand         |
| TAKHZYRO        | LANADELUMAB-FLYO INJ 300 MG/2ML (150 MG/ML)                     | 85842040202020 | Brand         |
| ORLADEYO        | BEROTRALSTAT HCL CAP 110 MG                                     | 85840010200120 | Brand         |
| ORLADEYO        | BEROTRALSTAT HCL CAP 150 MG                                     | 85840010200130 | Brand         |

1 - Diagnosis of Hereditary Angioedema (HAE)

AND

- **2** One of the following:

  - History of ≥ 2 attacks per month Symptoms are moderate to severe

**AND** 

- **3** One of the following:
- 3.1 Low C4 AND low C1 inhibitor level or function

OR

### **3.2** Both of the following:

- Normal C1 inhibitor level with a family history of HAE
- High dose antihistamines did not control symptoms

#### **AND**

**4** - Prescribed by or in consultation with an allergist or other provider experienced in the treatment of HAE

#### **AND**

**5** - All medications that may cause angioedema have been discontinued (e.g., ACE inhibitors, estrogens, ARBs)

#### **AND**

**6** - Requested medication will not be used in combination with other approved HAE prevention treatments

| Product Name: Haegarda, Orladeyo, Takhzyro |                                       |  |
|--|---------------------------------------|--|
| Diagnosis                                  | Long Term Prevention/Prophylaxis      |  |
| Approval Length                            | 12 month(s)                           |  |
| Therapy Stage                              | Reauthorization                       |  |
| Guideline Type                             | Prior Authorization - IL and MN Plans |  |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| HAEGARDA        | C1 ESTERASE INHIBITOR (HUMAN) FOR<br>SUBCUTANEOUS INJ 2000 UNIT | 85802022002130 | Brand         |
| HAEGARDA        | C1 ESTERASE INHIBITOR (HUMAN) FOR<br>SUBCUTANEOUS INJ 3000 UNIT | 85802022002140 | Brand         |
| TAKHZYRO        | LANADELUMAB-FLYO SOLN PREF SYRINGE 150<br>MG/ML                 | 8584204020E510 | Brand         |
| TAKHZYRO        | LANADELUMAB-FLYO SOLN PREF SYRINGE 300<br>MG/2ML (150 MG/ML)    | 8584204020E520 | Brand         |
| TAKHZYRO        | LANADELUMAB-FLYO INJ 300 MG/2ML (150 MG/ML)                     | 85842040202020 | Brand         |

| ORLADEYO | BEROTRALSTAT HCL CAP 110 MG | 85840010200120 | Brand |
|----------|-----------------------------|----------------|-------|
| ORLADEYO | BEROTRALSTAT HCL CAP 150 MG | 85840010200130 | Brand |

1 - For members new to plan\* (as evidenced by coverage effective date of less than or equal to 90 days)\*\*: Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member has experienced positive clinical response to therapy with the requested drug

#### OR

- 2 For members requesting renewal (reauthorization), ALL of the following:
- **2.1** Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member has experienced positive clinical response to therapy with the requested drug

#### **AND**

**2.2** For Takhzyro and Orladeyo requests ONLY: Submission of medical records (e.g., chart notes) supporting member has experienced no attacks during the preceding 12 months

#### **AND**

**2.3** For Haegarda requests ONLY: Confirmation there are no weight changes warranting different quantity limits

| Notes | Member is new to the plan (as evidenced by coverage effective date of less than or equal to 90 days) who are established on therapy, will hav e coverage under their drug benefit for the remainder of the current tre atment course. Restrictions to specific network pharmacies and particip ation in medication management programs may apply. |
|-------|---|
|       | **Member new to the plan (as evidenced by coverage effective date of less than or equal to 90 days) who initiated therapy using a manufactur er-sponsored free drug program, provider samples, and/or vouchers wil I go through initial criteria, otherwise for continuation of therapy for new to plan, reauthorization criteria applies         |

# 2. Revision History

| Date       | Notes                   |
|------------|-------------------------|
| 10/25/2023 | 2024 New Implementation |

| Hetlioz (tasimelteon) |  |  |  |  |  |
|-----------------------|--|--|--|--|--|
| The bit and image can | nei bedigigger. Thefis may have been moved, we wond, or dide | ted. Verily that he led problem the convertile and invation. |  |  |  |
|                       |  |  |  |  |  |

# **Prior Authorization Guideline**

| Guideline ID          | GL-131133             |
|-----------------------|-----------------------|
| <b>Guideline Name</b> | Hetlioz (tasimelteon) |
| Formulary             | Quartz                |

# **Guideline Note:**

| Effective Date: |
|-----------------|
|-----------------|

# 1. Criteria

| Product Name: Generic tasimelteon, Hetlioz LQ                         |  |  |
|---|--|--|
| Approval Length 12/31/2039  |  |  |
| Guideline Type Prior Authorization - ALL Plans Except IL and MN Plans |  |  |

| Product<br>Name | Generic Name                  | GPI            | Brand/Generic |
|-----------------|-------------------------------|----------------|---------------|
| TASIMELTEON     | TASIMELTEON CAPSULE 20 MG     | 60250070000130 | Generic       |
| HETLIOZ LQ      | TASIMELTEON ORAL SUSP 4 MG/ML | 60250070001820 | Brand         |

# **Approval Criteria**

- 1 One of the following:
- **1.1** Both of the following:

1.1.1 Diagnosis of Smith-Magenis syndrome

#### AND

**1.1.2** Trial and failure, contraindication, or intolerance to 3 months of melatonin

OR

- **1.2** All of the following:
- **1.2.1** Diagnosis of a non-24-hour sleep-wake disorder

#### **AND**

1.2.2 Member is completely blind

#### **AND**

1.2.3 Trial and failure, contraindication, or intolerance to 3 months of generic ramelteon

### **AND**

**1.2.4** Prescribed by, or in consultation with a sleep specialist

| Product Name: Generic tasimelteon, Hetlioz LQ |                                       |  |
|---|---------------------------------------|--|
| Approval Length 12 month(s)                   |                                       |  |
| Therapy Stage                                 | Initial Authorization                 |  |
| Guideline Type                                | Prior Authorization - IL and MN Plans |  |

| Product<br>Name | Generic Name                  | GPI            | Brand/Generic |
|-----------------|-------------------------------|----------------|---------------|
| TASIMELTEON     | TASIMELTEON CAPSULE 20 MG     | 60250070000130 | Generic       |
| HETLIOZ LQ      | TASIMELTEON ORAL SUSP 4 MG/ML | 60250070001820 | Brand         |
|                 |                               |                |               |

| Approval Criteria  |
|--|
| 1 - One of the following:  |
| 1.1 Both of the following:   |
| 1.1.1 Diagnosis of Smith-Magenis syndrome  |
| AND  |
| 1.1.2 Trial and failure, contraindication, or intolerance to 3 months of melatonin         |
| OR   |
| 1.2 All of the following:  |
| 1.2.1 Diagnosis of a non-24-hour sleep-wake disorder                                       |
| AND  |
| 1.2.2 Member is completely blind   |
| AND  |
| 1.2.3 Trial and failure, contraindication, or intolerance to 3 months of generic ramelteon |
| AND  |

| Product Name: Generic tasimelteon, Hetlioz LQ |             |
|---|-------------|
| Approval Length                               | 12 month(s) |

\*Members new to the plan (as evidenced by coverage effective date of less than or equal to 90 days) must meet the initial criteria for coverage

1.2.4 Prescribed by, or in consultation with a sleep specialist

Notes

| Therapy Stage  | Reauthorization                       |
|----------------|---------------------------------------|
| Guideline Type | Prior Authorization - IL and MN Plans |

| Product<br>Name | Generic Name                  | GPI            | Brand/Generic |
|-----------------|-------------------------------|----------------|---------------|
| TASIMELTEON     | TASIMELTEON CAPSULE 20 MG     | 60250070000130 | Generic       |
| HETLIOZ LQ      | TASIMELTEON ORAL SUSP 4 MG/ML | 60250070001820 | Brand         |

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug

| Notes | *Members new to the plan (as evidenced by coverage effective date of       |
|-------|--|
|       | less than or equal to 90 days) must meet the initial criteria for coverage |

# 2. Revision History

| Date      | Notes                   |
|-----------|-------------------------|
| 10/6/2023 | 2024 New Implementation |

| Human Chorionic Gonadotropin (Novarel, Pregnyl equivalents) and Clomiphene (Clomid) Prior A |  |  |  |  |  |
|---|--|--|--|--|--|
|   | The bill and appeared to displayed. To be the second service, a classed with place the provide and business. |  |  |  |  |
|   |  |  |  |  |  |

# **Prior Authorization Guideline**

| Guideline ID | GL-129112  |
|--------------|--|
|              | Human Chorionic Gonadotropin (Novarel, Pregnyl equivalents) and Clomiphene (Clomid) Prior Auth |
| Formulary    | Quartz   |

# **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

# 1. Criteria

| Product Name: Clomid |   |  |
|----------------------|---|--|
| Approval Length      | 12/31/2039  |  |
| Guideline Type       | Prior Authorization - All Plans Except IL and MN Plans* |  |
|                      |   |  |

| Product Generic Name<br>Name |        | Generic Name                 | GPI            | Brand/Generic |
|------------------------------|--------|------------------------------|----------------|---------------|
| C                            | CLOMID | CLOMIPHENE CITRATE TAB 50 MG | 30066030100305 | Brand         |

# **Approval Criteria**

- **1** All of the following:
- 1.1 Diagnosis of hypogonadism not seeking fertility treatment

#### **AND**

**1.2** Submission of medical records (e.g., chart notes) documenting two low morning testosterone levels (or within 3 hours of waking for shift workers) including the normal ranges for the laboratory

#### **AND**

**1.3** Submission of medical records (e.g., chart notes) documenting symptoms due to low testosterone other than sexual dysfunction or decreased libido

#### OR

**2** - Submission of medical records (e.g., chart notes) documenting reduction of the uterine lining or fibroid size prior to surgical procedures, unrelated to infertility (e.g., endometriosis, uterine fibroids)

| Notes | *Coverage of clomiphene for use in infertility is limited to members who have the artificial insemination rider attached to their benefit and coverage is limited to the |
|-------|--|
|       | e duration and cost share amounts as defined in the rider.   |

| Product Name: Clomid |  |  |
|----------------------|--|--|
| Approval Length      | 12 month(s)                            |  |
| Therapy Stage        | Initial Authorization                  |  |
| Guideline Type       | Prior Authorization - IL and MN Plans* |  |

| Product<br>Name | Generic Name                 | GPI            | Brand/Generic |
|-----------------|------------------------------|----------------|---------------|
| CLOMID          | CLOMIPHENE CITRATE TAB 50 MG | 30066030100305 | Brand         |

### **Approval Criteria**

- **1** All of the following:
- 1.1 Diagnosis of hypogonadism not seeking fertility treatment

#### **AND**

**1.2** Submission of medical records (e.g., chart notes) documenting two low morning testosterone levels (or within 3 hours of waking for shift workers) including the normal ranges for the laboratory

#### **AND**

**1.3** Submission of medical records (e.g., chart notes) documenting symptoms due to low testosterone other than sexual dysfunction or decreased libido

#### OR

**2** - Submission of medical records (e.g., chart notes) documenting reduction of the uterine lining or fibroid size prior to surgical procedures, unrelated to infertility (e.g., endometriosis, uterine fibroids)

#### OR

- 3 For Illinois Plans Only: All of the following:
- 3.1 Member has Quartz plan issued in the state of Illinois

#### AND

3.2 Infertility coverage as outlined in Illinois Insurance Code 215 ILCS 5/356m

| Notes | *Coverage of clomiphene for use in infertility for MN plans is limited to members who have the artificial insemination rider attached to their benefit and coverage is limited to the duration and cost share amounts as defined in the rider. |
|-------|--|
|-------|--|

| Product Name: Clomid        |                 |  |
|-----------------------------|-----------------|--|
| Approval Length 12 month(s) |                 |  |
| Therapy Stage               | Reauthorization |  |

| Guideline Type            |                                    | Prior Authorization - IL and MN Plans* |                |       |
|---------------------------|------------------------------------|--|----------------|-------|
| Product Generic Name Name |                                    | GPI                                    | Brand/Generic  |       |
| CLOMID                    | LOMID CLOMIPHENE CITRATE TAB 50 MG |  | 30066030100305 | Brand |

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug

| Notes | *Coverage of clomiphene for use in infertility for MN plans is limited to members who have the artificial insemination rider attached to their benefit and coverage is limited to the duration and cost share amounts as defined in |
|-------|---|
| Notes | members who have the artificial insemination rider attached to their benefit and coverage is limited to   |

| Product Name: Human Chorionic Gonadotropin                             |  |  |  |
|--|--|--|--|
| Approval Length 12/31/2039   |  |  |  |
| Guideline Type Prior Authorization - All Plans Except IL and MN Plans* |  |  |  |

| Product Name                                   | Generic Name                                    | GPI            | Brand/Generic |
|--|---|----------------|---------------|
| NOVAREL  | CHORIONIC GONADOTROPIN FOR IM INJ 5000 UNIT     | 30062020002130 | Brand         |
| NOVAREL  | CHORIONIC GONADOTROPIN FOR IM INJ 10000<br>UNIT | 30062020002140 | Brand         |
| PREGNYL<br>W/DILUENT<br>BENZYL<br>ALCOHOL/NACL | CHORIONIC GONADOTROPIN FOR IM INJ 10000<br>UNIT | 30062020002140 | Brand         |
| CHORIONIC<br>GONADOTROPIN                      | CHORIONIC GONADOTROPIN FOR IM INJ 10000<br>UNIT | 30062020002140 | Brand         |

## **Approval Criteria**

1 - Diagnosis of hypogonadism not seeking fertility treatment

#### AND

**2** - Submission of medical records (e.g., chart notes) documenting two low morning testosterone levels (or within 3 hours of waking for shift workers) including the normal ranges

for the laboratory

#### **AND**

**3** - Submission of medical records (e.g., chart notes) documenting symptoms due to low testosterone other than sexual dysfunction or decreased libido

### **AND**

4 - Trial and failure, contraindication or intolerance to clomiphene

### **AND**

**5** - The drug is being self-administered by the individual and not by a health care professional

| Notes | *Coverage of chorionic gonadotropin for the treatment of hypogonadis m is limited to the prescription drug benefit and not covered on the medical benefit. Chorionic gonadotropin is covered on the medical benefit without restriction for indications that are not excluded from coverage based by the plan ben efits (e.g. treatment of prepuberal cryptorchidism). Diagnoses such as the treatment of infertility are excluded from coverage. |
|-------|---|
|       | ded from coverage.  |

| Product Name: Human Chorionic Gonadotropin            |  |  |
|---|--|--|
| Approval Length 12 month(s)                           |  |  |
| Therapy Stage Initial Authorization                   |  |  |
| Guideline Type Prior Authorization - IL and MN Plans* |  |  |

| Product Name                                   | Generic Name                                    | GPI            | Brand/Generic |
|--|---|----------------|---------------|
| NOVAREL  | CHORIONIC GONADOTROPIN FOR IM INJ 5000<br>UNIT  | 30062020002130 | Brand         |
| NOVAREL  | CHORIONIC GONADOTROPIN FOR IM INJ 10000<br>UNIT | 30062020002140 | Brand         |
| PREGNYL<br>W/DILUENT<br>BENZYL<br>ALCOHOL/NACL | CHORIONIC GONADOTROPIN FOR IM INJ 10000<br>UNIT | 30062020002140 | Brand         |
| CHORIONIC<br>GONADOTROPIN                      | CHORIONIC GONADOTROPIN FOR IM INJ 10000<br>UNIT | 30062020002140 | Brand         |

| Approval Criteria   |
|---|
| 1 - All of the following must be met:   |
| 1.1 Diagnosis of hypogonadism not seeking fertility treatment   |
| AND   |
| <b>1.2</b> Submission of medical records (e.g., chart notes) documenting two low morning testosterone levels (or within 3 hours of waking for shift workers) including the normal ranges for the laboratory |
| AND   |
| <b>1.3</b> Submission of medical records (e.g., chart notes) documenting symptoms due to low testosterone other than sexual dysfunction or decreased libido   |
| AND   |
| 1.4 Trial and failure, contraindication or intolerance to clomiphene  |
| AND   |
| 1.5 The drug is being self-administered by the individual and not by a health care professional   |
| OR  |
| 2 - For Illinois Plans Only : All of the following:   |
| 2.1 Member has Quartz plan issued in the state of Illinois  |

AND

2.2 Infertility coverage as outlined in Illinois Insurance Code 215 ILCS 5/356m

| Notes | *Coverage of chorionic gonadotropin for the treatment of hypogonadis m is limited to the prescription drug benefit and not covered on the medical benefit. Chorionic gonadotropin is covered on the medical benefit without restriction for indications that are not excluded from coverage based by the plan ben efits (e.g. treatment of prepuberal cryptorchidism). Diagnoses such as the treatment of infertility are excluded from coverage.  *Members new to the plan (as evidenced by coverage effective date of less than or equal to 90 days) must meet initial criteria for coverage |
|-------|--|
|-------|--|

| Product Name: Human Chorionic Gonadotropin            |                          |  |  |  |
|---|--------------------------|--|--|--|
| Approval Length                                       | roval Length 12 month(s) |  |  |  |
| Therapy Stage   | Reauthorization          |  |  |  |
| Guideline Type Prior Authorization - IL and MN Plans* |                          |  |  |  |

| Product Name                                   | Generic Name                                    | GPI            | Brand/Generic |
|--|---|----------------|---------------|
| CLOMID   | CLOMIPHENE CITRATE TAB 50 MG                    | 30066030100305 | Brand         |
| NOVAREL  | CHORIONIC GONADOTROPIN FOR IM INJ 5000<br>UNIT  | 30062020002130 | Brand         |
| NOVAREL  | CHORIONIC GONADOTROPIN FOR IM INJ 10000<br>UNIT | 30062020002140 | Brand         |
| PREGNYL<br>W/DILUENT<br>BENZYL<br>ALCOHOL/NACL | CHORIONIC GONADOTROPIN FOR IM INJ 10000<br>UNIT | 30062020002140 | Brand         |
| CHORIONIC<br>GONADOTROPIN                      | CHORIONIC GONADOTROPIN FOR IM INJ 10000<br>UNIT | 30062020002140 | Brand         |

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug

| Notes | *Coverage of chorionic gonadotropin for the treatment of hypogonadis m is limited to the prescription drug benefit and not covered on the medical benefit. Chorionic gonadotropin is covered on the medical benefit without restriction for indications that are not excluded from coverage based by the plan ben efits (e.g. treatment of prepuberal cryptorchidism). Diagnoses such as the treatment of infertility are excluded from coverage.  *Members new to the plan (as evidenced by coverage effective date of less than or equal to 90 days) must meet initial criteria for coverage |
|-------|--|
|-------|--|

# 2. Revision History

| Date     | Notes                   |
|----------|-------------------------|
| 9/8/2023 | 2024 New Implementation |

| Hydrod   | codone ER   |                  |  |
|--|---|------------------|--|
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# **Prior Authorization Guideline**

| Guideline ID          | GL-127837      |
|-----------------------|----------------|
| <b>Guideline Name</b> | Hydrocodone ER |
| Formulary             | Quartz         |

# **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

# 1. Criteria

| Product Name: Generic Hydrocodone ER          |  |  |  |
|---|--|--|--|
| Approval Length 12 month(s)                   |  |  |  |
| Therapy Stage Initial Authorization           |  |  |  |
| Guideline Type Step Therapy - IL and MN Plans |  |  |  |
|   |  |  |  |

| Product Name                 | Generic Name                                | GPI            | Brand/Generic |
|------------------------------|---|----------------|---------------|
| HYDROCODONE<br>BITARTRATE ER | HYDROCODONE BITARTRATE CAP ER 12HR 10<br>MG | 65100030106910 | Generic       |
| HYDROCODONE<br>BITARTRATE ER | HYDROCODONE BITARTRATE CAP ER 12HR 15<br>MG | 65100030106915 | Generic       |
| HYDROCODONE<br>BITARTRATE ER | HYDROCODONE BITARTRATE CAP ER 12HR 20<br>MG | 65100030106920 | Generic       |
| HYDROCODONE<br>BITARTRATE ER | HYDROCODONE BITARTRATE CAP ER 12HR 30<br>MG | 65100030106930 | Generic       |
| HYDROCODONE<br>BITARTRATE ER | HYDROCODONE BITARTRATE CAP ER 12HR 40<br>MG | 65100030106940 | Generic       |

| HYDROCODONE<br>BITARTRATE ER | HYDROCODONE BITARTRATE CAP ER 12HR 50<br>MG | 65100030106950 | Generic |
|------------------------------|---|----------------|---------|
|                              | INIG  |                |         |

- 1 Trial and failure of at least 2 of the following preferred long-acting opioids:
  - morphine ERT (generic of MS Contin)
  - morphine ERC (generic of Kadian)
  - Oxycodone ER (Oxycontin)

OR

**2** - For Minnesota Plans step therapy does not apply if member has stage four metastatic cancer and the requested drug is being used to treat cancer-related pain

| Product Name: Generic Hydrocodone ER |                                |  |
|--------------------------------------|--------------------------------|--|
| Approval Length                      | 12 month(s)                    |  |
| Therapy Stage                        | Reauthorization                |  |
| Guideline Type                       | Step Therapy - IL and MN Plans |  |

| Product Name                 | Generic Name                                | GPI            | Brand/Generic |
|------------------------------|---|----------------|---------------|
| HYDROCODONE<br>BITARTRATE ER | HYDROCODONE BITARTRATE CAP ER 12HR 10<br>MG | 65100030106910 | Generic       |
| HYDROCODONE<br>BITARTRATE ER | HYDROCODONE BITARTRATE CAP ER 12HR 15<br>MG | 65100030106915 | Generic       |
| HYDROCODONE<br>BITARTRATE ER | HYDROCODONE BITARTRATE CAP ER 12HR 20<br>MG | 65100030106920 | Generic       |
| HYDROCODONE<br>BITARTRATE ER | HYDROCODONE BITARTRATE CAP ER 12HR 30<br>MG | 65100030106930 | Generic       |
| HYDROCODONE<br>BITARTRATE ER | HYDROCODONE BITARTRATE CAP ER 12HR 40<br>MG | 65100030106940 | Generic       |
| HYDROCODONE<br>BITARTRATE ER | HYDROCODONE BITARTRATE CAP ER 12HR 50<br>MG | 65100030106950 | Generic       |

### **Approval Criteria**

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug

| Product Name: Generic Hydrocodone ER |   |  |
|--------------------------------------|---|--|
| Approval Length                      | 12/31/2039                                      |  |
| Guideline Type                       | Step Therapy - All plans except IL and MN Plans |  |

| Product Name                 | Generic Name                                | GPI            | Brand/Generic |
|------------------------------|---|----------------|---------------|
| HYDROCODONE<br>BITARTRATE ER | HYDROCODONE BITARTRATE CAP ER 12HR 10<br>MG | 65100030106910 | Generic       |
| HYDROCODONE<br>BITARTRATE ER | HYDROCODONE BITARTRATE CAP ER 12HR 15<br>MG | 65100030106915 | Generic       |
| HYDROCODONE<br>BITARTRATE ER | HYDROCODONE BITARTRATE CAP ER 12HR 20<br>MG | 65100030106920 | Generic       |
| HYDROCODONE<br>BITARTRATE ER | HYDROCODONE BITARTRATE CAP ER 12HR 30<br>MG | 65100030106930 | Generic       |
| HYDROCODONE<br>BITARTRATE ER | HYDROCODONE BITARTRATE CAP ER 12HR 40<br>MG | 65100030106940 | Generic       |
| HYDROCODONE<br>BITARTRATE ER | HYDROCODONE BITARTRATE CAP ER 12HR 50<br>MG | 65100030106950 | Generic       |

- **1** Trial and failure of at least 2 of the following preferred long-acting opioids:
  - morphine ERT (generic of MS Contin) morphine ERC (generic of Kadian) Oxycodone ER (Oxycontin)

# 2. Revision History

| Date      | Notes       |
|-----------|-------------|
| 8/25/2023 | New Program |

| ١ | Inbrija (Levodopa inhalation powder)  |  |  |
|---|---|--|--|
|   | Thistory were induper. Toking twice county or sizes only fall below proach to worth sortales. |  |  |
|   |   |  |  |

| Guideline ID          | GL-129635                            |
|-----------------------|--------------------------------------|
| <b>Guideline Name</b> | Inbrija (Levodopa inhalation powder) |
| Formulary             | Quartz                               |

# **Guideline Note:**

| Effective Date: |
|-----------------|
|-----------------|

# 1. Criteria

| Product Name: Inbrija |                                       |
|-----------------------|---------------------------------------|
| Approval Length       | 12 month(s)                           |
| Therapy Stage         | Initial Authorization                 |
| Guideline Type        | Prior Authorization - IL and MN Plans |

| Product<br>Name | Generic Name                    | GPI            | Brand/Generic |
|-----------------|---------------------------------|----------------|---------------|
| INBRIJA         | LEVODOPA INHAL POWDER CAP 42 MG | 73200040000160 | Brand         |

# **Approval Criteria**

1 - Diagnosis of Parkinson's disease

## AND

2 - Prescribed by, or in consultation with, a Neurologist

## AND

3 - Current treatment with combination of long-acting and short-acting carbidopa/levodopa

## AND

**4** - Person experiencing intermittent "off" episodes despite adequate trial with appropriate dosage adjustment with carbidopa/levodopa

| Product Name: Inbrija |                                       |
|-----------------------|---------------------------------------|
| Approval Length       | 12 month(s)                           |
| Therapy Stage         | Reauthorization                       |
| Guideline Type        | Prior Authorization - IL and MN Plans |

| Product<br>Name | Generic Name                    | GPI            | Brand/Generic |
|-----------------|---------------------------------|----------------|---------------|
| INBRIJA         | LEVODOPA INHAL POWDER CAP 42 MG | 73200040000160 | Brand         |

## **Approval Criteria**

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug.

| Product Name: Inbrija |  |  |
|-----------------------|--|--|
| Approval Length       | 12/31/2039                                       |  |
| Therapy Stage         | Initial Authorization                            |  |
| Guideline Type        | Prior Authorization - All plans except IL and MN |  |

| Product<br>Name | Generic Name                    | GPI            | Brand/Generic |
|-----------------|---------------------------------|----------------|---------------|
| INBRIJA         | LEVODOPA INHAL POWDER CAP 42 MG | 73200040000160 | Brand         |

1 - Diagnosis of Parkinson's disease

### **AND**

2 - Prescribed by, or in consultation with, a Neurologist

## **AND**

3 - Current treatment with combination of long-acting and short-acting carbidopa/levodopa

## **AND**

**4** - Person experiencing intermittent "off" episodes despite adequate trial with appropriate dosage adjustment with carbidopa/levodopa

| Date      | Notes       |
|-----------|-------------|
| 10/6/2023 | New Program |

| Increlex (mecasermin)  |  |  |  |
|--|--|--|--|
| The State Strange second to a Specific complete from the content of an about the State Sta |  |  |  |
|  |  |  |  |
|  |  |  |  |

| Guideline ID          | GL-129115             |
|-----------------------|-----------------------|
| <b>Guideline Name</b> | Increlex (mecasermin) |
| Formulary             | Quartz                |

# **Guideline Note:**

| Effective Date: |
|-----------------|
|-----------------|

# 1. Criteria

| Product Name: Increlex   |                                     |    |                |               |
|--|-------------------------------------|----|----------------|---------------|
| Approval Length 12/31/2039   |                                     |    |                |               |
| Guideline Type Prior Authorization - ALL Plans Except IL and MN Plans* |                                     | s* |                |               |
| Product<br>Name  | Generic Name                        |    | GPI            | Brand/Generic |
| INCRELEX   | MECASERMIN INJ 40 MG/4ML (10 MG/ML) |    | 30160045002020 | Brand         |

## **Approval Criteria**

- 1 One of the following:
- **1.1** Diagnosis of one of the following:

- Primary insulin-like growth factor deficiency (IGFD)
- Low insulin-like growth factor-1 (IGF-1) levels
- Growth hormone deletion with neutralizing antibodies to growth hormone

### OR

**1.2** Submission of medical records (e.g., chart notes) documenting lack of response to growth hormone following therapeutic trial of somatropin (for members with growth hormone deficiency)

### **AND**

2 - Member is less than 18 years of age

#### **AND**

3 - Member has confirmed open epiphyses

#### **AND**

4 - Prescribed by or in consultation with a pediatric endocrinologist

| Notes | *Increlex is not indicated to treat secondary IGFD due to GH deficiency , malnutrition, hypothyroidism or other                  |
|-------|--|
|       | causes   |
|       | *Increlex is not covered for treatment of idiopathic short stature *Increlex is not a substitute for growth hormone (somatropin) |
|       | 9 ( 1 )  |

| Product Name: Increlex                                |                       |
|---|-----------------------|
| Approval Length 12 month(s)                           |                       |
| Therapy Stage   | Initial Authorization |
| Guideline Type Prior Authorization - IL and MN Plans* |                       |

| Product<br>Name | Generic Name                        | GPI            | Brand/Generic |
|-----------------|-------------------------------------|----------------|---------------|
| INCRELEX        | MECASERMIN INJ 40 MG/4ML (10 MG/ML) | 30160045002020 | Brand         |

- 1 One of the following:
- **1.1** Diagnosis of one of the following:
  - Primary insulin-like growth factor deficiency (IGFD)
  - Low insulin-like growth factor-1 (IGF-1) levels
  - Growth hormone deletion with neutralizing antibodies to growth hormone

### OR

**1.2** Submission of medical records (e.g., chart notes) documenting lack of response to growth hormone following therapeutic trial of somatropin (for members with growth hormone deficiency)

#### **AND**

2 - Member is less than 18 years of age

**AND** 

3 - Member has confirmed open epiphyses

#### **AND**

4 - Prescribed by or in consultation with a pediatric endocrinologist

| Notes | *Increlex is not indicated to treat secondary IGFD due to GH deficiency , malnutrition, hypothyroidism or other |  |
|-------|---|--|
|       | causes  |  |
|       | *Increlex is not covered for treatment of idiopathic short stature  |  |
|       | *Increlex is not a substitute for growth hormone (somatropin)   |  |

| Product Name: Increlex      |                 |
|-----------------------------|-----------------|
| Approval Length 12 month(s) |                 |
| Therapy Stage               | Reauthorization |

| Guideline Type Prior Authorization - IL and MN Plans* |  |                            |                |               |  |
|---|--|----------------------------|----------------|---------------|--|
|   | ·  |                            |                | I I           |  |
| Product<br>Name                                       | Generic Na   | me                         | GPI            | Brand/Generic |  |
| INCRELEX  | MECASERMII   | N INJ 40 MG/4ML (10 MG/ML) | 30160045002020 | Brand         |  |
|   |  |                            |                |               |  |
| Approval C  | riteria  |                            |                |               |  |
| 1 - One of the  | he following:  |                            |                |               |  |
| 1.1 Diagno  | osis of one o  | f the following:           |                |               |  |
| • Low   |  |                            |                |               |  |
|   |  | OR                         |                |               |  |
|   | <b>1.2</b> Submission of medical records (e.g., chart notes) documenting lack of response to growth hormone following therapeutic trial of somatropin (for members with growth hormone deficiency) |                            |                |               |  |
|   | AND  |                            |                |               |  |
| <b>2</b> - Member                                     | 2 - Member is less than 18 years of age  |                            |                |               |  |
| AND   |  |                            |                |               |  |
| <b>3</b> - Member                                     | 3 - Member has confirmed open epiphyses  |                            |                |               |  |
| AND   |  |                            |                |               |  |
| <b>4</b> - Prescrib                                   | 4 - Prescribed by or in consultation with a pediatric endocrinologist  |                            |                |               |  |
|   | AND  |                            |                |               |  |

| <b>5</b> - Submission of medical records (e.g., chart notes) documenting that within the past 12 months, the member remains on therapy |   |
|--|---|
| Notes  | *Increlex is not indicated to treat secondary IGFD due to GH deficiency , malnutrition, hypothyroidism or other causes *Increlex is not covered for treatment of idiopathic short stature *Increlex is not a substitute for growth hormone (somatropin) |

| Date      | Notes                   |
|-----------|-------------------------|
| 7/31/2023 | 2024 New Implementation |

| Ingrezza (valbenazine)   |  |  |  |  |  |
|--|--|--|--|--|--|
| (3) the best angues on the depart of the ten ten tends on the control of the best process to control out states. |  |  |  |  |  |
|  |  |  |  |  |  |

| Guideline ID          | GL-130583             |  |
|-----------------------|-----------------------|--|
| <b>Guideline Name</b> | ngrezza (valbenazine) |  |
| Formulary             | Quartz                |  |

# **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

## Note:

Member new to the plan (as evidenced by coverage effective date of less than or equal to 90 days) who initiated therapy using a manufacturer-sponsored free drug program, provider samples, and/or vouchers will go through initial criteria, otherwise for continuation of therapy for new to plan, reauthorization criteria applies

## 1. Criteria

| Product Na  | Product Name: Ingrezza |                                       |       |               |
|---|------------------------|---------------------------------------|-------|---------------|
| Approval Length   |                        | 12 month(s)                           |       |               |
| Therapy Stage   |                        | Initial Authorization                 |       |               |
| Guideline Type  |                        | Prior Authorization - IL and MN Plans |       |               |
| Product<br>Name   | Generic Name           |                                       | GPI   | Brand/Generic |
| INGREZZA VALBENAZINE TOSYLATE CAP THERAPY PACK 40 MG (7) & 80 MG (21) |                        | 6238008020B220                        | Brand |               |

| INGREZZA | VALBENAZINE TOSYLATE CAP 40 MG (BASE EQUIV) | 62380080200120 | Brand |
|----------|---|----------------|-------|
| INGREZZA | VALBENAZINE TOSYLATE CAP 60 MG (BASE EQUIV) | 62380080200130 | Brand |
| INGREZZA | VALBENAZINE TOSYLATE CAP 80 MG (BASE EQUIV) | 62380080200140 | Brand |

1 - Diagnosis of tardive dyskinesia (TD)

### **AND**

- **2** Prescribed by or in consultation with one of the following:
  - Neurologist
  - Psychiatrist
  - Specialist in the treatment of TD

### **AND**

- 3 One of the following:
- **3.1** Symptoms persist despite stopping the dopamine receptor blocking drug that caused TD

OR

**3.2** Submission of medical records (e.g., chart notes) documenting evidence-based clinical rationale why discontinuation of the drug is not a treatment option for the person based on their diagnosis and previous treatment history

#### **AND**

4 - Trial and failure, contraindication, or intolerance to clonazepam

### **AND**

5 - (For patients whose primary symptomology is tardive dystonia ONLY): Trial and failure,

contraindication, or intolerance to trihexyphenidyl

| Product Name: Ingrezza |                                       |
|------------------------|---------------------------------------|
| Approval Length        | 12 month(s)                           |
| Therapy Stage          | Initial Authorization                 |
| Guideline Type         | Prior Authorization - IL and MN Plans |

| Product<br>Name | Generic Name   | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| INGREZZA        | VALBENAZINE TOSYLATE CAP THERAPY PACK 40 MG (7) & 80 MG (21) | 6238008020B220 | Brand         |
| INGREZZA        | VALBENAZINE TOSYLATE CAP 40 MG (BASE EQUIV)                  | 62380080200120 | Brand         |
| INGREZZA        | VALBENAZINE TOSYLATE CAP 60 MG (BASE EQUIV)                  | 62380080200130 | Brand         |
| INGREZZA        | VALBENAZINE TOSYLATE CAP 80 MG (BASE EQUIV)                  | 62380080200140 | Brand         |

# **Approval Criteria**

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug

| Product Name: Ingrezza |  |
|------------------------|--|
| Approval Length        | 12/31/2039   |
| Guideline Type         | Prior Authorization - All Plans Except IL and MN Plans |

| Product<br>Name | Generic Name   | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| INGREZZA        | VALBENAZINE TOSYLATE CAP THERAPY PACK 40 MG (7) & 80 MG (21) | 6238008020B220 | Brand         |
| INGREZZA        | VALBENAZINE TOSYLATE CAP 40 MG (BASE EQUIV)                  | 62380080200120 | Brand         |
| INGREZZA        | VALBENAZINE TOSYLATE CAP 60 MG (BASE EQUIV)                  | 62380080200130 | Brand         |
| INGREZZA        | VALBENAZINE TOSYLATE CAP 80 MG (BASE EQUIV)                  | 62380080200140 | Brand         |

# **Approval Criteria**

**1** - Diagnosis of tardive dyskinesia (TD)

#### **AND**

- **2** Prescribed by or in consultation with one of the following:
  - Neurologist
  - Psychiatrist
  - Specialist in the treatment of TD

### **AND**

- **3** One of the following:
- 3.1 Symptoms persist despite stopping the dopamine receptor blocking drug that caused TD

OR

**3.2** Submission of medical records (e.g., chart notes) documenting evidence-based clinical rationale why discontinuation of the drug is not a treatment option for the person based on their diagnosis and previous treatment history

#### **AND**

4 - Trial and failure, contraindication, or intolerance to clonazepam

#### **AND**

**5** - (For patients whose primary symptomology is tardive dystonia ONLY): Trial and failure, contraindication, or intolerance to trihexyphenidyl

| Date      | Notes                   |
|-----------|-------------------------|
| 8/16/2023 | 2024 New Implementation |

| I | Inhaled Bronchodilators for Chronic Obstructive Pulmonary Disease  |  |  |
|---|--|--|--|
|   | interlage and halpen. To the Residence of season will have beginning and halpens are halpens and halpens are halpe |  |  |

| Guideline ID          | GL-129738   |  |
|-----------------------|---|--|
| <b>Guideline Name</b> | Inhaled Bronchodilators for Chronic Obstructive Pulmonary Disease |  |
| Formulary             | Quartz  |  |

# **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

# 1. Criteria

| Product Name: Stiolto Respimat |                                       |
|--------------------------------|---------------------------------------|
| Approval Length                | 12 month(s)                           |
| Therapy Stage                  | Initial Authorization                 |
| Guideline Type                 | Prior Authorization - IL and MN Plans |

| Product<br>Name | Generic Name   | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
|                 | TIOTROPIUM BR-OLODATEROL INHAL AERO SOLN 2.5-2.5 MCG/ACT | 44209902923420 | Brand         |

# **Approval Criteria**

1 - Diagnosis of chronic obstructive pulmonary disease (COPD)

## AND

**2** - Trial and failure, contraindication or intolerance to use of umeclidinium/vilanterol (Anoro Ellipta)

| Product Name: Stiolto Respimat |                                       |  |
|--------------------------------|---------------------------------------|--|
| Approval Length 12 month(s)    |                                       |  |
| Therapy Stage                  | Reauthorization                       |  |
| Guideline Type                 | Prior Authorization - IL and MN Plans |  |

| Product<br>Name     | Generic Name   | GPI            | Brand/Generic |
|---------------------|--|----------------|---------------|
| STIOLTO<br>RESPIMAT | TIOTROPIUM BR-OLODATEROL INHAL AERO SOLN 2.5-2.5 MCG/ACT | 44209902923420 | Brand         |

## **Approval Criteria**

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug

| Product Name: Stiolto Respimat                                  |  |  |
|---|--|--|
| Approval Length 12/31/2039                                      |  |  |
| Guideline Type Prior Authorization - All plans except IL and MN |  |  |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
|                 | TIOTROPIUM BR-OLODATEROL INHAL AERO SOLN<br>2.5-2.5 MCG/ACT | 44209902923420 | Brand         |

## **Approval Criteria**

**1** - Diagnosis of chronic obstructive pulmonary disease (COPD)

## **AND**

**2** - Trial and failure, contraindication or intolerance to use of umeclidinium/vilanterol (Anoro Ellipta)

| Date      | Notes       |
|-----------|-------------|
| 10/6/2023 | New Program |

| Inhaled Corticosteroid Step therapy   |  |  |  |
|---|--|--|--|
| 3 Nationary was distington Trailing to be to see count or seed or seed of leaf to be presented or country or co |  |  |  |
|   |  |  |  |

| Guideline ID          | GL-143611                           |
|-----------------------|-------------------------------------|
| <b>Guideline Name</b> | Inhaled Corticosteroid Step therapy |
| Formulary             | Quartz                              |

# **Guideline Note:**

| Effective Date:    | 4/1/2024  |
|--------------------|-----------|
| P&T Approval Date: | 2/15/2022 |
| P&T Revision Date: | 7/18/2023 |

## 1. Criteria

HFA

 $\mathsf{HFA}$ 

**ASMANEX** 

SUSPENSION 100 MCG/ACT

SUSPENSION 200 MCG/ACT

MOMETASONE FUROATE INHAL AEROSOL

| Product Name: Asmanex, Asmanex HFA |   |                                  |                |               |
|------------------------------------|---|----------------------------------|----------------|---------------|
| Approval Length                    |   | 12 month(s)                      |                |               |
| Therapy Stage                      |   | Initial Authorization            |                |               |
| Guideline Type                     |   | Step Therapy - IL and MN Plans   |                |               |
| Product<br>Name                    | Generic N   | lame                             | GPI            | Brand/Generic |
| ASMANEX<br>HFA                     | MOMETASONE FUROATE INHAL AEROSOL<br>SUSPENSION 50 MCG/ACT |                                  | 44400036203210 | Brand         |
| ASMANEX                            | MOMETAS   | MOMETASONE FUROATE INHAL AEROSOL |                | Brand         |

Brand

44400036203230

| ASMANEX<br>TWISTHALER<br>30 METERED<br>DOSES     | MOMETASONE FUROATE INHAL POWD 110<br>MCG/ACT (BREATH ACTIVATED) | 44400036208010 | Brand |
|--|---|----------------|-------|
| ASMANEX<br>TWISTHALER<br>14 METERED<br>DOSES     | MOMETASONE FUROATE INHAL POWD 220<br>MCG/ACT (BREATH ACTIVATED) | 44400036208020 | Brand |
| ASMANEX<br>TWISTHALER<br>60 METERED<br>DOSES     | MOMETASONE FUROATE INHAL POWD 220<br>MCG/ACT (BREATH ACTIVATED) | 44400036208020 | Brand |
| ASMANEX<br>TWISTHALER<br>120<br>METERED<br>DOSES | MOMETASONE FUROATE INHAL POWD 220<br>MCG/ACT (BREATH ACTIVATED) | 44400036208020 | Brand |
| ASMANEX<br>TWISTHALER<br>30 METERED<br>DOSES     | MOMETASONE FUROATE INHAL POWD 220<br>MCG/ACT (BREATH ACTIVATED) | 44400036208020 | Brand |

- **1** Trial and failure, intolerance, or contraindication to one of the following:
  - an inhaled fluticasone propionate product an inhaled fluticasone furoate product

| Product Name: Asmanex, Asmanex HFA |                                |  |
|------------------------------------|--------------------------------|--|
| Approval Length 12 month(s)        |                                |  |
| Therapy Stage                      | Reauthorization                |  |
| Guideline Type                     | Step Therapy - IL and MN Plans |  |

| Product<br>Name       | Generic Name  | GPI            | Brand/Generic |
|-----------------------|---|----------------|---------------|
| ASMANEX<br>HFA        | MOMETASONE FUROATE INHAL AEROSOL<br>SUSPENSION 50 MCG/ACT       | 44400036203210 | Brand         |
| ASMANEX<br>HFA        | MOMETASONE FUROATE INHAL AEROSOL<br>SUSPENSION 100 MCG/ACT      | 44400036203220 | Brand         |
| ASMANEX<br>HFA        | MOMETASONE FUROATE INHAL AEROSOL<br>SUSPENSION 200 MCG/ACT      | 44400036203230 | Brand         |
| ASMANEX<br>TWISTHALER | MOMETASONE FUROATE INHAL POWD 110<br>MCG/ACT (BREATH ACTIVATED) | 44400036208010 | Brand         |

| 30 METERED<br>DOSES                              |   |                | -     |
|--|---|----------------|-------|
| ASMANEX<br>TWISTHALER<br>14 METERED<br>DOSES     | MOMETASONE FUROATE INHAL POWD 220<br>MCG/ACT (BREATH ACTIVATED) | 44400036208020 | Brand |
| ASMANEX<br>TWISTHALER<br>60 METERED<br>DOSES     | MOMETASONE FUROATE INHAL POWD 220<br>MCG/ACT (BREATH ACTIVATED) | 44400036208020 | Brand |
| ASMANEX<br>TWISTHALER<br>120<br>METERED<br>DOSES | MOMETASONE FUROATE INHAL POWD 220<br>MCG/ACT (BREATH ACTIVATED) | 44400036208020 | Brand |
| ASMANEX<br>TWISTHALER<br>30 METERED<br>DOSES     | MOMETASONE FUROATE INHAL POWD 220<br>MCG/ACT (BREATH ACTIVATED) | 44400036208020 | Brand |

**1** - Submission of medical notes (e.g. chart notes) from the past 12 months that member is continuing therapy with the requested drug

| Product Name: Asmanex, Asmanex HFA |  |                                       |            |  |
|------------------------------------|--|---------------------------------------|------------|--|
| Approval Length 12/31/2039         |  |                                       |            |  |
| Guideline Type                     |  | Step Therapy - All plans except IL an | d MN Plans |  |
| Product Congric Name GPI Bran      |  | Brand/Generic                         |            |  |

| Product<br>Name                              | Generic Name  | GPI            | Brand/Generic |
|--|---|----------------|---------------|
| ASMANEX<br>HFA                               | MOMETASONE FUROATE INHAL AEROSOL<br>SUSPENSION 50 MCG/ACT       | 44400036203210 | Brand         |
| ASMANEX<br>HFA                               | MOMETASONE FUROATE INHAL AEROSOL<br>SUSPENSION 100 MCG/ACT      | 44400036203220 | Brand         |
| ASMANEX<br>HFA                               | MOMETASONE FUROATE INHAL AEROSOL<br>SUSPENSION 200 MCG/ACT      | 44400036203230 | Brand         |
| ASMANEX<br>TWISTHALER<br>30 METERED<br>DOSES | MOMETASONE FUROATE INHAL POWD 110<br>MCG/ACT (BREATH ACTIVATED) | 44400036208010 | Brand         |
| ASMANEX<br>TWISTHALER<br>14 METERED<br>DOSES | MOMETASONE FUROATE INHAL POWD 220<br>MCG/ACT (BREATH ACTIVATED) | 44400036208020 | Brand         |

| ASMANEX<br>TWISTHALER<br>60 METERED<br>DOSES     | MOMETASONE FUROATE INHAL POWD 220<br>MCG/ACT (BREATH ACTIVATED) | 44400036208020 | Brand |
|--|---|----------------|-------|
| ASMANEX<br>TWISTHALER<br>120<br>METERED<br>DOSES | MOMETASONE FUROATE INHAL POWD 220<br>MCG/ACT (BREATH ACTIVATED) | 44400036208020 | Brand |
| ASMANEX<br>TWISTHALER<br>30 METERED<br>DOSES     | MOMETASONE FUROATE INHAL POWD 220<br>MCG/ACT (BREATH ACTIVATED) | 44400036208020 | Brand |

- **1** Trial and failure, intolerance, or contraindication to one of the following:
  - an inhaled fluticasone propionate product an inhaled fluticasone furoate product

| Date      | Notes       |
|-----------|-------------|
| 2/28/2024 | New Program |

| Injectable Calcitonin Gene-Related Peptide (CGRP) Inhibito |  |  |  |  |  |
|--|--|--|--|--|--|
|  | (3) Makanguan hababa haba kasala han mara a dala kabab kasala ka dan kabab kasala ka dalah |  |  |  |  |

| Guideline ID          | GL-129533  |
|-----------------------|--|
| <b>Guideline Name</b> | Injectable Calcitonin Gene-Related Peptide (CGRP) Inhibitors |
| Formulary             | Quartz   |

# **Guideline Note:**

| Effective Date: |
|-----------------|
|-----------------|

# 1. Criteria

| Product Name: Aimovig, Emgality                                       |            |  |
|---|------------|--|
| Diagnosis Preventative Treatment of Migraine                          |            |  |
| Approval Length   | 12/31/2039 |  |
| Guideline Type Prior Authorization - ALL Plans Except IL and MN Plans |            |  |

| Product<br>Name | Generic Name   | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| AIMOVIG         | ERENUMAB-AOOE SUBCUTANEOUS SOLN AUTO-INJECTOR 70 MG/ML         | 6770202010D520 | Brand         |
| AIMOVIG         | ERENUMAB-AOOE SUBCUTANEOUS SOLN AUTO-<br>INJECTOR 140 MG/ML    | 6770202010D540 | Brand         |
| EMGALITY        | GALCANEZUMAB-GNLM SUBCUTANEOUS SOLN<br>AUTO-INJECTOR 120 MG/ML | 6770203530D520 | Brand         |
| EMGALITY        | GALCANEZUMAB-GNLM SUBCUTANEOUS SOLN PREFILLED SYR 100 MG/ML    | 6770203530E515 | Brand         |

| EMGALITY | GALCANEZUMAB-GNLM SUBCUTANEOUS SOLN<br>PREFILLED SYR 120 MG/ML | 6770203530E520 | Brand |
|----------|--|----------------|-------|
|----------|--|----------------|-------|

**1** - Submission of medical records (e.g., chart notes) documenting member has greater than or equal to 4 migraine days per month with headaches that are disabling (e.g., unable to work/attend school, unable to participate in activities of daily living [ADLs], moderate to severe MIDAS score)

### **AND**

2 - Drug must be self-administered

### **AND**

**3** - Trial and failure, intolerance, or contraindication to 2 generic preventive migraine medications (e.g., anti-hypertensives, antiepileptics, antidepressants, botulinum toxin)

#### **AND**

**4** - Drug is not being used in combination with another CGRP inhibitor for the preventative treatment of migraines

| Product Name: Aimovig, Emgality              |  |  |
|--|--|--|
| Diagnosis Preventative Treatment of Migraine |  |  |
| Approval Length                              | 12 month(s)  |  |
| Therapy Stage                                | Stage Initial Authorization                          |  |
| Guideline Type                               | uideline Type Prior Authorization - IL and MN Plans* |  |

| Product<br>Name | Generic Name   | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| AIMOVIG         | ERENUMAB-AOOE SUBCUTANEOUS SOLN AUTO-<br>INJECTOR 70 MG/ML | 6770202010D520 | Brand         |
| AIMOVIG         | ERENUMAB-AOOE SUBCUTANEOUS SOLN AUTO-INJECTOR 140 MG/ML    | 6770202010D540 | Brand         |
| EMGALITY        | GALCANEZUMAB-GNLM SUBCUTANEOUS SOLN                        | 6770203530D520 | Brand         |

|          | AUTO-INJECTOR 120 MG/ML  |                |       |
|----------|--|----------------|-------|
| EMGALITY | GALCANEZUMAB-GNLM SUBCUTANEOUS SOLN<br>PREFILLED SYR 100 MG/ML | 6770203530E515 | Brand |
| EMGALITY | GALCANEZUMAB-GNLM SUBCUTANEOUS SOLN<br>PREFILLED SYR 120 MG/ML | 6770203530E520 | Brand |

**1** - Submission of medical records (e.g., chart notes) documenting member has greater than or equal to 4 migraine days per month with headaches that are disabling (e.g., unable to work/attend school, unable to participate in activities of daily living [ADLs], moderate to severe MIDAS score)

#### **AND**

2 - Drug must be self-administered

### **AND**

**3** - Trial and failure, intolerance, or contraindication to 2 generic preventive migraine medications (e.g., anti-hypertensives, antiepileptics, antidepressants, botulinum toxin)

#### AND

**4** - Drug is not being used in combination with another CGRP inhibitor used for the preventative treatment of migraines

| Notes | *Member new to the plan (as evidenced by coverage effective date of I ess than or equal to 90 days) who initiated therapy using a manufactur er-sponsored free drug program, provider samples, and/or vouchers wil I go through initial criteria, otherwise for continuation of therapy for new |
|-------|---|
|       | I go through initial criteria, otherwise for continuation of therapy for new to plan, reauthorization criteria applies  |

| Product Name: Aimovig, Emgality                       |                              |  |
|---|------------------------------|--|
| Diagnosis Preventative Treatment of Migraine          |                              |  |
| Approval Length                                       | 12 month(s)                  |  |
| Therapy Stage   | herapy Stage Reauthorization |  |
| Guideline Type Prior Authorization - IL and MN Plans* |                              |  |

| Product<br>Name | Generic Name   | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| AIMOVIG         | ERENUMAB-AOOE SUBCUTANEOUS SOLN AUTO-<br>INJECTOR 70 MG/ML     | 6770202010D520 | Brand         |
| AIMOVIG         | ERENUMAB-AOOE SUBCUTANEOUS SOLN AUTO-<br>INJECTOR 140 MG/ML    | 6770202010D540 | Brand         |
| EMGALITY        | GALCANEZUMAB-GNLM SUBCUTANEOUS SOLN<br>AUTO-INJECTOR 120 MG/ML | 6770203530D520 | Brand         |
| EMGALITY        | GALCANEZUMAB-GNLM SUBCUTANEOUS SOLN PREFILLED SYR 100 MG/ML    | 6770203530E515 | Brand         |
| EMGALITY        | GALCANEZUMAB-GNLM SUBCUTANEOUS SOLN<br>PREFILLED SYR 120 MG/ML | 6770203530E520 | Brand         |

1 - Submission of medical records (e.g., chart notes) documenting that within the previous 12 months the member is showing a response to therapy (e.g., symptom improvement such as decreased frequency or severity of headaches from baseline, reduced cluster headache frequency, improved ability to participate in therapies/ADLs, improved MIDAS score, less acute medication use, fewer ER/UC visits for migraine, ability to return to work/school)

### AND

**2** - Drug is not being used in combination with another CGRP inhibitor used for the preventative treatment of migraines

| *Member new to the plan (as evidenced by coverage effective date of I ess than or equal to 90 days) who initiated therapy using a manufactur er-sponsored free drug program, provider samples, and/or vouchers wil I go through initial criteria, otherwise for continuation of therapy for new to plan, reauthorization criteria applies |
|---|
| to plan, reauthorization criteria applies   |

| Product Name: Ajovy |  |  |
|---------------------|--|--|
| Diagnosis           | Preventative Treatment of Migraine                     |  |
| Approval Length     | 12/31/2039   |  |
| Guideline Type      | Prior Authorization - ALL Plans Except IL and MN Plans |  |

| Product<br>Name | Generic Name   | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| AJOVY           | FREMANEZUMAB-VFRM SUBCUTANEOUS SOLN<br>AUTO-INJ 225 MG/1.5ML | 6770203020D520 | Brand         |

| AJOVY | FREMANEZUMAB-VFRM SUBCUTANEOUS SOLN<br>PREF SYR 225 MG/1.5ML | 6770203020E520 | Brand |
|-------|--|----------------|-------|
|-------|--|----------------|-------|

**1** - Submission of medical records (e.g., chart notes) documenting member has greater than or equal to 4 migraine days per month with headaches that are disabling (e.g., unable to work/attend school, unable to participate in activities of daily living [ADLs], moderate to severe MIDAS score)

#### **AND**

2 - Drug must be self-administered

#### **AND**

**3** - Trial and failure, contraindication or intolerance to 2 generic preventive migraine medications (e.g., anti-hypertensives, antiepileptics, antidepressants, botulinum toxin)

#### **AND**

- 4 Trial and failure, contraindication or intolerance to both of the following:
  - Aimovig
  - Emgality

## AND

**5** - Drug is not being used in combination with another CGRP inhibitor for the preventative treatment of migraines

| Product Name: Ajovy |                                    |  |
|---------------------|------------------------------------|--|
| Diagnosis           | Preventative Treatment of Migraine |  |
| Approval Length     | 12 month(s)                        |  |
| Therapy Stage       | Initial Authorization              |  |

| Guideline Type  |   | Prior Authorization - IL and MN Plans* |                |               |
|-----------------|---|--|----------------|---------------|
| Product<br>Name | Generic Name  |  | GPI            | Brand/Generic |
| AJOVY           | FREMANEZUMAB-VFRM SUBCUTANEOUS SOLN<br>AUTO-INJ 225 MG/1.5ML    |  | 6770203020D520 | Brand         |
| AJOVY           | AJOVY FREMANEZUMAB-VFRM SUBCUTANEOUS SOLN PREF SYR 225 MG/1.5ML |  | 6770203020E520 | Brand         |

**1** - Submission of medical records (e.g., chart notes) documenting member has greater than or equal to 4 migraine days per month with headaches that are disabling (e.g., unable to work/attend school, unable to participate in activities of daily living [ADLs], moderate to severe MIDAS score)

#### **AND**

2 - Drug must be self-administered

### AND

**3** - Trial and failure, contraindication or intolerance to 2 generic preventive migraine medications (e.g., anti-hypertensives, antiepileptics, antidepressants, botulinum toxin)

#### **AND**

- 4 Trial and failure, contraindication or intolerance to both of the following:
  - Aimovig
  - Emgality

#### **AND**

**5** - Drug is not being used in combination with another CGRP inhibitor used for the preventative treatment of migraines

| Notes | *Member new to the plan (as evidenced by coverage effective date of I  |
|-------|--|
|       | ess than or equal to 90 days) who initiated therapy using a manufactur |

| er-sponsored free drug program, provider samples, and/or vouchers will go through initial criteria, otherwise for continuation of therapy for new to plan, reauthorization criteria applies |
|---|
| to plan, reauthorization criteria applies   |

| Product Name: Ajovy                          |  |  |
|--|--|--|
| Diagnosis Preventative Treatment of Migraine |  |  |
| Approval Length                              | 12 month(s)                            |  |
| Therapy Stage                                | Reauthorization                        |  |
| Guideline Type                               | Prior Authorization - IL and MN Plans* |  |

| Product<br>Name | Generic Name   | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| AJOVY           | FREMANEZUMAB-VFRM SUBCUTANEOUS SOLN<br>AUTO-INJ 225 MG/1.5ML | 6770203020D520 | Brand         |
| AJOVY           | FREMANEZUMAB-VFRM SUBCUTANEOUS SOLN<br>PREF SYR 225 MG/1.5ML | 6770203020E520 | Brand         |

1 - Submission of medical records (e.g., chart notes) documenting that within the previous 12 months the member is showing a response to therapy (e.g., symptom improvement such as decreased frequency or severity of headaches from baseline, reduced cluster headache frequency, improved ability to participate in therapies/ADLs, improved MIDAS score, less acute medication use, fewer ER/UC visits for migraine, ability to return to work/school)

## **AND**

**2** - Drug is not being used in combination with another CGRP inhibitor used for the preventative treatment of migraines

| Notes | *Member new to the plan (as evidenced by coverage effective date of I ess than or equal to 90 days) who initiated therapy using a manufactur er-sponsored free drug program, provider samples, and/or vouchers wil I go through initial criteria, otherwise for continuation of therapy for new to plan, reauthorization criteria applies |
|-------|---|
|-------|---|

| Product Name: Emgality              |            |  |  |
|-------------------------------------|------------|--|--|
| Diagnosis Episodic Cluster Headache |            |  |  |
| Approval Length                     | 12/31/2039 |  |  |

| Guideline Type  |  | Prior Authorization - ALL Plans Except IL and MN Plans |                |               |
|-----------------|--|--|----------------|---------------|
| Product<br>Name | Generic Name   |  | GPI            | Brand/Generic |
| EMGALITY        | GALCANEZUMAB-GNLM SUBCUTANEOUS SOLN<br>AUTO-INJECTOR 120 MG/ML |  | 6770203530D520 | Brand         |
| EMGALITY        | GALCANEZUMAB-GNLM SUBCUTANEOUS SOLN<br>PREFILLED SYR 100 MG/ML |  | 6770203530E515 | Brand         |
| EMGALITY        | GALCANEZUMAB-GNLM SUBCUTANEOUS SOLN<br>PREFILLED SYR 120 MG/ML |  | 6770203530E520 | Brand         |

1 - Diagnosis of cluster headaches that are not rebound headaches due to medication overuse

## AND

2 - Drug must be self-administered

## AND

3 - Patient is 18 years of age or older

| Product Name: Emgality                                |                       |  |
|---|-----------------------|--|
| Diagnosis Episodic Cluster Headache                   |                       |  |
| Approval Length                                       | 12 month(s)           |  |
| Therapy Stage   | Initial Authorization |  |
| Guideline Type Prior Authorization - IL and MN Plans* |                       |  |

| Product<br>Name | Generic Name   | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| EMGALITY        | GALCANEZUMAB-GNLM SUBCUTANEOUS SOLN<br>AUTO-INJECTOR 120 MG/ML | 6770203530D520 | Brand         |
| EMGALITY        | GALCANEZUMAB-GNLM SUBCUTANEOUS SOLN<br>PREFILLED SYR 100 MG/ML | 6770203530E515 | Brand         |
| EMGALITY        | GALCANEZUMAB-GNLM SUBCUTANEOUS SOLN<br>PREFILLED SYR 120 MG/ML | 6770203530E520 | Brand         |

1 - Diagnosis of cluster headaches that are not rebound headaches due to medication overuse

#### AND

2 - Drug must be self-administered

### **AND**

3 - Patient is 18 years of age or older

| Notes | *Member new to the plan (as evidenced by coverage effective date of I ess than or equal to 90 days) who initiated therapy using a manufactur er-sponsored free drug program, provider samples, and/or vouchers wil I go through initial criteria, otherwise for continuation of therapy for new |
|-------|---|
|       | I go through initial criteria, otherwise for continuation of therapy for new to plan, reauthorization criteria applies  |

| Product Name: Emgality                                |                 |  |  |
|---|-----------------|--|--|
| Diagnosis Episodic Cluster Headache                   |                 |  |  |
| Approval Length                                       | 12 month(s)     |  |  |
| Therapy Stage   | Reauthorization |  |  |
| Guideline Type Prior Authorization - IL and MN Plans* |                 |  |  |

| Product<br>Name | Generic Name   | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| EMGALITY        | GALCANEZUMAB-GNLM SUBCUTANEOUS SOLN<br>AUTO-INJECTOR 120 MG/ML | 6770203530D520 | Brand         |
| EMGALITY        | GALCANEZUMAB-GNLM SUBCUTANEOUS SOLN PREFILLED SYR 100 MG/ML    | 6770203530E515 | Brand         |
| EMGALITY        | GALCANEZUMAB-GNLM SUBCUTANEOUS SOLN<br>PREFILLED SYR 120 MG/ML | 6770203530E520 | Brand         |

## **Approval Criteria**

**1** - Submission of medical records (e.g., chart notes) documenting that within the previous 12 months the member is showing a response to therapy (e.g., symptom improvement such as decreased frequency or severity of headaches from baseline, reduced cluster headache

frequency, improved ability to participate in therapies/ADLs, improved MIDAS score, less acute medication use, fewer ER/UC visits for migraine, ability to return to work/school)

## **AND**

 ${\bf 2}$  - Drug is not being used in combination with another CGRP inhibitor used for the preventative treatment of migraines

| *Member new to the plan (as evidenced by coverage effective date of I ess than or equal to 90 days) who initiated therapy using a manufactur er-sponsored free drug program, provider samples, and/or vouchers wil I go through initial criteria, otherwise for continuation of therapy for new |
|---|
| I go through initial criteria, otherwise for continuation of therapy for new to plan, reauthorization criteria applies  |

| Date     | Notes                   |
|----------|-------------------------|
| 8/8/2023 | 2024 New Implementation |

| Interferons   |   |  |  |
|---|---|--|--|
| (3) habiterappears that the last term and consider a state that the basis to provide a consideration. | _ |  |  |

| Guideline ID   | GL-130130   |
|----------------|-------------|
| Guideline Name | Interferons |
| Formulary      | Quartz      |

# **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

## Note:

Member new to the plan (as evidenced by coverage effective date of less than or equal to 90 days) who initiated therapy using a manufacturer-sponsored free drug program, provider samples, and/or vouchers will go through initial criteria, otherwise for continuation of therapy for new to plan, reauthorization criteria applies

## 1. Criteria

| Product Name: Alferon N            |  |                       |                |               |
|------------------------------------|--|-----------------------|----------------|---------------|
| Approval Le                        | ength                                  | 12 month(s)           |                |               |
| Therapy Sta                        | age                                    | Initial Authorization |                |               |
| Guideline Type Prior Authorization |  |                       |                |               |
| Product<br>Name                    | Generic Name GF                        |                       | GPI            | Brand/Generic |
| ALFERON<br>N                       | INTERFERON ALFA-N3 INJ 5000000 UNIT/ML |                       | 21700060302020 | Brand         |

1 - Diagnosis of external genital or perianal warts

## **AND**

2 - Must be self-administered or administered by family member or caretaker

| Product Name: Alferon N            |                 |
|------------------------------------|-----------------|
| Approval Length 12 month(s)        |                 |
| Therapy Stage                      | Reauthorization |
| Guideline Type Prior Authorization |                 |

| Product<br>Name | Generic Name                           | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| ALFERON<br>N    | INTERFERON ALFA-N3 INJ 5000000 UNIT/ML | 21700060302020 | Brand         |

## **Approval Criteria**

1 - Diagnosis of external genital or perianal warts

## **AND**

2 - Must be self-administered or administered by family member or caretaker

## **AND**

**3** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member demonstrates positive clinical response to therapy

| Product Name: Actimmune |             |
|-------------------------|-------------|
| Approval Length         | 12 month(s) |

| Therapy Stage  | Initial Authorization |
|----------------|-----------------------|
| Guideline Type | Prior Authorization   |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| _               | INTERFERON GAMMA-1B INJ 100 MCG/0.5ML<br>(2000000 UNIT/0.5ML) | 21700060702020 | Brand         |

- 1 Diagnosis of ONE of the following:
  - Chronic granulomatous disease
  - Congenital malignant osteopetrosis

## **AND**

2 - Must be self-administered or administered by family member or caretaker

| Product Name: Actimmune            |                 |
|------------------------------------|-----------------|
| Approval Length 12 month(s)        |                 |
| Therapy Stage                      | Reauthorization |
| Guideline Type Prior Authorization |                 |

| Product<br>Name  | Generic Name | GPI            | Brand/Generic |
|--|--------------|----------------|---------------|
| ACTIMMUNE INTERFERON GAMMA-1B INJ 100 MCG/0.5ML (2000000 UNIT/0.5ML) |              | 21700060702020 | Brand         |

## **Approval Criteria**

- 1 Diagnosis of ONE of the following:
  - Chronic granulomatous disease
  - Congenital malignant osteopetrosis

## **AND**

2 - Must be self-administered or administered by family member or caretaker

## **AND**

**3** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member demonstrates positive clinical response to therapy

| Date      | Notes                   |
|-----------|-------------------------|
| 8/15/2023 | 2024 New Implementation |

| Itraconazole/Onychomycosis  |  |  |
|---|--|--|
| (2) Indicates were violated. This is trained used, seed, seed, seed, seed, seed, seed on seed decision. |  |  |

| Guideline ID          | GL-130138                  |
|-----------------------|----------------------------|
| <b>Guideline Name</b> | Itraconazole/Onychomycosis |
| Formulary             | Quartz                     |

# **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

## Note:

For systemic infections only: Member new to the plan (as evidenced by coverage effective date of less than or equal to 90 days) who initiated therapy using a manufacturer-sponsored free drug program, provider samples, and/or vouchers will go through initial criteria, otherwise for continuation of therapy for new to plan, reauthorization criteria applies

## 1. Criteria

| Product Name: Itraconazole (generic Sporanox) |                             |  |                |         |
|---|-----------------------------|--|----------------|---------|
| Diagnosis                                     |                             | Onychomycosis                                    |                |         |
| Approval Length                               |                             | 4 month(s)                                       |                |         |
| Guideline Type                                |                             | Prior Authorization – All plans except IL and MN |                |         |
| Product<br>Name                               | Generic Name GPI Brand/Gene |  | Brand/Generic  |         |
| ITRACONAZOLE                                  | ITRACO                      | NAZOLE CAP 100 MG                                | 11407035000120 | Generic |
| ITRACONAZOLE                                  | ITRACO                      | NAZOLE ORAL SOLN 10 MG/ML                        | 11407035002020 | Generic |

1 - Diagnosis of fungal or mold infection confirmed by culture or positive KOH test

#### **AND**

**2** - Submission of medical records (e.g., chart notes) documenting functional disability due to onychomycosis, peripheral vascular disease, diabetes, immunosuppressed or immunocompromised state, or history of recurrent cellulitis

#### AND

3 - Trial and failure, contraindication, or intolerance to terbinafine therapy

| Product Name: Itraconazole (generic Sporanox) |                                      |  |
|---|--------------------------------------|--|
| Diagnosis                                     | Onychomycosis                        |  |
| Approval Length                               | 12 month(s)                          |  |
| Guideline Type                                | Prior Authorization- IL and MN Plans |  |

| Product<br>Name | Generic Name                    | GPI            | Brand/Generic |
|-----------------|---------------------------------|----------------|---------------|
| ITRACONAZOLE    | ITRACONAZOLE CAP 100 MG         | 11407035000120 | Generic       |
| ITRACONAZOLE    | ITRACONAZOLE ORAL SOLN 10 MG/ML | 11407035002020 | Generic       |

## **Approval Criteria**

1 - Diagnosis of fungal or mold infection confirmed by culture or positive KOH test

### **AND**

**2** - Submission of medical records (e.g., chart notes) documenting functional disability due to onychomycosis, peripheral vascular disease, diabetes, immunosuppressed or immunocompromised state, or history of recurrent cellulitis

#### AND

3 - Trial and failure, contraindication, or intolerance to terbinafine therapy

| Product Name: Jublia, Kerydin   |            |  |
|---|------------|--|
| Diagnosis Onychomycosis   |            |  |
| Approval Length   | 6 month(s) |  |
| Guideline Type Prior Authorization - All plans except IL and MN Plans |            |  |

| Product<br>Name | Generic Name           | GPI            | Brand/Generic |
|-----------------|------------------------|----------------|---------------|
| JUBLIA          | EFINACONAZOLE SOLN 10% | 90154037002020 | Brand         |
| KERYDIN         | TAVABOROLE SOLN 5%     | 90156080002010 | Brand         |

## **Approval Criteria**

1 - Diagnosis of fungal or mold infection confirmed by culture or positive KOH test

#### **AND**

**2** - Submission of medical records (e.g., chart notes) documenting functional disability due to onychomycosis, peripheral vascular disease, diabetes, immunosuppressed or immunocompromised state, or history of recurrent cellulitis

### **AND**

- **3** Trial and failure, contraindication, or intolerance to both of the following:
  - Oral terbinafine
  - Oral itraconazole

| Product Name: Jublia, Kerydin |               |
|-------------------------------|---------------|
| Diagnosis                     | Onychomycosis |

| Approval Length | 12 month(s)                           |
|-----------------|---------------------------------------|
| Guideline Type  | Prior Authorization – IL and MN plans |

| Product<br>Name | Generic Name           | GPI            | Brand/Generic |
|-----------------|------------------------|----------------|---------------|
| JUBLIA          | EFINACONAZOLE SOLN 10% | 90154037002020 | Brand         |
| KERYDIN         | TAVABOROLE SOLN 5%     | 90156080002010 | Brand         |
| TAVABOROLE      | TAVABOROLE SOLN 5%     | 90156080002010 | Generic       |

1 - Diagnosis of fungal or mold infection confirmed by culture or positive KOH test

### AND

**2** - Submission of medical records (e.g., chart notes) documenting functional disability due to onychomycosis, peripheral vascular disease, diabetes, immunosuppressed or immunocompromised state, or history of recurrent cellulitis

### AND

- **3** Trial and failure, contraindication, or intolerance to both of the following:
  - Oral terbinafine
  - Oral itraconazole

| Product Name: Tolsura       |                                       |  |
|-----------------------------|---------------------------------------|--|
| Diagnosis                   | Onychomycosis                         |  |
| Approval Length 12 month(s) |                                       |  |
| Guideline Type              | Prior Authorization - IL and MN Plans |  |

| TOLSURA ITRACONAZOLE CAP 65 MG 11407035000113 Brand |  |
|---|--|

1 - Diagnosis of fungal or mold infection confirmed by culture or positive KOH test

#### AND

**2** - Submission of medical records (e.g., chart notes) documenting functional disability due to onychomycosis, peripheral vascular disease, diabetes, immunosuppressed or immunocompromised state, or history of recurrent cellulitis

### **AND**

**3** - Trial and failure, contraindication, or intolerance to use of generic itraconazole (Sporanox equivalent)

| Product Name: Tolsura   |  |  |
|---|--|--|
| Diagnosis Onychomycosis   |  |  |
| Approval Length 6 month(s)  |  |  |
| Guideline Type Prior Authorization - All plans except IL and MN Plans |  |  |

| Product<br>Name | Generic Name           | GPI            | Brand/Generic |
|-----------------|------------------------|----------------|---------------|
| TOLSURA         | ITRACONAZOLE CAP 65 MG | 11407035000113 | Brand         |

### **Approval Criteria**

1 - Diagnosis of fungal or mold infection confirmed by culture or positive KOH test

### **AND**

**2** - Submission of medical records (e.g., chart notes) documenting functional disability due to onychomycosis, peripheral vascular disease, diabetes, immunosuppressed or immunocompromised state, or history of recurrent cellulitis

### **AND**

**3** - Trial and failure, contraindication, or intolerance to use of generic itraconazole (Sporanox equivalent)

| Product Name: Itraconazole (generic Sporanox) |                       |  |
|---|-----------------------|--|
| Diagnosis                                     | Systemic Infections   |  |
| Approval Length                               | 12 month(s)           |  |
| Therapy Stage                                 | Initial Authorization |  |
| Guideline Type                                | Prior Authorization   |  |

| Product<br>Name | Generic Name                    | GPI            | Brand/Generic |
|-----------------|---------------------------------|----------------|---------------|
| ITRACONAZOLE    | ITRACONAZOLE CAP 100 MG         | 11407035000120 | Generic       |
| ITRACONAZOLE    | ITRACONAZOLE ORAL SOLN 10 MG/ML | 11407035002020 | Generic       |

### **Approval Criteria**

**1** - Diagnosis of Blastomycosis, Histoplasmosis, Aspergillosis or other verified systemic fungal infection susceptible to itraconazole

### OR

2 - (Illinois plans only): The drug is being used for the long-term treatment of tick-borne disease

| Product Name: Tolsura |                       |  |
|-----------------------|-----------------------|--|
| Diagnosis             | Systemic Infections   |  |
| Approval Length       | 12 month(s)           |  |
| Therapy Stage         | Initial Authorization |  |
| Guideline Type        | Prior Authorization   |  |

| Product<br>Name | Generic Name           | GPI            | Brand/Generic |
|-----------------|------------------------|----------------|---------------|
| TOLSURA         | ITRACONAZOLE CAP 65 MG | 11407035000113 | Brand         |
|                 |                        |                |               |

- **1** One of the following:
- **1.1** Diagnosis of Blastomycosis, Histoplasmosis, Aspergillosis or other verified systemic fungal infection susceptible to itraconazole

### OR

**1.2** (Illinois Plans Only): The drug is being used for the long-term treatment of tick-borne disease

#### **AND**

**2** - Trial and failure, contraindication, or intolerance to use of generic itraconazole (Sporanox equivalent)

| Product Name: Itraconazole (generic Sporanox), Tolsura |                              |  |  |
|--|------------------------------|--|--|
| Diagnosis  | iagnosis Systemic Infections |  |  |
| Approval Length  | 12 month(s)                  |  |  |
| Therapy Stage  | Reauthorization              |  |  |
| Guideline Type   | Prior Authorization          |  |  |

| Product<br>Name | Generic Name                    | GPI            | Brand/Generic |
|-----------------|---------------------------------|----------------|---------------|
| ITRACONAZOLE    | ITRACONAZOLE CAP 100 MG         | 11407035000120 | Generic       |
| ITRACONAZOLE    | ITRACONAZOLE ORAL SOLN 10 MG/ML | 11407035002020 | Generic       |
| TOLSURA         | ITRACONAZOLE CAP 65 MG          | 11407035000113 | Brand         |

### **Approval Criteria**

**1** - New to the plan (within the past 90 days and submission of medical records (e.g., chart notes) documenting that within the past 12 months treatment of the condition is ongoing

OR

- **2** BOTH of the following:
- **2.1** ONE of the following:
  - Diagnosis of Blastomycosis, Histoplasmosis, Aspergillosis or other verified systemic fungal infection susceptible to itraconazole
  - (Illinois plans only): The drug is being used for the long-term treatment of tick-borne disease

### **AND**

**2.2** Submission of medical records (e.g., chart notes) documenting that within the past 12 months treatment of the condition is ongoing

| Date      | Notes                   |
|-----------|-------------------------|
| 10/5/2023 | 2024 New Implementation |

| Juxtapid (lomitapide)  |  |  |
|--|--|--|
| (S) Third the second state of the second state |  |  |

| Guideline ID GL-136594 |                       |  |
|------------------------|-----------------------|--|
| <b>Guideline Name</b>  | Juxtapid (lomitapide) |  |
| Formulary              | Quartz                |  |

### **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

### Note:

Member new to the plan (as evidenced by coverage effective date of less than or equal to 90 days) who initiated therapy using a manufacturer-sponsored free drug program, provider samples, and/or vouchers will go through initial criteria, otherwise for continuation of therapy for new to plan, reauthorization criteria applies.

### 1. Criteria

| Product Name: Juxtapid |   |                                 |                |       |
|------------------------|---|---------------------------------|----------------|-------|
| Approval Length        |   | 12 month(s)                     |                |       |
| Therapy Stage          |   | Initial Authorization           |                |       |
| Guideline Type         |   | Prior Authorization – All Plans |                |       |
| Product<br>Name        | Generic Name GPI Brand  |                                 | Brand/Generic  |       |
| JUXTAPID               | LOMITAPIDE MESYLATE CAP 5 MG (BASE EQUIV)                       |                                 | 39480050200120 | Brand |
| JUXTAPID               | LOMITAPIDE MESYLATE CAP 10 MG (BASE EQUIV) 39480050200130 Brand |                                 | Brand          |       |

| JUXTAPID | LOMITAPIDE MESYLATE CAP 20 MG (BASE EQUIV) | 39480050200140 | Brand |
|----------|--|----------------|-------|
| JUXTAPID | LOMITAPIDE MESYLATE CAP 30 MG (BASE EQUIV) | 39480050200150 | Brand |

- 1 Diagnosis of homozygous familial hypercholesteremia (HoFH) with one of the following:
  - Clinical diagnosis (LDL-C greater than 500 mg/dL with xanthomas or family history of both parents with LDL-C levels greater than 250 mg/dL)
  - Genetic verification of HoFH

### **AND**

**2** - Prescribed by, or in consultation with, a Cardiologist or other specialist in the treatment of congenital lipid disorders

#### **AND**

3 - LDL-C level is greater than 70 mg/dL

### AND

**4** - Trial and failure, contraindication, or intolerance to a proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor unless there is genetic verification of receptor negative (null-null mutation) HoFH

| Product Name: Juxtapid |                                       |
|------------------------|---------------------------------------|
| Approval Length        | 12 month(s)                           |
| Therapy Stage          | Reauthorization                       |
| Guideline Type         | Prior Authorization - IL and MN Plans |

| Product<br>Name | Generic Name                               | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| JUXTAPID        | LOMITAPIDE MESYLATE CAP 5 MG (BASE EQUIV)  | 39480050200120 | Brand         |
| JUXTAPID        | LOMITAPIDE MESYLATE CAP 10 MG (BASE EQUIV) | 39480050200130 | Brand         |

| JUXTAPID | LOMITAPIDE MESYLATE CAP 20 MG (BASE EQUIV) | 39480050200140 | Brand |
|----------|--|----------------|-------|
| JUXTAPID | LOMITAPIDE MESYLATE CAP 30 MG (BASE EQUIV) | 39480050200150 | Brand |

- 1 Diagnosis of homozygous familial hypercholesteremia (HoFH) with one of the following:
  - Clinical diagnosis (LDL-C greater than 500 mg/dL with xanthomas or family history of both parents with LDL-C levels greater than 250 mg/dL)
  - Genetic verification of HoFH

### **AND**

**2** - Prescribed by, or in consultation with, a Cardiologist or other specialist in the treatment of congenital lipid disorders

### **AND**

**3** - Submission of medical records (e.g., chart notes) documenting a clinically meaningful (at least 10%) reduction in LDL-C from baseline

| Product Name: Juxtapid  |  |
|---|--|
| Approval Length 12/31/2039  |  |
| Therapy Stage Reauthorization   |  |
| Guideline Type Prior Authorization - All Plans except IL and MN Plans |  |

| Product<br>Name | Generic Name                               | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| JUXTAPID        | LOMITAPIDE MESYLATE CAP 5 MG (BASE EQUIV)  | 39480050200120 | Brand         |
| JUXTAPID        | LOMITAPIDE MESYLATE CAP 10 MG (BASE EQUIV) | 39480050200130 | Brand         |
| JUXTAPID        | LOMITAPIDE MESYLATE CAP 20 MG (BASE EQUIV) | 39480050200140 | Brand         |
| JUXTAPID        | LOMITAPIDE MESYLATE CAP 30 MG (BASE EQUIV) | 39480050200150 | Brand         |

### **Approval Criteria**

- 1 Diagnosis of homozygous familial hypercholesteremia (HoFH) with one of the following:
  - Clinical diagnosis (LDL-C greater than 500 mg/dL with xanthomas or family history of both parents with LDL-C levels greater than 250 mg/dL)
  - Genetic verification of HoFH

### **AND**

**2** - Prescribed by, or in consultation with, a Cardiologist or other specialist in the treatment of congenital lipid disorders

### **AND**

**3** - Submission of medical records (e.g., chart notes) documenting a clinically meaningful (at least 10%) reduction in LDL-C from baseline

| Date       | Notes                   |
|------------|-------------------------|
| 11/20/2023 | 2024 New Implementation |

| Jynarque (Tolvaptan)   |  |  |  |  |
|--|--|--|--|--|
| The hand the speciment in the speciment is the specimen of the |  |  |  |  |
|  |  |  |  |  |

| Guideline ID          | GL-131947            |
|-----------------------|----------------------|
| <b>Guideline Name</b> | Jynarque (Tolvaptan) |
| Formulary             | Quartz               |

# **Guideline Note:**

| Effective Date: |
|-----------------|
|-----------------|

# 1. Criteria

| Product Name: Jynarque             |                       |
|------------------------------------|-----------------------|
| Approval Length 12 month(s)        |                       |
| Therapy Stage                      | Initial Authorization |
| Guideline Type Prior Authorization |                       |

| Product<br>Name | Generic Name                          | GPI            | Brand/Generic |
|-----------------|---------------------------------------|----------------|---------------|
| JYNARQUE        | TOLVAPTAN TAB THERAPY PACK 15 MG      | 3045406000B710 | Brand         |
| JYNARQUE        | TOLVAPTAN TAB THERAPY PACK 30 & 15 MG | 3045406000B720 | Brand         |
| JYNARQUE        | TOLVAPTAN TAB THERAPY PACK 45 & 15 MG | 3045406000B725 | Brand         |
| JYNARQUE        | TOLVAPTAN TAB THERAPY PACK 60 & 30 MG | 3045406000B735 | Brand         |
| JYNARQUE        | TOLVAPTAN TAB THERAPY PACK 90 & 30 MG | 3045406000B745 | Brand         |
| TOLVAPTAN       | TOLVAPTAN TAB 15 MG                   | 30454060000320 | Generic       |

| JYNARQUE  | TOLVAPTAN TAB 15 MG | 30454060000320 | Brand   |
|-----------|---------------------|----------------|---------|
| TOLVAPTAN | TOLVAPTAN TAB 30 MG | 30454060000330 | Generic |
| JYNARQUE  | TOLVAPTAN TAB 30 MG | 30454060000330 | Brand   |

**1** - Diagnosis of autosomal dominant polycystic kidney disease (ADPKD)

### **AND**

**2** - Prescribed by, or on the recommendation of, a Nephrologist or other expert in kidney disease

### **AND**

3 - Age greater than or equal to 18 years

### **AND**

**4** - Estimated glomerular filtration rate ≥ 25 ml/min

| Product Name: Jynarque             |                 |
|------------------------------------|-----------------|
| Approval Length                    | 12 month(s)     |
| Therapy Stage                      | Reauthorization |
| Guideline Type Prior Authorization |                 |

| Product<br>Name | Generic Name                          | GPI            | Brand/Generic |
|-----------------|---------------------------------------|----------------|---------------|
| JYNARQUE        | TOLVAPTAN TAB THERAPY PACK 15 MG      | 3045406000B710 | Brand         |
| JYNARQUE        | TOLVAPTAN TAB THERAPY PACK 30 & 15 MG | 3045406000B720 | Brand         |
| JYNARQUE        | TOLVAPTAN TAB THERAPY PACK 45 & 15 MG | 3045406000B725 | Brand         |
| JYNARQUE        | TOLVAPTAN TAB THERAPY PACK 60 & 30 MG | 3045406000B735 | Brand         |
| JYNARQUE        | TOLVAPTAN TAB THERAPY PACK 90 & 30 MG | 3045406000B745 | Brand         |

| TOLVAPTAN | TOLVAPTAN TAB 15 MG | 30454060000320 | Generic |
|-----------|---------------------|----------------|---------|
| JYNARQUE  | TOLVAPTAN TAB 15 MG | 30454060000320 | Brand   |
| TOLVAPTAN | TOLVAPTAN TAB 30 MG | 30454060000330 | Generic |
| JYNARQUE  | TOLVAPTAN TAB 30 MG | 30454060000330 | Brand   |

**1** - Submission of medical records (e.g., chart notes) documenting that current laboratory values for liver and kidneys remain within acceptable treatment ranges

| Date       | Notes       |
|------------|-------------|
| 10/31/2023 | New program |

| Kerendia (finerenone)  |  |  |  |
|--|--|--|--|
| (2) The bill and ringer come to design out. There has been bound, contained, and distributed by particular to be convertible and design. |  |  |  |
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| Guideline ID          | GL-129742             |
|-----------------------|-----------------------|
| <b>Guideline Name</b> | Kerendia (finerenone) |
| Formulary             | Quartz                |

## **Guideline Note:**

| Effective Date: |
|-----------------|
|-----------------|

## 1. Criteria

| Product Name: Kerendia                                    |                 |  |
|---|-----------------|--|
| Approval Length   | gth 12 month(s) |  |
| Guideline Type Prior Authorization - IL and MN Plans Only |                 |  |
|   |                 |  |

| Product<br>Name | Generic Name         | GPI            | Brand/Generic |
|-----------------|----------------------|----------------|---------------|
| KERENDIA        | FINERENONE TAB 10 MG | 30354030000310 | Brand         |
| KERENDIA        | FINERENONE TAB 20 MG | 30354030000320 | Brand         |

## **Approval Criteria**

1 - Diagnosis of chronic kidney disease (CKD) associated with type 2 diabetes

#### AND

- 2 Diagnosis is confirmed by one of the following:
  - Urine albumin creatinine ratio (UACR) between 30 mg/g and 300 mg/g and estimated glomerular filtration rate (eGFR) of 25 to 60 mL/min
  - UACR > 300 mg/g and eGFR of 25 to 75 mL/min

#### **AND**

3 - Serum potassium level ≤ 5 mEq/L

### **AND**

- **4** Trial and failure of a maximally tolerated dose, contraindication or intolerance to both of the following:
  - Ace-inhibitor (ACE-I) or angiotensin receptor blocker (ARB)
  - Sodium-glucose cotransporter-2 (SGLT2) drug that has an indication for CKD benefit (e.g., dapagliflozin, canagliflozin, empagliflozin)

### **AND**

**5** - UACR remains above 30 mg/g despite use of ACE-I/ARB and SGLT2 (unless contraindicated or not tolerated)

| Product Name: Kerendia  |                       |
|---|-----------------------|
| Approval Length 12/31/2039                                      |                       |
| Therapy Stage   | Initial Authorization |
| Guideline Type Prior Authorization - All plans except IL and MN |                       |

| Product<br>Name | Generic Name         | GPI            | Brand/Generic |
|-----------------|----------------------|----------------|---------------|
| KERENDIA        | FINERENONE TAB 10 MG | 30354030000310 | Brand         |
| KERENDIA        | FINERENONE TAB 20 MG | 30354030000320 | Brand         |

1 - Diagnosis of chronic kidney disease (CKD) associated with type 2 diabetes

#### **AND**

- 2 Diagnosis is confirmed by one of the following:
  - Urine albumin creatinine ratio (UACR) between 30 mg/g and 300 mg/g and estimated glomerular filtration rate (eGFR) of 25 to 60 mL/min
  - UACR > 300 mg/g and eGFR of 25 to 75 mL/min

#### **AND**

3 - Serum potassium level ≤ 5 mEq/L

#### **AND**

- **4** Trial and failure of a maximally tolerated dose, contraindication or intolerance to both of the following:
  - Ace-inhibitor (ACE-I) or angiotensin receptor blocker (ARB)
  - Sodium-glucose cotransporter-2 (SGLT2) drug that has an indication for CKD benefit (e.g., dapagliflozin, canagliflozin, empagliflozin)

#### **AND**

**5** - UACR remains above 30 mg/g despite use of ACE-I/ARB and SGLT2 (unless contraindicated or not tolerated)

| Product Name: Kerendia |                            |                                       |     |               |
|------------------------|----------------------------|---------------------------------------|-----|---------------|
| Approval Le            | ength 12 month(s)          |                                       |     |               |
| Therapy Sta            | rapy Stage Reauthorization |                                       |     |               |
| Guideline Type         |                            | Prior Authorization - IL and MN plans |     |               |
| Product<br>Name        | Generic Name               |                                       | GPI | Brand/Generic |

| KERENDIA | FINERENONE TAB 10 MG | 30354030000310 | Brand |
|----------|----------------------|----------------|-------|
| KERENDIA | FINERENONE TAB 20 MG | 30354030000320 | Brand |

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug

| Date       | Notes                   |
|------------|-------------------------|
| 10/31/2023 | 2024 New Implementation |

| Ketor                                   | olac Inje   | ction   |  |
|---|---|---|--|
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|   |   |   |  |

| Guideline ID          | GL-132775           |  |
|-----------------------|---------------------|--|
| <b>Guideline Name</b> | Ketorolac Injection |  |
| Formulary             | Quartz              |  |

# **Guideline Note:**

| Effective Date: |
|-----------------|
|-----------------|

## 1. Criteria

| Product Name: Ketorlac Injection                                |                       |  |
|---|-----------------------|--|
| Approval Length   | n 12 month(s)         |  |
| Therapy Stage   | Initial Authorization |  |
| Guideline Type Quantity Limit - Applies to IL and MN plans only |                       |  |

| Product Name              | Generic Name                                       | GPI            | Brand/Generic |
|---------------------------|--|----------------|---------------|
| KETOROLAC<br>TROMETHAMINE | KETOROLAC TROMETHAMINE INJ 15 MG/ML                | 66100037102015 | Generic       |
| KETOROLAC<br>TROMETHAMINE | KETOROLAC TROMETHAMINE IM INJ 60 MG/2ML (30 MG/ML) | 66100037102071 | Generic       |
| KETOROLAC<br>TROMETHAMINE | KETOROLAC TROMETHAMINE INJ 30 MG/ML                | 66100037102030 | Generic       |

# **Approval Criteria**

- **1** Submission of medical records (e.g., chart notes) documenting that the member does not have one of the following:
  - reduced kidney function
  - history of gastrointestinal ulcers/bleeds

| Product Name: Ketorlac Injection                                |  |  |
|---|--|--|
| Approval Length 12 month(s)                                     |  |  |
| Therapy Stage Reauthorization                                   |  |  |
| Guideline Type Quantity Limit - Applies to IL and MN plans only |  |  |

| Product Name              | Generic Name                                       | GPI            | Brand/Generic |
|---------------------------|--|----------------|---------------|
| KETOROLAC<br>TROMETHAMINE | KETOROLAC TROMETHAMINE INJ 15 MG/ML                | 66100037102015 | Generic       |
| KETOROLAC<br>TROMETHAMINE | KETOROLAC TROMETHAMINE IM INJ 60 MG/2ML (30 MG/ML) | 66100037102071 | Generic       |
| KETOROLAC<br>TROMETHAMINE | KETOROLAC TROMETHAMINE INJ 30 MG/ML                | 66100037102030 | Generic       |

**1** - Submission of medical records (e.g., chart notes) from the past 12 months that the member is having a positive response to therapy

| Product Name: Ketorlac Injection |  |  |
|----------------------------------|--|--|
| Approval Length 12/31/2039       |  |  |
| Guideline Type                   | Quantity Limit - Applies to all plans except IL and MN |  |

| Product Name              | Generic Name                                       | GPI            | Brand/Generic |
|---------------------------|--|----------------|---------------|
| KETOROLAC<br>TROMETHAMINE | KETOROLAC TROMETHAMINE INJ 15 MG/ML                | 66100037102015 | Generic       |
| KETOROLAC<br>TROMETHAMINE | KETOROLAC TROMETHAMINE IM INJ 60 MG/2ML (30 MG/ML) | 66100037102071 | Generic       |
| KETOROLAC<br>TROMETHAMINE | KETOROLAC TROMETHAMINE INJ 30 MG/ML                | 66100037102030 | Generic       |

### **Approval Criteria**

- 1 Submission of medical records (e.g., chart notes) documenting that the member does not have one of the following:

  - reduced kidney function history of gastrointestinal ulcers/bleeds

| Date       | Notes       |
|------------|-------------|
| 10/31/2023 | New Program |

| Kevey  | Keveyis (Dichlorphenamide)  |  |  |  |  |
|--|---|--|--|--|--|
| The little of image current is a slighty self. The | with the first and control or added the first first for particular according and relative |  |  |  |  |
|  |   |  |  |  |  |

| Guideline ID          | GL-131972                  |
|-----------------------|----------------------------|
| <b>Guideline Name</b> | Keveyis (Dichlorphenamide) |
| Formulary             | Quartz                     |

## **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

## 1. Criteria

| Product Name: Generic Dichlorphenamide |  |  |
|--|--|--|
| Approval Length 12 month(s)            |  |  |
| Therapy Stage                          | Initial Authorization                    |  |
| Guideline Type                         | Prior Authorization-IL and MN Plans Only |  |

| Product Name     | Generic Name               | GPI            | Brand/Generic |
|------------------|----------------------------|----------------|---------------|
| DICHLORPHENAMIDE | DICHLORPHENAMIDE TAB 50 MG | 37100020000305 | Generic       |

### **Approval Criteria**

**1** - Diagnosis of primary hyperkalemic periodic paralysis, primary hypokalemic periodic paralysis, or related variants

### AND

### 2 - Age greater than or equal to 18

| Product Name: Generic Dichlorphenamide                  |  |                 |     |               |
|---|--|-----------------|-----|---------------|
| Approval Length   |  | 12 month(s)     |     |               |
| Therapy Stage   |  | Reauthorization |     |               |
| Guideline Type Prior Authorization-IL and MN Plans Only |  |                 |     |               |
| Product Name Generic Nan                                |  | eneric Name     | GPI | Brand/Generic |

| Product Name     | Generic Name               | GPI            | Brand/Generic |
|------------------|----------------------------|----------------|---------------|
| DICHLORPHENAMIDE | DICHLORPHENAMIDE TAB 50 MG | 37100020000305 | Generic       |

### **Approval Criteria**

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug.

| Product Name: Generic Dichlorphenamide |  |
|--|--|
| Approval Length 12/31/2039             |  |
| Guideline Type                         | Prior Authorization-All plans except IL and MN |

| Product Name     | Generic Name               | GPI            | Brand/Generic |
|------------------|----------------------------|----------------|---------------|
| DICHLORPHENAMIDE | DICHLORPHENAMIDE TAB 50 MG | 37100020000305 | Generic       |

### **Approval Criteria**

**1** - Diagnosis of primary hyperkalemic periodic paralysis, primary hypokalemic periodic paralysis, or related variants

### **AND**

2 - Age greater than or equal to 18

| Date       | Notes       |
|------------|-------------|
| 10/31/2023 | New program |

| Kineret (anakinra)   |
|--|
| (a) The Standings control buildings on The Box Stand Stands of Stands St |
|  |
|  |

| Guideline ID          | GL-137218          |
|-----------------------|--------------------|
| <b>Guideline Name</b> | Kineret (anakinra) |
| Formulary             | Quartz             |

# **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

## 1. Criteria

| Product Name: Kineret |  |  |
|-----------------------|--|--|
| Diagnosis             | Moderate to Severely Active Rheumatoid Arthritis (RA), Juvenile Idiopathic Arthritis (JIA) |  |
| Approval Length       | 12/31/2039   |  |
| Guideline Type        | Prior Authorization – All Plans except IL and MN Plans                                     |  |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| KINERET         | ANAKINRA SUBCUTANEOUS SOLN PREFILLED<br>SYRINGE 100 MG/0.67ML | 6626001000E520 | Brand         |

# **Approval Criteria**

1 - Diagnosis of one of the following:

| <ul> <li>Moderate to severely active rheumatoid arthritis (RA)</li> <li>Juvenile idiopathic arthritis (JIA)</li> </ul>  |
|---|
| AND   |
| <b>2</b> - Submission of medical records (e.g., chart notes) documenting a 3-month trial and failure, intolerance, or contraindication to ONE of the following: |
| <ul> <li>Methotrexate (MTX)*</li> <li>Leflunomide</li> <li>Hydroxychloroquine</li> <li>Sulfasalazine</li> </ul>   |
| AND   |
| 3 - Medication will be self-administered (not in clinic or provider office)   |
| AND   |
| 4 - Prescribed by or in consultation with a rheumatologist  |
| AND   |
| <b>5</b> - Not used in combination with other biologic DMARDs (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)                          |
| AND   |
| <b>6</b> - Both of the following:   |

**6.1** Trial and failure, contraindication, or intolerance to TWO of the following:

- Certolizumab
- Etanercept Adalimumab (biosimilars or Humira) Upadacitinib
- . Golimumab

Tofacitinib/ER

### **AND**

- **6.2** Trial and failure, contraindication, or intolerance to BOTH of the following:
  - Tocilizumab
  - Abatacept

| Notes | *Absolute contraindications to methotrexate are pregnancy, nursing, al   |
|-------|--|
|       | coholism, alcoholic liver disease or other chronic liver disease, immuno |
|       | deficiency syndromes, bone marrow hyperplasia, leukopenia, thromboc      |
|       | ytopenia or significant anemia, or hypersensitivity to methotrexate.     |

| Product Name: Kineret |  |  |
|-----------------------|--|--|
| Diagnosis             | Moderate to Severely Active Rheumatoid Arthritis (RA), Juvenile Idiopathic Arthritis (JIA) |  |
| Approval Length       | 12 month(s)  |  |
| Therapy Stage         | Initial Authorization  |  |
| Guideline Type        | Prior Authorization – IL and MN Plans  |  |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| KINERET         | ANAKINRA SUBCUTANEOUS SOLN PREFILLED<br>SYRINGE 100 MG/0.67ML | 6626001000E520 | Brand         |

### **Approval Criteria**

- 1 Diagnosis of one of the following:
  - Moderate to severely active rheumatoid arthritis (RA)
  - Juvenile idiopathic arthritis (JIA)

### **AND**

- **2** Submission of medical records (e.g., chart notes) documenting a 3-month trial and failure, intolerance, or contraindication to ONE of the following:
  - Methotrexate (MTX)\*

LeflunomideHydroxychloroquineSulfasalazine

#### **AND**

3 - Medication will be self-administered (not in clinic or provider office)

### **AND**

4 - Prescribed by or in consultation with a rheumatologist

#### AND

**5** - Not used in combination with other biologic DMARDs (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

### **AND**

- **6** Both of the following:
- **6.1** Trial and failure, contraindication, or intolerance to TWO of the following:
  - Certolizumab
  - Etanercept
  - Adalimumab (biosimilars or Humira)
  - Upadacitinib
  - Golimumab
  - Tofacitinib/ER

### **AND**

- **6.2** Trial and failure, contraindication, or intolerance to BOTH of the following:
  - Tocilizumab
  - Abatacept

Notes \*Absolute contraindications to methotrexate are pregnancy, nursing, al

| coholism, alcoholic liver disease or other chronic liver disease, immuno |
|--|
| deficiency syndromes, bone marrow hyperplasia, leukopenia, thromboc      |
| ytopenia or significant anemia, or hypersensitivity to methotrexate.     |

| Product Name: Kineret |  |  |
|-----------------------|--|--|
| Diagnosis             | Cryopyrin Associated Periodic Syndromes (CAPS)         |  |
| Approval Length       | 12/31/2039   |  |
| Guideline Type        | Prior Authorization – All Plans except IL and MN Plans |  |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| KINERET         | ANAKINRA SUBCUTANEOUS SOLN PREFILLED<br>SYRINGE 100 MG/0.67ML | 6626001000E520 | Brand         |

**1** - Diagnosis of cryopyrin associated periodic syndromes (CAPS) including Muckle Wells, neonatal-onset multisystemic inflammatory disorder, familial cold autoinflammatory syndrome, or other periodic syndromes

### **AND**

2 - Prescribed by or in consultation with a rheumatologist

### **AND**

**3** - Not used in combination with other biologic DMARDs (e.g., canakinumab)

### **AND**

| Product Name: Kineret |  |  |
|-----------------------|--|--|
| Diagnosis             | Cryopyrin Associated Periodic Syndromes (CAPS) |  |
| Approval Length       | 12 month(s)                                    |  |

| Therapy Stage  | Initial Authorization                 |
|----------------|---------------------------------------|
| Guideline Type | Prior Authorization – IL and MN Plans |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| KINERET         | ANAKINRA SUBCUTANEOUS SOLN PREFILLED<br>SYRINGE 100 MG/0.67ML | 6626001000E520 | Brand         |

**1** - Diagnosis of cryopyrin associated periodic syndromes (CAPS) including Muckle Wells, neonatal-onset multisystemic inflammatory disorder, familial cold autoinflammatory syndrome, or other periodic syndromes

### **AND**

2 - Prescribed by or in consultation with a rheumatologist

### **AND**

**3** - Not used in combination with other biologic DMARDs (e.g., canakinumab)

### **AND**

| Product Name: Kineret |  |  |
|-----------------------|--|--|
| Diagnosis             | Systemic Juvenile Arthritis, Adult-Onset Still's Disease |  |
| Approval Length       | 12/31/2039   |  |
| Guideline Type        | Prior Authorization – All Plans except IL and MN Plans   |  |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| KINERET         | ANAKINRA SUBCUTANEOUS SOLN PREFILLED<br>SYRINGE 100 MG/0.67ML | 6626001000E520 | Brand         |

1 - Diagnosis of systemic juvenile arthritis or adult-onset Still's disease

#### **AND**

2 - Prescribed by or in consultation with a rheumatologist

### AND

- 3 Trial and failure, contraindication, or intolerance to ONE of the following for 3 months:
  - corticosteroids
  - methotrexate
  - nonsteroidal anti-inflammatory drugs (NSAIDs)

### **AND**

4 - Not used in combination with other biologic DMARDs (e.g., canakinumab)

### **AND**

| Product Name: Kineret |  |  |
|-----------------------|--|--|
| Diagnosis             | Systemic Juvenile Arthritis, Adult-Onset Still's Disease |  |
| Approval Length       | 12 month(s)  |  |
| Therapy Stage         | Initial Authorization                                    |  |
| Guideline Type        | Prior Authorization – IL and MN Plans                    |  |

| T T T T T T T T T T T T T T T T T T T                                      |                |       |
|--|----------------|-------|
| KINERET ANAKINRA SUBCUTANEOUS SOLN PREFILLED 6626<br>SYRINGE 100 MG/0.67ML | 6626001000E520 | Brand |

1 - Diagnosis of systemic juvenile arthritis or adult-onset Still's disease

#### **AND**

2 - Prescribed by or in consultation with a rheumatologist

### AND

- 3 Trial and failure, contraindication, or intolerance to ONE of the following for 3 months:
  - corticosteroids
  - methotrexate
  - nonsteroidal anti-inflammatory drugs (NSAIDs)

### **AND**

4 - Not used in combination with other biologic DMARDs (e.g., canakinumab)

### **AND**

| Product Name: Kineret |                                       |  |
|-----------------------|---------------------------------------|--|
| Diagnosis             | All Indications                       |  |
| Approval Length       | 12 month(s)                           |  |
| Therapy Stage         | Reauthorization                       |  |
| Guideline Type        | Prior Authorization – IL and MN Plans |  |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| KINERET         | ANAKINRA SUBCUTANEOUS SOLN PREFILLED<br>SYRINGE 100 MG/0.67ML | 6626001000E520 | Brand         |
|                 |   |                |               |

**1** - Prescriber provides clinical documentation from the previous 12 months that describes the member's response as stable disease or improvement seen on therapy

| Date      | Notes                   |
|-----------|-------------------------|
| 12/4/2023 | 2024 New Implementation |

| ŀ   | Kuvan  | (sapropterin  | ) |  |
|-----|--|---|---|--|
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|     |  |   |   |  |

| Guideline ID          | GL-131589           |
|-----------------------|---------------------|
| <b>Guideline Name</b> | Kuvan (sapropterin) |
| Formulary             | Quartz              |

### **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

### Note:

Member new to the plan (as evidenced by coverage effective date of less than or equal to 90 days) who initiated therapy using a manufacturer-sponsored free drug program, provider samples, and/or vouchers will go through initial criteria, otherwise for continuation of therapy for new to plan, reauthorization criteria applies.

### 1. Criteria

| Product Name: Generic sapropterin     |     |  |                |               |
|---------------------------------------|-----|--|----------------|---------------|
| Approval Length                       |     | 2 month(s)                                       |                |               |
| Therapy Stage                         |     | Initial Authorization                            |                |               |
| Guideline Type                        |     | Prior Authorization - All plans except IL and MN |                |               |
| Product Name                          | Gei | neric Name                                       | GPI            | Brand/Generic |
| SAPROPTERIN SAF<br>DIHYDROCHLORIDE MG |     | PROPTERIN DIHYDROCHLORIDE TAB 100                | 30908565100320 | Generic       |
| SAPROPTERIN SAF                       |     | PROPTERIN DIHYDROCHLORIDE                        | 30908565103020 | Generic       |

| DIHYDROCHLORIDE                | POWDER PACKET 100 MG                                |                |         |
|--------------------------------|---|----------------|---------|
| SAPROPTERIN<br>DIHYDROCHLORIDE | SAPROPTERIN DIHYDROCHLORIDE<br>POWDER PACKET 500 MG | 30908565103040 | Generic |

1 - Diagnosis of phenylketonuria (PKU)

### AND

2 - Used in conjunction with a phenylalanine (Phe) restricted diet

### **AND**

**3** - Member is not on concurrent pegvaliase therapy

| Product Name: Generic sapropterin |  |  |
|-----------------------------------|--|--|
| Approval Length 12 month(s)       |  |  |
| Therapy Stage                     | Initial Authorization                      |  |
| Guideline Type                    | Prior Authorization - IL and MN Plans Only |  |

| Product Name                   | Generic Name  | GPI            | Brand/Generic |
|--------------------------------|---|----------------|---------------|
| SAPROPTERIN<br>DIHYDROCHLORIDE | SAPROPTERIN DIHYDROCHLORIDE TAB 100 MG              | 30908565100320 | Generic       |
| SAPROPTERIN<br>DIHYDROCHLORIDE | SAPROPTERIN DIHYDROCHLORIDE<br>POWDER PACKET 100 MG | 30908565103020 | Generic       |
| SAPROPTERIN<br>DIHYDROCHLORIDE | SAPROPTERIN DIHYDROCHLORIDE<br>POWDER PACKET 500 MG | 30908565103040 | Generic       |

### **Approval Criteria**

1 - Diagnosis of phenylketonuria (PKU)

### **AND**

2 - Used in conjunction with a phenylalanine (Phe) restricted diet

### **AND**

3 - Member is not on concurrent pegvaliase therapy

| Product Name: Generic sapropterin |  |  |
|-----------------------------------|--|--|
| Diagnosis                         | After 2 month initial fill                       |  |
| Approval Length                   | 12 month(s)                                      |  |
| Therapy Stage                     | Reauthorization                                  |  |
| Guideline Type                    | Prior Authorization - All plans except IL and MN |  |

| Product Name                   | Generic Name  | GPI            | Brand/Generic |
|--------------------------------|---|----------------|---------------|
| SAPROPTERIN<br>DIHYDROCHLORIDE | SAPROPTERIN DIHYDROCHLORIDE TAB 100 MG              | 30908565100320 | Generic       |
| SAPROPTERIN<br>DIHYDROCHLORIDE | SAPROPTERIN DIHYDROCHLORIDE<br>POWDER PACKET 100 MG | 30908565103020 | Generic       |
| SAPROPTERIN<br>DIHYDROCHLORIDE | SAPROPTERIN DIHYDROCHLORIDE<br>POWDER PACKET 500 MG | 30908565103040 | Generic       |

### **Approval Criteria**

 ${\bf 1}$  - Clinical documentation of a 30% or more reduction in Phe levels from baseline on sapropterin treatment

### **AND**

2 - Used in conjunction with a phenylalanine (Phe) restricted diet

### **AND**

3 - Member will continue to have blood Phe levels measured periodically during treatment

### **AND**

### 4 - Member is not on concurrent pegvaliase therapy

| Product Name: Generic sapropterin |                                 |  |
|-----------------------------------|---------------------------------|--|
| Diagnosis                         | Continuation of Coverage        |  |
| Approval Length                   | 12 month(s)                     |  |
| Therapy Stage                     | Reauthorization                 |  |
| Guideline Type                    | Prior Authorization - All Plans |  |

| Product Name                   | Generic Name  | GPI            | Brand/Generic |
|--------------------------------|---|----------------|---------------|
| SAPROPTERIN<br>DIHYDROCHLORIDE | SAPROPTERIN DIHYDROCHLORIDE TAB 100 MG              | 30908565100320 | Generic       |
| SAPROPTERIN<br>DIHYDROCHLORIDE | SAPROPTERIN DIHYDROCHLORIDE<br>POWDER PACKET 100 MG | 30908565103020 | Generic       |
| SAPROPTERIN<br>DIHYDROCHLORIDE | SAPROPTERIN DIHYDROCHLORIDE<br>POWDER PACKET 500 MG | 30908565103040 | Generic       |

### **Approval Criteria**

1 - Used in conjunction with a phenylalanine (Phe) restricted diet

### **AND**

2 - Member will continue to have blood Phe levels measured periodically during treatment

### **AND**

3 - Member is not on concurrent pegvaliase therapy

| Date       | Notes                   |
|------------|-------------------------|
| 10/27/2023 | 2024 New Implementation |

| Lescol (Fluvastatin), Lescol XL (Fluvastatin XR)   |  |  |  |
|--|--|--|--|
| The behavior of the behavior of the second o |  |  |  |

| Guideline ID          | GL-131974  |  |
|-----------------------|--|--|
| <b>Guideline Name</b> | Lescol (Fluvastatin), Lescol XL (Fluvastatin XR) |  |
| Formulary             | Quartz   |  |

# **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

# 1. Criteria

| Product Name: Generic: Fluvastatin, Fluvastatin XR      |                         |  |
|---|-------------------------|--|
| Approval Length 12 month(s)                             |                         |  |
| Therapy Stage   | e Initial Authorization |  |
| Guideline Type Prior Authorization-IL and MN Plans Only |                         |  |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
|                 | FLUVASTATIN SODIUM TAB ER 24 HR 80 MG (BASE EQUIVALENT) | 39400030107530 | Generic       |
| FLUVASTATIN     | FLUVASTATIN SODIUM CAP 20 MG (BASE EQUIVALENT)          | 39400030100120 | Generic       |
| FLUVASTATIN     | FLUVASTATIN SODIUM CAP 40 MG (BASE EQUIVALENT)          | 39400030100140 | Generic       |

**1** - Trial and failure, contraindication or intolerance to all generic preferred statins (atorvastatin, lovastatin, pravastatin, rosuvastatin and simvastatin)

| Product Name: Generic: Fluvastatin, Fluvastatin XR      |                 |
|---|-----------------|
| Approval Length 12 month(s)                             |                 |
| Therapy Stage   | Reauthorization |
| Guideline Type Prior Authorization-IL and MN Plans Only |                 |

| Product<br>Name          | Generic Name  | GPI            | Brand/Generic |
|--------------------------|---|----------------|---------------|
| FLUVASTATIN<br>SODIUM ER | FLUVASTATIN SODIUM TAB ER 24 HR 80 MG (BASE EQUIVALENT) | 39400030107530 | Generic       |
| FLUVASTATIN              | FLUVASTATIN SODIUM CAP 20 MG (BASE EQUIVALENT)          | 39400030100120 | Generic       |
| FLUVASTATIN              | FLUVASTATIN SODIUM CAP 40 MG (BASE EQUIVALENT)          | 39400030100140 | Generic       |

### **Approval Criteria**

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug.

| Product Name: Generic: Fluvastatin, Fluvastatin XR            |  |
|---|--|
| Approval Length 12/31/2039                                    |  |
| Guideline Type Prior Authorization-All plans except IL and MN |  |

| Product<br>Name          | Generic Name  | GPI            | Brand/Generic |
|--------------------------|---|----------------|---------------|
| FLUVASTATIN<br>SODIUM ER | FLUVASTATIN SODIUM TAB ER 24 HR 80 MG (BASE EQUIVALENT) | 39400030107530 | Generic       |
| FLUVASTATIN              | FLUVASTATIN SODIUM CAP 20 MG (BASE EQUIVALENT)          | 39400030100120 | Generic       |
| FLUVASTATIN              | FLUVASTATIN SODIUM CAP 40 MG (BASE EQUIVALENT)          | 39400030100140 | Generic       |

### **Approval Criteria**

**1** - Trial and failure, contraindication or intolerance to all generic preferred statins (atorvastatin, lovastatin, pravastatin, rosuvastatin and simvastatin)

| Date       | Notes       |
|------------|-------------|
| 10/31/2023 | New program |

| Leukine (Sargramostim)                        |  |                      |  |  |
|---|--|----------------------|--|--|
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|   |  |                      |  |  |
|   |  |                      |  |  |

| Guideline ID          | GL-136712              |  |
|-----------------------|------------------------|--|
| <b>Guideline Name</b> | Leukine (Sargramostim) |  |
| Formulary             | Quartz                 |  |

## **Guideline Note:**

| Effective Date: |
|-----------------|
|-----------------|

## 1. Criteria

| Product Name: Leukine |  |                     |                |               |
|-----------------------|--|---------------------|----------------|---------------|
| Approval Length       |  | 12 month(s)         |                |               |
| Guideline Type        |  | Prior Authorization |                |               |
| Product<br>Name       | Generic Name                             |                     | GPI            | Brand/Generic |
| LEUKINE               | SARGRAMOSTIM LYOPHILIZED FOR INJ 250 MCG |                     | 82402050002120 | Brand         |

### **Approval Criteria**

- 1 One of the following:
- **1.1** Trial and failure, contraindication, or intolerance to tbo-filgrastim (i.e. Granix)

OR

- **1.2** Both of the following:
- 1.2.1 Diagnosis if neuroblastoma

**AND** 

1.2.2 Used in combination with naxitamab (Danyelza)

OR

**1.3** Minnesota plans only: The person has stage four metastatic cancer and the requested drug is being used as supportive care for their cancer treatment.

| Date       | Notes            |
|------------|------------------|
| 11/27/2023 | Criteria updated |

| Leuprolide daily injection   |  |  |
|--|--|--|
| Analysis of the state of the st |  |  |
|  |  |  |

| Guideline ID          | GL-132743                  |  |
|-----------------------|----------------------------|--|
| <b>Guideline Name</b> | Leuprolide daily injection |  |
| Formulary             | Quartz                     |  |

## **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

## 1. Criteria

| Product Name: Leuprolide Injection |   |
|------------------------------------|---|
| Approval Length                    | 12/31/2039                                      |
| Guideline Type                     | Prior Authorization - All plans except MN Plans |

| Product<br>Name       | Generic Name                       | GPI            | Brand/Generic |
|-----------------------|------------------------------------|----------------|---------------|
| LEUPROLIDE<br>ACETATE | LEUPROLIDE ACETATE INJ KIT 5 MG/ML | 21405010106407 | Generic       |

## **Approval Criteria**

1 - The injections will be self-administered

### AND

**2** - Use is for a diagnosis other than infertility (e.g.,. prostate cancer, endometriosis, dysmenorrhea, etc.)

| Product Name: Leuprolide Injection |                                |
|------------------------------------|--------------------------------|
| Approval Length                    | 12 month(s)                    |
| Therapy Stage                      | Initial Authorization          |
| Guideline Type                     | Prior Authorization - MN Plans |

| Product<br>Name       | Generic Name                       | GPI            | Brand/Generic |
|-----------------------|------------------------------------|----------------|---------------|
| LEUPROLIDE<br>ACETATE | LEUPROLIDE ACETATE INJ KIT 5 MG/ML | 21405010106407 | Generic       |

### **Approval Criteria**

1 - The injections will be self-administered

#### **AND**

**2** - Use is for a diagnosis other than infertility (e.g.,. prostate cancer, endometriosis, dysmenorrhea, etc.)

| Product Name: Leuprolide Injection |                                |
|------------------------------------|--------------------------------|
| Approval Length                    | 12 month(s)                    |
| Therapy Stage                      | Reauthorization                |
| Guideline Type                     | Prior Authorization - MN Plans |

| Product<br>Name       | Generic Name                       | GPI            | Brand/Generic |
|-----------------------|------------------------------------|----------------|---------------|
| LEUPROLIDE<br>ACETATE | LEUPROLIDE ACETATE INJ KIT 5 MG/ML | 21405010106407 | Generic       |

### **Approval Criteria**

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug

| Date       | Notes                   |
|------------|-------------------------|
| 10/31/2023 | 2024 New Implementation |

| Levemir (insulin detemir)  |  |  |  |
|--|--|--|--|
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|  |  |  |  |

| Guideline ID          | GL-129856                 |
|-----------------------|---------------------------|
| <b>Guideline Name</b> | Levemir (insulin detemir) |
| Formulary             | Quartz                    |

## **Guideline Note:**

| Effective Date: |
|-----------------|
|-----------------|

## 1. Criteria

| Product Name: Levemir |                                       |
|-----------------------|---------------------------------------|
| Approval Length       | 12 month(s)                           |
| Therapy Stage         | Initial Authorization                 |
| Guideline Type        | Prior Authorization - IL and MN Plans |

| Product<br>Name    | Generic Name                                  | GPI            | Brand/Generic |
|--------------------|---|----------------|---------------|
| LEVEMIR<br>FLEXPEN | INSULIN DETEMIR SOLN PEN-INJECTOR 100 UNIT/ML | 2710400600D220 | Brand         |
| LEVEMIR            | INSULIN DETEMIR INJ 100 UNIT/ML               | 27104006002020 | Brand         |

### **Approval Criteria**

**1** - Both of the following:

- Member is currently pregnant
- Diagnosis of gestational diabetes

#### **AND**

- 2 Prescribed by or in consultation with one of the following:
  - Endocrinologist
  - Diabetes specialist

#### **AND**

- **3** One of the following:
- **3.1** Member cannot meet their glycemic goals despite an adequate trial of insulin isophane (NPH) including:
  - Dose escalation, unless dose increases cannot be tolerated due to nocturnal hypoglycemia or at least one severe low blood sugar event (requiring assistance from another) or would not be appropriate given the person's self-monitoring blood glucose profile
  - Submission of medical records (e.g., chart notes) documenting use of a specific adherence intervention deployed by a health care professional if nonadherence is evident

OR

3.2 Member is intolerant to insulin isophane (NPH)

| Product Name: Levemir |                                       |  |
|-----------------------|---------------------------------------|--|
| Approval Length       | 12 month(s)                           |  |
| Therapy Stage         | Reauthorization                       |  |
| Guideline Type        | Prior Authorization - IL and MN Plans |  |

| Product<br>Name    | Generic Name                                  | GPI            | Brand/Generic |
|--------------------|---|----------------|---------------|
| LEVEMIR<br>FLEXPEN | INSULIN DETEMIR SOLN PEN-INJECTOR 100 UNIT/ML | 2710400600D220 | Brand         |

| LEVEMIR | INSULIN DETEMIR INJ 100 UNIT/ML | 27104006002020 | Brand |
|---------|---------------------------------|----------------|-------|
|---------|---------------------------------|----------------|-------|

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug

| Product Name: Levemir      |  |  |
|----------------------------|--|--|
| Approval Length 12/31/2039 |  |  |
| Guideline Type             | Prior Authorization - All Plans Except IL and MN Plans |  |

| Product<br>Name    | Generic Name                                  | GPI            | Brand/Generic |
|--------------------|---|----------------|---------------|
| LEVEMIR<br>FLEXPEN | INSULIN DETEMIR SOLN PEN-INJECTOR 100 UNIT/ML | 2710400600D220 | Brand         |
| LEVEMIR            | INSULIN DETEMIR INJ 100 UNIT/ML               | 27104006002020 | Brand         |

### **Approval Criteria**

- **1** Both of the following:
  - Member is currently pregnant
  - Diagnosis of gestational diabetes

### **AND**

- **2** Prescribed by or in consultation with one of the following:
  - Endocrinologist
  - Diabetes specialist

#### **AND**

- 3 One of the following:
- **3.1** Member cannot meet their glycemic goals despite adequate trials of insulin isophane (NPH) including:

- Dose escalation, unless dose increases cannot be tolerated due to nocturnal hypoglycemia or at least one severe low blood sugar event (requiring assistance from another) or would not be appropriate given the person's self-monitoring blood glucose profile
- Submission of medical records (e.g., chart notes) documenting use of a specific adherence intervention deployed by a health care provider if nonadherence is evident

OR

**3.2** Member is intolerant to insulin isophane (NPH)

| Date       | Notes                   |
|------------|-------------------------|
| 10/12/2023 | 2024 New Implementation |

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| Guideline ID          | GL-135578              |
|-----------------------|------------------------|
| <b>Guideline Name</b> | Livmarli (maralixibat) |
| Formulary             | Quartz                 |

## **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

## 1. Criteria

| Product Name: Livmarli |                       |  |
|------------------------|-----------------------|--|
| Approval Length        | 12 month(s)           |  |
| Therapy Stage          | Initial Authorization |  |
| Guideline Type         | Prior Authorization   |  |

| Product<br>Name | Generic Name                             | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| LIVMARLI        | MARALIXIBAT CHLORIDE ORAL SOLN 9.5 MG/ML | 52350050102020 | Brand         |

# **Approval Criteria**

1 - Diagnosis of Alagille syndrome (ALGS)

| AND   |  |  |  |  |
|---|--|--|--|--|
| 2 - Molecular genetic testing confirms mutations in the JAG1 or NOTCH2 gene   |  |  |  |  |
| AND   |  |  |  |  |
| 3 - One of the following:   |  |  |  |  |
| <ul> <li>Total serum bile acid greater than 3x the upper limit of normal (ULN)</li> <li>Conjugated bilirubin greater than 1 mg/dL</li> <li>Fat soluble vitamin deficiency otherwise unexplainable</li> <li>Gamma-glutamyl transpeptidase (GGT) greater than 3x ULN</li> </ul> |  |  |  |  |
| AND   |  |  |  |  |
| 4 - Member is experiencing moderate to severe cholestatic pruritus  |  |  |  |  |
| AND   |  |  |  |  |
| 5 - Member has not had a liver transplant or decompensated liver disease  |  |  |  |  |
| AND   |  |  |  |  |
| <b>6</b> - Trial and failure, contraindication or intolerance to TWO of the following medications for pruritis:   |  |  |  |  |
| <ul> <li>Ursodeoxycholic acid (e.g., Ursodiol)</li> <li>Antihistamines (e.g., diphenhydramine, hydroxyzine)</li> <li>Rifampin</li> <li>Bile acid sequestrants (e.g., Questran, Colestid, Welchol)</li> </ul>  |  |  |  |  |

### AND

- **7** Prescribed by or in consultation with one of the following:
  - Hepatologist

| Expert in the | treatment of cholestasis   |
|---------------|--|
| Notes         | *Member new to the plan (as evidenced by coverage effective date of I ess than or equal to 90 days) who initiated therapy using a manufactur er-sponsored free drug program, provider samples, and/or vouchers wil I go through initial criteria, otherwise for continuation of therapy for new to plan, reauthorization criteria applies.  **For members new to plan (as evidenced by coverage effective date of less than or equal to 90 days) prescriber provides submission of medical records (e.g., chart notes) documenting that from the previous 12 months, member demonstrates an improvement or stabilization in pruritus and the member is tolerating therapy. |

| Product Name: Livmarli |                     |  |
|------------------------|---------------------|--|
| Approval Length        | 12 month(s)         |  |
| Therapy Stage          | Reauthorization     |  |
| Guideline Type         | Prior Authorization |  |
|                        |                     |  |

| Product<br>Name | Generic Name                             | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| LIVMARLI        | MARALIXIBAT CHLORIDE ORAL SOLN 9.5 MG/ML | 52350050102020 | Brand         |

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months of therapy, member is experiencing improvement or stabilization in pruritus compared to baseline (e.g., change in member reported pruritus, change in sleeping habits due to itch) and the member is tolerating therapy (e.g., does not have chronic diarrhea requiring ongoing intravenous fluids, bile acid reduction)

| intraverious nuius, blie adia reduction) |  |  |
|--|--|--|
| Notes                                    | *Member new to the plan (as evidenced by coverage effective date of I ess than or equal to 90 days) who initiated therapy using a manufactur er-sponsored free drug program, provider samples, and/or vouchers wil I go through initial criteria, otherwise for continuation of therapy for new to plan, reauthorization criteria applies.  **For members new to plan (as evidenced by coverage effective date of less than or equal to 90 days) prescriber provides submission of medical records (e.g., chart notes) documenting that from the previous 12 months, member demonstrates an improvement or stabilization in pruritus and the member is tolerating therapy. |  |

| Date       | Notes                   |
|------------|-------------------------|
| 10/30/2023 | 2024 New Implementation |

| ı | Livtencity (maribavir)  |                                     |                                       |                             |            |  |  |  |  |
|---|-------------------------|-------------------------------------|---------------------------------------|-----------------------------|------------|--|--|--|--|
|   | The bited inagrounce be | diplojusi. The fire may have have s | moned, warred, or dilatels. Verily is | ha hi points the constilled | of leader. |  |  |  |  |

| Guideline ID          | L-129857             |  |  |
|-----------------------|----------------------|--|--|
| <b>Guideline Name</b> | vtencity (maribavir) |  |  |
| Formulary             | Quartz               |  |  |

### **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

### Note:

Member new to the plan (as evidenced by coverage effective date of less than or equal to 90 days) who initiated therapy using a manufacturer-sponsored free drug program, provider samples, and/or vouchers will go through initial criteria, otherwise for continuation of therapy for new to plan, reauthorization criteria applies

### 1. Criteria

| Product Name: Livtencity   |                                    |            |                |               |
|----------------------------|------------------------------------|------------|----------------|---------------|
| Approval Length 16 Week(s) |                                    |            |                |               |
| Therapy Sta                | Stage Initial Authorization        |            |                |               |
| Guideline T                | Guideline Type Prior Authorization |            |                |               |
| Product<br>Name            | Generic Na                         | ame        | GPI            | Brand/Generic |
| LIVTENCITY                 | MARIBAVIR                          | TAB 200 MG | 12200050000320 | Brand         |
|                            |                                    |            |                |               |

**1** - Diagnosis of cytomegalovirus (CMV) infection based on clinical history and laboratory testing

#### AND

2 - History of stem cell or solid organ transplant

#### AND

- **3** Prescribed by or in consultation with one of the following:
  - Hematologist
  - Oncologist
  - Infectious Disease Specialist
  - Transplant Specialist

#### AND

**4** - Submission of medical records (e.g., chart notes) documenting baseline viral load prior to initiating therapy

### **AND**

- **5** Trial and failure, contraindication, or intolerance to one of the following:
  - Ganciclovir
  - Valganciclovir
  - Cidofovir
  - Foscarnet

| *Continuation of therapy/coverage criteria will not be applied to person<br>s who were not previously approved for<br>coverage whose therapy was initiated using a manufacturer-sponsored<br>free drug program, provider samples, and/or |
|--|
| vouchers.  |

| Product Name: Livtencity |                     |  |
|--------------------------|---------------------|--|
| Approval Length          | 16 Week(s)          |  |
| Therapy Stage            | Reauthorization     |  |
| Guideline Type           | Prior Authorization |  |

| Product<br>Name | Generic Name         | GPI            | Brand/Generic |
|-----------------|----------------------|----------------|---------------|
| LIVTENCITY      | MARIBAVIR TAB 200 MG | 12200050000320 | Brand         |

**1** - Submission of medical records (e.g., chart notes) supporting treatment response and evidence-based clinical rationale for use beyond 16 weeks of therapy

OR

**2** - Members new to coverage (as evidenced by coverage effective date of less than or equal to 90 days) who are established on therapy will have coverage under their drug benefit for the remainder of the current treatment course (to a maximum of 16 weeks)

| Notes | *Continuation of therapy/coverage criteria will not be applied to person  |
|-------|---|
|       | s who were not previously approved for  |
|       | coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or |
|       | vouchers.   |

| Date      | Notes                   |
|-----------|-------------------------|
| 8/21/2023 | 2024 New Implementation |

| Lupkynis (voclosporin) |   |   |  |  |  |
|------------------------|---|---|--|--|--|
| 1                      | The later anguest in this face, The later are and consider a finish they later his points to consolidate trade. | _ |  |  |  |
|                        |   |   |  |  |  |

| Guideline ID   | GL-132812              |
|----------------|------------------------|
| Guideline Name | Lupkynis (voclosporin) |
| Formulary      | Quartz                 |

## **Guideline Note:**

| Effective Date: |
|-----------------|
|-----------------|

## 1. Criteria

| Product Name: Lupkynis                                    |  |  |
|---|--|--|
| Approval Length 12 month(s)                               |  |  |
| Therapy Stage Initial Authorization                       |  |  |
| Guideline Type Prior Authorization - IL and MN plans only |  |  |

| Product<br>Name | Generic Name           | GPI            | Brand/Generic |
|-----------------|------------------------|----------------|---------------|
| LUPKYNIS        | VOCLOSPORIN CAP 7.9 MG | 99402080000120 | Brand         |

# **Approval Criteria**

1 - Diagnosis of biopsy-proven lupus nephritis

#### AND

- **2** Prescribed by or in consultation with one of the following:
  - Nephrologist
  - Rheumatologist
  - · specialist in the treatment of lupus nephritis

### **AND**

**3** - Trial and failure, contraindication, or intolerance to concurrent use of mycophenolate with corticosteroids

#### AND

**4** - Requested drug will be used in combination with mycophenolate and corticosteroids unless contraindicated or not tolerated

#### **AND**

5 - Requested drug will not be used in combination with cyclophosphamide

| Product Name: Lupkynis  |  |  |
|---|--|--|
| Approval Length 6 month(s)                                      |  |  |
| Therapy Stage Initial Authorization                             |  |  |
| Guideline Type Prior Authorization - All plans except IL and MN |  |  |

| Product<br>Name | Generic Name           | GPI            | Brand/Generic |
|-----------------|------------------------|----------------|---------------|
| LUPKYNIS        | VOCLOSPORIN CAP 7.9 MG | 99402080000120 | Brand         |

### **Approval Criteria**

1 - Diagnosis of biopsy-proven lupus nephritis

#### AND

- **2** Prescribed by or in consultation with one of the following:
  - Nephrologist
  - Rheumatologist
  - · specialist in the treatment of lupus nephritis

### **AND**

**3** - Trial and failure, contraindication, or intolerance to concurrent use of mycophenolate with corticosteroids

#### AND

**4** - Requested drug will be used in combination with mycophenolate and corticosteroids unless contraindicated or not tolerated

#### **AND**

5 - Requested drug will not be used in combination with cyclophosphamide

| Product Name: Lupkynis                         |  |  |
|--|--|--|
| Approval Length 12 month(s)                    |  |  |
| Therapy Stage Reauthorization                  |  |  |
| Guideline Type Prior Authorization - All plans |  |  |

| Product<br>Name | Generic Name           | GPI            | Brand/Generic |
|-----------------|------------------------|----------------|---------------|
| LUPKYNIS        | VOCLOSPORIN CAP 7.9 MG | 99402080000120 | Brand         |

### **Approval Criteria**

1 - Patient has demonstrated a positive response to therapy

| Date      | Notes       |
|-----------|-------------|
| 11/1/2023 | New Program |

| Muc                                 | osal Prote  | ectants                                       |  |
|-------------------------------------|---|---|--|
| The list of image current to displa | yer). The fire may have have necesal, understay, or defects (let b) that he | liké politik teller conserific and lisuation. |  |
|                                     |   |   |  |

| Guideline ID          | GL-137862           |
|-----------------------|---------------------|
| <b>Guideline Name</b> | Mucosal Protectants |
| Formulary             | Quartz              |

# **Guideline Note:**

| Effective Date: |
|-----------------|
|-----------------|

## 1. Criteria

| Product Name: Mugard, Episil, Oramagicrx |                     |
|--|---------------------|
| Approval Length                          | 12 month(s)         |
| Guideline Type                           | Prior Authorization |

| Product<br>Name | Generic Name                                     | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| MUGARD          | *ORAL WOUND CARE PRODUCTS - LIQUID<br>RINSE***   | 88502050000900 | Brand         |
| EPISIL          | *ORAL WOUND CARE PRODUCTS - LIQUID PUMP***       | 88502050000950 | Brand         |
| ORAMAGICRX      | *ORAL WOUND CARE PRODUCTS - FOR SUSP<br>RINSE*** | 88502050001900 | Brand         |

## **Approval Criteria**

**1** - Diagnosis of grade 3 or 4 mucositis due to chemotherapy and/or radiation (i.e. oral mucositis: severe pain, interferes with oral intake, oral ulceration, difficulty with speech and swallowing)

#### **AND**

- 2 Both of the following:
- **2.1** Trial and failure or intolerance to ONE of any moisturizing salivation agents:
  - Rinses / Mouthwashes (i.e. OTC sodium/sodium bicarbonate, OTC Biotene, OTC Oasis)
  - Gel, Spray (i.e. OTC Biotene, OTC Mouthkote)

### **AND**

**2.2** Trial and failure or intolerance to ONE Muco-protectant with or without anesthetic agent [i.e., Mylanta, magic mouthwash (lidocaine/diphenhydramine/Mylanta)]

| Product Name: Prothelial, Orafate, Silatrix |                     |
|---|---------------------|
| Approval Length                             | 12 month(s)         |
| Guideline Type                              | Prior Authorization |

| Product<br>Name | Generic Name                    | GPI            | Brand/Generic |
|-----------------|---------------------------------|----------------|---------------|
| PROTHELIAL      | *SUCRALFATE-MALATE PASTE 10%*** | 88502002804410 | Brand         |
| ORAFATE         | *SUCRALFATE-MALATE PASTE 10%*** | 88502002804410 | Brand         |
| SILATRIX        | *SUCRALFATE-MALATE GEL 10%***   | 88502002804010 | Brand         |

### **Approval Criteria**

**1** - Diagnosis of grade 3 or 4 mucositis due to chemotherapy and/or radiation (i.e. oral mucositis: severe pain, interferes with oral intake, oral ulceration, difficulty with speech and swallowing)

#### **AND**

- 2 Both of the following:
  - **2.1** Trial and failure or intolerance to ONE of any moisturizing salivation agents:
    - Rinses / Mouthwashes (i.e. OTC sodium/sodium bicarbonate, OTC Biotene, OTC Oasis)
    - Gel, Spray (i.e. OTC Biotene, OTC Mouthkote)

#### **AND**

**2.2** Trial and failure or intolerance to ONE Muco-protectant with or without anesthetic agent [i.e., Mylanta, magic mouthwash (lidocaine/diphenhydramine/Mylanta)]

#### **AND**

**3** - Trial and failure, contraindication or intolerance to ONE bioadhesive gel (i.e., Gelclair, Oramagic Rx, Mugard or Episil)

| Date       | Notes  |
|------------|--------|
| 12/15/2023 | Update |

| Multiple Sclerosis   |
|--|
| The behavior and the second of |
|  |
|  |

| Guideline ID          | GL-129162          |
|-----------------------|--------------------|
| <b>Guideline Name</b> | Multiple Sclerosis |
| Formulary             | Quartz             |

# **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

# 1. Criteria

| Product Name: Avonex, Extavia, Generic dimethyl fumarate, Generic fingolimod, Generic glatiramer acetate, Generic teriflunomide, Glatopa, Plegridy, Rebif |  |
|---|--|
| Approval Length   | 12/31/2039   |
| Guideline Type  | Prior Authorization - ALL Plans Except IL and MN Plans |

| Product Name                        | Generic Name   | GPI            | Brand/Generic |
|-------------------------------------|--|----------------|---------------|
| DIMETHYL<br>FUMARATE<br>STARTERPACK | DIMETHYL FUMARATE CAPSULE DR STARTER<br>PACK 120 MG & 240 MG | 62405525006320 | Generic       |
| DIMETHYL<br>FUMARATE                | DIMETHYL FUMARATE CAPSULE DELAYED<br>RELEASE 120 MG          | 62405525006520 | Generic       |
| DIMETHYL<br>FUMARATE                | DIMETHYL FUMARATE CAPSULE DELAYED<br>RELEASE 240 MG          | 62405525006540 | Generic       |
| FINGOLIMOD                          | FINGOLIMOD HCL CAP 0.5 MG (BASE EQUIV)                       | 62407025100120 | Generic       |
| GLATOPA                             | GLATIRAMER ACETATE SOLN PREFILLED<br>SYRINGE 20 MG/ML        | 6240003010E520 | Generic       |

| GLATIRAMER<br>ACETATE                  | GLATIRAMER ACETATE SOLN PREFILLED<br>SYRINGE 20 MG/ML           | 6240003010E520 | Generic |
|--|---|----------------|---------|
| GLATOPA                                | GLATIRAMER ACETATE SOLN PREFILLED<br>SYRINGE 40 MG/ML           | 6240003010E540 | Generic |
| GLATIRAMER<br>ACETATE                  | GLATIRAMER ACETATE SOLN PREFILLED<br>SYRINGE 40 MG/ML           | 6240003010E540 | Generic |
| AVONEX PEN                             | INTERFERON BETA-1A IM AUTO-INJECTOR KIT<br>30 MCG/0.5ML         | 6240306045F530 | Brand   |
| AVONEX                                 | INTERFERON BETA-1A IM PREFILLED SYRINGE<br>KIT 30 MCG/0.5ML     | 6240306045F830 | Brand   |
| REBIF<br>REBIDOSE                      | INTERFERON BETA-1A SOLN AUTO-INJ 22<br>MCG/0.5ML                | 6240306045D520 | Brand   |
| REBIF<br>REBIDOSE                      | INTERFERON BETA-1A SOLN AUTO-INJ 44<br>MCG/0.5ML                | 6240306045D540 | Brand   |
| REBIF<br>REBIDOSE<br>TITRATION<br>PACK | INTERFERON BETA-1A AUTO-INJ 6X8.8<br>MCG/0.2ML & 6X22 MCG/0.5ML | 6240306045D560 | Brand   |
| REBIF                                  | INTERFERON BETA-1A SOLN PREF SYR 22<br>MCG/0.5ML                | 6240306045E520 | Brand   |
| REBIF                                  | INTERFERON BETA-1A SOLN PREF SYR 44<br>MCG/0.5ML                | 6240306045E540 | Brand   |
| REBIF<br>TITRATION<br>PACK             | INTERFERON BETA-1A PREF SYR 6X8.8<br>MCG/0.2ML & 6X22 MCG/0.5ML | 6240306045E560 | Brand   |
| EXTAVIA                                | INTERFERON BETA-1B FOR INJ KIT 0.3 MG                           | 62403060506420 | Brand   |
| PLEGRIDY                               | PEGINTERFERON BETA-1A SOLN PEN-<br>INJECTOR 125 MCG/0.5ML       | 6240307530D220 | Brand   |
| PLEGRIDY<br>STARTER PACK               | PEGINTERFERON BETA-1A SOLN PEN-INJ 63 & 94 MCG/0.5ML PACK       | 6240307530D250 | Brand   |
| PLEGRIDY                               | PEGINTERFERON BETA-1A SOLN PREFILLED<br>SYRINGE 125 MCG/0.5ML   | 6240307530E520 | Brand   |
| PLEGRIDY                               | PEGINTERFERON BETA-1A IM SOLN PREFILLED<br>SYR 125 MCG/0.5ML    | 6240307530E521 | Brand   |
| PLEGRIDY<br>STARTER PACK               | PEGINTERFERON BETA-1A SOLN PREF SYR 63<br>& 94 MCG/0.5ML PACK   | 6240307530E550 | Brand   |
| TERIFLUNOMIDE                          | TERIFLUNOMIDE TAB 7 MG  | 62404070000320 | Generic |
| TERIFLUNOMIDE                          | TERIFLUNOMIDE TAB 14 MG   | 62404070000330 | Generic |

- 1 One of the following:
- **1.1** Diagnosis of one of the following relapsing forms of multiple sclerosis:

- Relapsing-Remitting
- Active secondary progressive
- Relapsing-progressive

#### OR

**1.2** Diagnosis of Clinically Isolated Syndrome (CIS) with a high probability of developing Clinically Definite MS (CDMS) (i.e. greater than or equal to 3 T2 white matter lesions or greater than or equal to 2 GdE lesions on MRI)

#### **AND**

2 - Drug will be self-administered at home

#### AND

**3** - Drug will not be used in combination with another disease modifying therapy for multiple sclerosis

### **AND**

**4** - Prescribed by or in consultation with a neurologist or other expert in the treatment of multiple sclerosis

| Product Name: Avonex, Extavia, Generic dimethyl fumarate, Generic fingolimod, Generic glatiramer acetate, Generic teriflunomide, Glatopa, Plegridy, Rebif |  |
|---|--|
| Approval Length   | 12 month(s)                            |
| Therapy Stage   | Initial Authorization                  |
| Guideline Type  | Prior Authorization - IL and MN Plans* |

| Product Name                        | Generic Name   | GPI            | Brand/Generic |
|-------------------------------------|--|----------------|---------------|
| DIMETHYL<br>FUMARATE<br>STARTERPACK | DIMETHYL FUMARATE CAPSULE DR STARTER<br>PACK 120 MG & 240 MG | 62405525006320 | Generic       |
| DIMETHYL<br>FUMARATE                | DIMETHYL FUMARATE CAPSULE DELAYED<br>RELEASE 120 MG          | 62405525006520 | Generic       |

| DIMETHYL<br>FUMARATE                   | DIMETHYL FUMARATE CAPSULE DELAYED<br>RELEASE 240 MG             | 62405525006540 | Generic |
|--|---|----------------|---------|
| FINGOLIMOD                             | FINGOLIMOD HCL CAP 0.5 MG (BASE EQUIV)                          | 62407025100120 | Generic |
| GLATOPA                                | GLATIRAMER ACETATE SOLN PREFILLED<br>SYRINGE 20 MG/ML           | 6240003010E520 | Generic |
| GLATIRAMER<br>ACETATE                  | GLATIRAMER ACETATE SOLN PREFILLED<br>SYRINGE 20 MG/ML           | 6240003010E520 | Generic |
| GLATOPA                                | GLATIRAMER ACETATE SOLN PREFILLED<br>SYRINGE 40 MG/ML           | 6240003010E540 | Generic |
| GLATIRAMER<br>ACETATE                  | GLATIRAMER ACETATE SOLN PREFILLED<br>SYRINGE 40 MG/ML           | 6240003010E540 | Generic |
| AVONEX PEN                             | INTERFERON BETA-1A IM AUTO-INJECTOR KIT<br>30 MCG/0.5ML         | 6240306045F530 | Brand   |
| AVONEX                                 | INTERFERON BETA-1A IM PREFILLED SYRINGE<br>KIT 30 MCG/0.5ML     | 6240306045F830 | Brand   |
| REBIF<br>REBIDOSE                      | INTERFERON BETA-1A SOLN AUTO-INJ 22<br>MCG/0.5ML                | 6240306045D520 | Brand   |
| REBIF<br>REBIDOSE                      | INTERFERON BETA-1A SOLN AUTO-INJ 44<br>MCG/0.5ML                | 6240306045D540 | Brand   |
| REBIF<br>REBIDOSE<br>TITRATION<br>PACK | INTERFERON BETA-1A AUTO-INJ 6X8.8<br>MCG/0.2ML & 6X22 MCG/0.5ML | 6240306045D560 | Brand   |
| REBIF                                  | INTERFERON BETA-1A SOLN PREF SYR 22<br>MCG/0.5ML                | 6240306045E520 | Brand   |
| REBIF                                  | INTERFERON BETA-1A SOLN PREF SYR 44<br>MCG/0.5ML                | 6240306045E540 | Brand   |
| REBIF<br>TITRATION<br>PACK             | INTERFERON BETA-1A PREF SYR 6X8.8<br>MCG/0.2ML & 6X22 MCG/0.5ML | 6240306045E560 | Brand   |
| EXTAVIA                                | INTERFERON BETA-1B FOR INJ KIT 0.3 MG                           | 62403060506420 | Brand   |
| PLEGRIDY                               | PEGINTERFERON BETA-1A SOLN PEN-<br>INJECTOR 125 MCG/0.5ML       | 6240307530D220 | Brand   |
| PLEGRIDY<br>STARTER PACK               | PEGINTERFERON BETA-1A SOLN PEN-INJ 63 & 94 MCG/0.5ML PACK       | 6240307530D250 | Brand   |
| PLEGRIDY                               | PEGINTERFERON BETA-1A SOLN PREFILLED<br>SYRINGE 125 MCG/0.5ML   | 6240307530E520 | Brand   |
| PLEGRIDY                               | PEGINTERFERON BETA-1A IM SOLN PREFILLED<br>SYR 125 MCG/0.5ML    | 6240307530E521 | Brand   |
| PLEGRIDY<br>STARTER PACK               | PEGINTERFERON BETA-1A SOLN PREF SYR 63<br>& 94 MCG/0.5ML PACK   | 6240307530E550 | Brand   |
| TERIFLUNOMIDE                          | TERIFLUNOMIDE TAB 7 MG  | 62404070000320 | Generic |
| TERIFLUNOMIDE                          | TERIFLUNOMIDE TAB 14 MG   | 62404070000330 | Generic |

- 1 One of the following:
- **1.1** Diagnosis of one of the following relapsing forms of multiple sclerosis:
  - Relapsing-Remitting
  - · Active secondary progressive
  - Relapsing-progressive

OR

**1.2** Diagnosis of Clinically Isolated Syndrome (CIS) with a high probability of developing Clinically Definite MS (CDMS) (i.e. greater than or equal to 3 T2 white matter lesions or greater than or equal to 2 GdE lesions on MRI)

**AND** 

2 - Drug will be self-administered at home

**AND** 

**3** - Drug will not be used in combination with another disease modifying therapy for multiple sclerosis

**AND** 

**4** - Prescribed by or in consultation with a neurologist or other expert in the treatment of multiple sclerosis

| Notes | *Member new to the plan (as evidenced by coverage effective date of I ess than or equal to 90 days) who initiated therapy using a manufactur      |
|-------|---|
|       | er-sponsored free drug program, provider samples, and/or vouchers will go through initial criteria, otherwise for continuation of therapy for new |
|       | to plan, reauthorization criteria applies   |

Product Name: Avonex, Extavia, Generic dimethyl fumarate, Generic fingolimod, Generic glatiramer acetate, Generic teriflunomide, Glatopa, Plegridy, Rebif

Approval Length 12 month(s)

| Therapy Stage  | Reauthorization                        |
|----------------|--|
| Guideline Type | Prior Authorization - IL and MN Plans* |

| Product Name                           | Generic Name  | GPI            | Brand/Generic |
|--|---|----------------|---------------|
| DIMETHYL<br>FUMARATE<br>STARTERPACK    | DIMETHYL FUMARATE CAPSULE DR STARTER<br>PACK 120 MG & 240 MG    | 62405525006320 | Generic       |
| DIMETHYL<br>FUMARATE                   | DIMETHYL FUMARATE CAPSULE DELAYED<br>RELEASE 120 MG             | 62405525006520 | Generic       |
| DIMETHYL<br>FUMARATE                   | DIMETHYL FUMARATE CAPSULE DELAYED<br>RELEASE 240 MG             | 62405525006540 | Generic       |
| FINGOLIMOD                             | FINGOLIMOD HCL CAP 0.5 MG (BASE EQUIV)                          | 62407025100120 | Generic       |
| GLATOPA                                | GLATIRAMER ACETATE SOLN PREFILLED<br>SYRINGE 20 MG/ML           | 6240003010E520 | Generic       |
| GLATIRAMER<br>ACETATE                  | GLATIRAMER ACETATE SOLN PREFILLED<br>SYRINGE 20 MG/ML           | 6240003010E520 | Generic       |
| GLATOPA                                | GLATIRAMER ACETATE SOLN PREFILLED<br>SYRINGE 40 MG/ML           | 6240003010E540 | Generic       |
| GLATIRAMER<br>ACETATE                  | GLATIRAMER ACETATE SOLN PREFILLED<br>SYRINGE 40 MG/ML           | 6240003010E540 | Generic       |
| AVONEX PEN                             | INTERFERON BETA-1A IM AUTO-INJECTOR KIT<br>30 MCG/0.5ML         | 6240306045F530 | Brand         |
| AVONEX                                 | INTERFERON BETA-1A IM PREFILLED SYRINGE<br>KIT 30 MCG/0.5ML     | 6240306045F830 | Brand         |
| REBIF<br>REBIDOSE                      | INTERFERON BETA-1A SOLN AUTO-INJ 22<br>MCG/0.5ML                | 6240306045D520 | Brand         |
| REBIF<br>REBIDOSE                      | INTERFERON BETA-1A SOLN AUTO-INJ 44<br>MCG/0.5ML                | 6240306045D540 | Brand         |
| REBIF<br>REBIDOSE<br>TITRATION<br>PACK | INTERFERON BETA-1A AUTO-INJ 6X8.8<br>MCG/0.2ML & 6X22 MCG/0.5ML | 6240306045D560 | Brand         |
| REBIF                                  | INTERFERON BETA-1A SOLN PREF SYR 22<br>MCG/0.5ML                | 6240306045E520 | Brand         |
| REBIF                                  | INTERFERON BETA-1A SOLN PREF SYR 44<br>MCG/0.5ML                | 6240306045E540 | Brand         |
| REBIF<br>TITRATION<br>PACK             | INTERFERON BETA-1A PREF SYR 6X8.8<br>MCG/0.2ML & 6X22 MCG/0.5ML | 6240306045E560 | Brand         |
| EXTAVIA                                | INTERFERON BETA-1B FOR INJ KIT 0.3 MG                           | 62403060506420 | Brand         |
| PLEGRIDY                               | PEGINTERFERON BETA-1A SOLN PEN-<br>INJECTOR 125 MCG/0.5ML       | 6240307530D220 | Brand         |
| PLEGRIDY<br>STARTER PACK               | PEGINTERFERON BETA-1A SOLN PEN-INJ 63 & 94 MCG/0.5ML PACK       | 6240307530D250 | Brand         |
| PLEGRIDY                               | PEGINTERFERON BETA-1A SOLN PREFILLED<br>SYRINGE 125 MCG/0.5ML   | 6240307530E520 | Brand         |

| PLEGRIDY                 | PEGINTERFERON BETA-1A IM SOLN PREFILLED<br>SYR 125 MCG/0.5ML  | 6240307530E521 | Brand   |
|--------------------------|---|----------------|---------|
| PLEGRIDY<br>STARTER PACK | PEGINTERFERON BETA-1A SOLN PREF SYR 63<br>& 94 MCG/0.5ML PACK | 6240307530E550 | Brand   |
| TERIFLUNOMIDE            | TERIFLUNOMIDE TAB 7 MG  | 62404070000320 | Generic |
| TERIFLUNOMIDE            | TERIFLUNOMIDE TAB 14 MG                                       | 62404070000330 | Generic |

- **1** Submission of medical records (e.g., chart notes) by the treating neurologist documenting that within the past 12 months member has BOTH of the following:
  - Relapsing form of multiple sclerosis
  - Member is established on therapy

### **AND**

**2** - Drug will not be used in combination with another disease modifying therapy for multiple sclerosis

| Notes | *Member new to the plan (as evidenced by coverage effective date of I ess than or equal to 90 days) who initiated therapy using a manufactur  |
|-------|---|
|       | er-sponsored free drug program, provider samples, and/or vouchers will go through initial criteria, otherwise for continuation of therapy for new to plan, reauthorization criteria applies |
|       | to plan, roadmonzation ontona applied   |

| Product Name: Kesimpta, Mavenclad |  |
|-----------------------------------|--|
| Approval Length                   | 12/31/2039   |
| Guideline Type                    | Prior Authorization - ALL Plans Except IL and MN Plans |

| Product<br>Name | Generic Name                               | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| KESIMPTA        | OFATUMUMAB SOLN AUTO-INJECTOR 20 MG/0.4ML  | 6240506500D520 | Brand         |
| MAVENCLAD       | CLADRIBINE TAB THERAPY PACK 10 MG (4 TABS) | 6240101500B718 | Brand         |
| MAVENCLAD       | CLADRIBINE TAB THERAPY PACK 10 MG (5 TABS) | 6240101500B722 | Brand         |
| MAVENCLAD       | CLADRIBINE TAB THERAPY PACK 10 MG (6 TABS) | 6240101500B726 | Brand         |
| MAVENCLAD       | CLADRIBINE TAB THERAPY PACK 10 MG (7 TABS) | 6240101500B732 | Brand         |
| MAVENCLAD       | CLADRIBINE TAB THERAPY PACK 10 MG (8 TABS) | 6240101500B736 | Brand         |

| MAVENCLAD | CLADRIBINE TAB THERAPY PACK 10 MG (9 TABS)  | 6240101500B740 | Brand |
|-----------|---|----------------|-------|
| MAVENCLAD | CLADRIBINE TAB THERAPY PACK 10 MG (10 TABS) | 6240101500B744 | Brand |

|   | _       |        |        |        |
|---|---------|--------|--------|--------|
| 1 | - ( )ne | of the | a toll | owing: |
|   |         |        |        |        |

- **1.1** Diagnosis of one of the following relapsing forms of multiple sclerosis:
  - Relapsing-Remitting
  - Active secondary progressive
  - Relapsing-progressive

OR

**1.2** Diagnosis of Clinically Isolated Syndrome (CIS) with a high probability of developing Clinically Definite MS (CDMS) (i.e. greater than or equal to 3 T2 white matter lesions or greater than or equal to 2 GdE lesions on MRI)

**AND** 

2 - Drug will be self-administered at home

**AND** 

**3** - Drug will not be used in combination with another disease modifying therapy for multiple sclerosis

**AND** 

- 4 One of the following:
- **4.1** Trial and failure (i.e., acute relapse or new lesion formation) while on one of the following:
  - dimethyl fumarate
  - fingolimod

### OR

- **4.2** Contraindication, intolerance, or the inability to take BOTH of the following:
  - · dimethyl fumarate
  - fingolimod

#### **AND**

**5** - Prescribed by or in consultation with a neurologist or other expert in the treatment of multiple sclerosis

| Product Name: Kesimpta, Mavenclad |  |  |
|-----------------------------------|--|--|
| Approval Length                   | 12 month(s)                            |  |
| Therapy Stage                     | Initial Authorization                  |  |
| Guideline Type                    | Prior Authorization - IL and MN Plans* |  |

| Product<br>Name | Generic Name                                | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| KESIMPTA        | OFATUMUMAB SOLN AUTO-INJECTOR 20 MG/0.4ML   | 6240506500D520 | Brand         |
| MAVENCLAD       | CLADRIBINE TAB THERAPY PACK 10 MG (4 TABS)  | 6240101500B718 | Brand         |
| MAVENCLAD       | CLADRIBINE TAB THERAPY PACK 10 MG (5 TABS)  | 6240101500B722 | Brand         |
| MAVENCLAD       | CLADRIBINE TAB THERAPY PACK 10 MG (6 TABS)  | 6240101500B726 | Brand         |
| MAVENCLAD       | CLADRIBINE TAB THERAPY PACK 10 MG (7 TABS)  | 6240101500B732 | Brand         |
| MAVENCLAD       | CLADRIBINE TAB THERAPY PACK 10 MG (8 TABS)  | 6240101500B736 | Brand         |
| MAVENCLAD       | CLADRIBINE TAB THERAPY PACK 10 MG (9 TABS)  | 6240101500B740 | Brand         |
| MAVENCLAD       | CLADRIBINE TAB THERAPY PACK 10 MG (10 TABS) | 6240101500B744 | Brand         |

### **Approval Criteria**

- **1** One of the following:
- **1.1** Diagnosis of one of the following relapsing forms of multiple sclerosis:
  - Relapsing-Remitting
  - Active secondary progressive

| Relapsing-progressive   |
|---|
| OR  |
| <b>1.2</b> Diagnosis of Clinically Isolated Syndrome (CIS) with a high probability of developing Clinically Definite MS (CDMS) (i.e. greater than or equal to 3 T2 white matter lesions or greater than or equal to 2 GdE lesions on MRI) |
| AND   |
| 2 - Drug will be self-administered at home  |
| AND   |
| <b>3</b> - Drug will not be used in combination with another disease modifying therapy for multiple sclerosis   |
| AND   |
| 4 - One of the following:   |
| <b>4.1</b> Trial and failure (i.e., acute relapse or new lesion formation) while on one of the following:   |
| <ul><li>dimethyl fumarate</li><li>fingolimod</li></ul>  |
| OR  |
| <b>4.2</b> Contraindication, intolerance, or the inability to take BOTH of the following:   |
| <ul><li>dimethyl fumarate</li><li>fingolimod</li></ul>  |
| AND   |
| <b>5</b> - Prescribed by or in consultation with a neurologist or other expert in the treatment of multiple sclerosis   |
|   |

|  | *Member new to the plan (as evidenced by coverage effective date of I ess than or equal to 90 days) who initiated therapy using a manufactur er-sponsored free drug program, provider samples, and/or vouchers wil I go through initial criteria, otherwise for continuation of therapy for new to plan, reauthorization criteria applies |
|--|---|
|--|---|

| Product Name: Kesimpta, Mavenclad |  |  |
|-----------------------------------|--|--|
| Approval Length 12 month(s)       |  |  |
| Therapy Stage                     | Reauthorization                        |  |
| Guideline Type                    | Prior Authorization - IL and MN Plans* |  |

| Product<br>Name | Generic Name                                | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| KESIMPTA        | OFATUMUMAB SOLN AUTO-INJECTOR 20 MG/0.4ML   | 6240506500D520 | Brand         |
| MAVENCLAD       | CLADRIBINE TAB THERAPY PACK 10 MG (4 TABS)  | 6240101500B718 | Brand         |
| MAVENCLAD       | CLADRIBINE TAB THERAPY PACK 10 MG (5 TABS)  | 6240101500B722 | Brand         |
| MAVENCLAD       | CLADRIBINE TAB THERAPY PACK 10 MG (6 TABS)  | 6240101500B726 | Brand         |
| MAVENCLAD       | CLADRIBINE TAB THERAPY PACK 10 MG (7 TABS)  | 6240101500B732 | Brand         |
| MAVENCLAD       | CLADRIBINE TAB THERAPY PACK 10 MG (8 TABS)  | 6240101500B736 | Brand         |
| MAVENCLAD       | CLADRIBINE TAB THERAPY PACK 10 MG (9 TABS)  | 6240101500B740 | Brand         |
| MAVENCLAD       | CLADRIBINE TAB THERAPY PACK 10 MG (10 TABS) | 6240101500B744 | Brand         |

- 1 Submission of medical records (e.g., chart notes) by the treating neurologist documenting that within the past 12 months member has BOTH of the following:
  - Relapsing form of multiple sclerosis Member is established on therapy

### **AND**

2 - Drug will not be used in combination with another disease modifying therapy for multiple sclerosis

| Notes | *Member new to the plan (as evidenced by coverage effective date of I ess than or equal to 90 days) who initiated therapy using a manufactur      |
|-------|---|
|       | er-sponsored free drug program, provider samples, and/or vouchers will go through initial criteria, otherwise for continuation of therapy for new |

| to plan, reauthorization criteria applies |  |
|---|--|
|---|--|

| Date      | Notes                   |
|-----------|-------------------------|
| 10/5/2023 | 2024 New Implementation |

| M     | Myalept (Metreleptin)   |           |  |
|-------|---|-----------|--|
| The B | arlangsvennet kridiglejon. Torde my han ken moust, varams, vr údelet bedy han he his jorden der enventle an | Electric. |  |
|       |   |           |  |

| Guideline ID          | GL-129645             |  |
|-----------------------|-----------------------|--|
| <b>Guideline Name</b> | Myalept (Metreleptin) |  |
| Formulary             | Quartz                |  |

## **Guideline Note:**

| Effective Date: | 1/1/2023 |
|-----------------|----------|
|-----------------|----------|

## 1. Criteria

| Product Name: Myalept |                                       |
|-----------------------|---------------------------------------|
| Approval Length       | 12 month(s)                           |
| Therapy Stage         | Initial Authorization                 |
| Guideline Type        | Prior Authorization - IL and MN Plans |

| Product<br>Name | Generic Name                             | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| MYALEPT         | METRELEPTIN FOR SUBCUTANEOUS INJ 11.3 MG | 30906050002120 | Brand         |

## **Approval Criteria**

1 - Diagnosis of congenital or acquired generalized lipodystrophy

### **AND**

**2** - Have experienced metabolic changes (e.g. increased triglycerides or fasting blood glucoses) despite an adequate trial of dietary modification

#### **AND**

**3** - Failure, intolerance, or contraindication to metformin

### **AND**

**4** - Failure, intolerance, or contraindication to at least one statin medication (e.g. atorvastatin, rosuvastatin)

| Product Name: Myalept |                                       |
|-----------------------|---------------------------------------|
| Approval Length       | 12 month(s)                           |
| Therapy Stage         | Reauthorization                       |
| Guideline Type        | Prior Authorization - IL and MN Plans |

| Product<br>Name | Generic Name                             | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| MYALEPT         | METRELEPTIN FOR SUBCUTANEOUS INJ 11.3 MG | 30906050002120 | Brand         |

### **Approval Criteria**

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug.

| Product Name: Myalept |  |
|-----------------------|--|
| Approval Length       | 12/31/2039                                       |
| Guideline Type        | Prior Authorization - All plans except IL and MN |

| Product<br>Name | Generic Name                             | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| MYALEPT         | METRELEPTIN FOR SUBCUTANEOUS INJ 11.3 MG | 30906050002120 | Brand         |
|                 |  |                |               |

1 - Diagnosis of congenital or acquired generalized lipodystrophy

#### **AND**

**2** - Have experienced metabolic changes (e.g. increased triglycerides or fasting blood glucoses) despite an adequate trial of dietary modification

### AND

**3** - Failure, intolerance, or contraindication to metformin

### **AND**

**4** - Failure, intolerance, or contraindication to at least one statin medication (e.g. atorvastatin, rosuvastatin)

| Date      | Notes       |
|-----------|-------------|
| 10/6/2023 | New program |

| Myrbetriq (mirabegron)  |  |  |  |
|---|--|--|--|
| An introducement had used to be the section most consist a side to be the provided constitution of the section |  |  |  |
|   |  |  |  |

| Guideline ID          | GL-127843              |
|-----------------------|------------------------|
| <b>Guideline Name</b> | Myrbetriq (mirabegron) |
| Formulary             | Quartz                 |

# **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

## 1. Criteria

| Product Name: Myrbetriq |                                |
|-------------------------|--------------------------------|
| Approval Length         | 12 month(s)                    |
| Therapy Stage           | Initial Authorization          |
| Guideline Type          | Step Therapy - IL and MN Plans |

| Product<br>Name | Generic Name   | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| MYRBETRIQ       | MIRABEGRON GRANULES FOR ORAL EXTENDED RELEASE SUSP 8 MG/ML | 5420005000G220 | Brand         |
| MYRBETRIQ       | MIRABEGRON TAB ER 24 HR 25 MG                              | 54200050007520 | Brand         |
| MYRBETRIQ       | MIRABEGRON TAB ER 24 HR 50 MG                              | 54200050007530 | Brand         |

## **Approval Criteria**

- **1** Trial and failure to one of the following:
  - trospium
  - oxybutynin
  - solifenacin
  - tolterodine
  - darifenacin
  - fesoterodine

| Product Name: Myrbetr | iq                             |
|-----------------------|--------------------------------|
| Approval Length       | 12 month(s)                    |
| Therapy Stage         | Reauthorization                |
| Guideline Type        | Step Therapy - IL and MN Plans |

| Product<br>Name | Generic Name   | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| MYRBETRIQ       | MIRABEGRON GRANULES FOR ORAL EXTENDED RELEASE SUSP 8 MG/ML | 5420005000G220 | Brand         |
| MYRBETRIQ       | MIRABEGRON TAB ER 24 HR 25 MG                              | 54200050007520 | Brand         |
| MYRBETRIQ       | MIRABEGRON TAB ER 24 HR 50 MG                              | 54200050007530 | Brand         |

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug

| Product Name: Myrbetriq |   |
|-------------------------|---|
| Approval Length         | 12/31/2039                                      |
| Guideline Type          | Step Therapy - All Plans except IL and MN Plans |

| Generic Name   | GPI  | Brand/Generic   |
|--|--|---|
| MIRABEGRON GRANULES FOR ORAL EXTENDED RELEASE SUSP 8 MG/ML | 5420005000G220   | Brand   |
| MIRABEGRON TAB ER 24 HR 25 MG                              | 54200050007520   | Brand   |
| MIRABEGRON TAB ER 24 HR 50 MG                              | 54200050007530   | Brand   |
|  | MIRABEGRON GRANULES FOR ORAL EXTENDED<br>RELEASE SUSP 8 MG/ML<br>MIRABEGRON TAB ER 24 HR 25 MG | MIRABEGRON GRANULES FOR ORAL EXTENDED RELEASE SUSP 8 MG/ML  MIRABEGRON TAB ER 24 HR 25 MG  54200050007520 |

- **1** Trial and failure to one of the following:

  - trospiumoxybutyninsolifenacin

  - tolterodine
  - darifenacin
  - fesoterodine

| Date      | Notes       |
|-----------|-------------|
| 8/25/2023 | New Program |

| New Indication Administrative Guideline  | e |
|--|---|
| (3) Intercongruent relation to the second control of the second co |   |

| Guideline ID          | GL-135282                               |  |
|-----------------------|---|--|
| <b>Guideline Name</b> | New Indication Administrative Guideline |  |
| Formulary             | Quartz                                  |  |

## **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

## 1. Criteria

| Diagnosis                               | Drugs with a prior authorization requirement for which a guideline is unavailable, OR new FDA-approved indications which are not addressed in the existing drug-specific prior authorization guideline |               |  |
|---|--|---------------|--|
| Approval Length                         | 12 month(s)  |               |  |
| Guideline Type                          | Administrative   |               |  |
| Product Name Generic Name GPI Brand/Gen |  | Brand/Generic |  |

### **Approval Criteria**

- 1 One of the following:
- **1.1** Both of the following:
- 1.1.1 Prescribed medication is being used for a Food and Drug Administration (FDA)-

| ap | proved | indication |
|----|--------|------------|
|    |        |            |

#### **AND**

- **1.1.2** Both of the following:
- **1.1.2.1** All components of the FDA approved indication are met (e.g., concomitant use, previous therapy requirements, age limitations, testing requirements, etc.)

#### **AND**

1.1.2.2 Prescribed medication will be used at a dose which is within FDA recommendations

#### OR

1.2 Meets the off-label administrative guideline criteria

#### **AND**

**2** - (For nonpreferred medications only) Trial and failure or intolerance, or contraindication to at least 1 preferred alternative for the same indication if available

| Date       | Notes       |
|------------|-------------|
| 11/27/2023 | New Program |

| Non-formulary Exceptions Administrative Guidelin |  |  |  |
|--|--|--|--|
|  |  |  |  |

| Guideline ID          | GL-143184   |
|-----------------------|---|
| <b>Guideline Name</b> | Non-formulary Exceptions Administrative Guideline |
| Formulary             | Quartz  |

## **Guideline Note:**

| Effective Date: | 2/15/2024 |
|-----------------|-----------|
|-----------------|-----------|

### 1. Criteria

| Product Name: Non-formulary drugs |                               |     |               |
|-----------------------------------|-------------------------------|-----|---------------|
| Approval Length                   | Approval Length 12 month(s)   |     |               |
| Guideline Type                    | Guideline Type Administrative |     |               |
| Product Name Gene                 | ric Name                      | GPI | Brand/Generic |

## **Approval Criteria**

- **1** Both of the following:
- **1.1** One of the following:
- **1.1.1** Provider attests that it is medically necessary for the individual to receive that specific contraceptive

OR

- **1.1.2** Both of the following:
- **1.1.2.1** One of the following:
- **1.1.2.1.1** Paid claims or submission of medical records (e.g. chart notes) show there have been adequate trials of ALL appropriate therapeutic alternatives and there was (a) inadequate clinical response, (b) inappropriate clinical response, (c) intolerance or (d) allergy to those medications

OR

**1.1.2.1.2** An exception to the formulary may be considered when ALL appropriate therapeutic alternatives have not been tried and there is documentation that ALL appropriate therapeutic alternatives will be (a) ineffective, (b) less effective or (c) will result in adverse effects

OR

- **1.1.2.1.3** An exception to the formulary may be considered when it is a situation that it is not clinically appropriate to have adequate trials of ALL therapeutic alternatives, such as the individual has complex medical conditions, would be subject to prolonged pain, or there is a risk of severe or significant adverse medical outcomes if there is significant delay in treating the condition AND one of the following were tried:
  - At least four formulary alternatives in the same drug class as the requested medication
  - If there are not four formulary alternatives in the same drug class, at least four formulary alternatives from three different drug classes (if available) when it is appropriate under the standards of acceptable medical practice for the treatment of the diagnosis to trial medications with different mechanisms of action
  - No formulary alternative is appropriate to treat the patient's condition

#### **AND**

**1.1.2.2** When there are prior authorization criteria for the drug class or therapeutic alternatives, an exception to the formulary should take into consideration those criteria and should not be less stringent for the non-formulary drug. An example would be phototherapy for biologics for psoriasis when requesting a non-formulary biologic for psoriasis.

#### AND

- **1.2** One of the following:
- **1.2.1** Requested drug is FDA-approved for the condition being treated

OR

**1.2.2** If requested for an off-label indication, the off-label guideline approval criteria have been met.

OR

**2** - For Illinois Plans only: Member is new to the plan (as evidenced by coverage effective date of less than or equal to 90 days) who are established on nonpreferred therapy, will have coverage under their drug benefit with submission of medical records (e.g., chart notes) documenting symptom improvement or disease stability

| Date      | Notes            |
|-----------|------------------|
| 2/14/2024 | Update Guideline |

| Non-Preferred Topical Steroids   |  |  |  |
|--|--|--|--|
| (a) Substrange and support fields to be transition count of each of principle contribution of the country of th |  |  |  |

| Guideline ID   | GL-131427                      |
|----------------|--------------------------------|
| Guideline Name | Non-Preferred Topical Steroids |
| Formulary      | Quartz                         |

## **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

## 1. Criteria

DESONIDE

VERDESO

| Approval Length 12 month(s) |     |  |   |               |  |
|-----------------------------|-----|--|---|---------------|--|
| Therapy Stage               |     | Initial Authorization                                      |   |               |  |
| Guideline Type              |     | Prior Authorization-IL and MN Plans                        | rior Authorization-IL and MN Plans Only |               |  |
| Product Name                | Ge  | neric Name   | GPI                                     | Brand/Generic |  |
| AMCINONIDE                  | AM  | CINONIDE OINT 0.1%   | 90550010004205                          | Generic       |  |
| SERNIVO                     | 1   | AMETHASONE DIPROPIONATE SPRAY<br>JLSION 0.05% (BASE EQUIV) | 90550020001620                          | Brand         |  |
| IMPOYZ                      | CLC | DBETASOL PROPIONATE CREAM 0.025%                           | 90550025103703                          | Brand         |  |
| CLOCORTOLONE<br>PIVALATE    | CLC | OCORTOLONE PIVALATE CREAM 0.1%                             | 90550030103705                          | Generic       |  |

DESONIDE CREAM 0.05%

DESONIDE FOAM 0.05%

Generic

Brand

90550035003705

90550035003920

| DESOXIMETASONE                             | DESOXIMETASONE SPRAY 0.25%                                  | 90550040000910 | Generic |
|--|---|----------------|---------|
| DESOXIMETASONE                             | DESOXIMETASONE CREAM 0.05%                                  | 90550040003705 | Generic |
| DESOXIMETASONE                             | DESOXIMETASONE CREAM 0.25%                                  | 90550040003710 | Generic |
| DESOXIMETASONE                             | DESOXIMETASONE GEL 0.05%                                    | 90550040004005 | Generic |
| DESOXIMETASONE                             | DESOXIMETASONE OINT 0.05%                                   | 90550040004203 | Generic |
| DESOXIMETASONE                             | DESOXIMETASONE OINT 0.25%                                   | 90550040004205 | Generic |
| DIFLORASONE<br>DIACETATE                   | DIFLORASONE DIACETATE CREAM 0.05%                           | 90550050103705 | Generic |
| DIFLORASONE<br>DIACETATE                   | DIFLORASONE DIACETATE OINT 0.05%                            | 90550050104205 | Generic |
| APEXICON E                                 | DIFLORASONE DIACETATE EMOLLIENT<br>BASE CREAM 0.05%         | 90550050153705 | Brand   |
| FLUOCINONIDE                               | FLUOCINONIDE CREAM 0.1%                                     | 90550060003710 | Generic |
| FLURANDRENOLIDE                            | FLURANDRENOLIDE CREAM 0.05%                                 | 90550065003710 | Generic |
| FLURANDRENOLIDE                            | FLURANDRENOLIDE LOTION 0.05%                                | 90550065004105 | Generic |
| HALCINONIDE                                | HALCINONIDE CREAM 0.1%                                      | 90550070003710 | Generic |
| HALOG                                      | HALCINONIDE OINT 0.1%                                       | 90550070004205 | Brand   |
| ULTRAVATE                                  | HALOBETASOL PROPIONATE LOTION 0.05%                         | 90550073104110 | Brand   |
| TEXACORT                                   | HYDROCORTISONE SOLN 2.5%                                    | 90550075002020 | Brand   |
| HYDROCORTISONE<br>BUTYRATE                 | HYDROCORTISONE BUTYRATE SOLN 0.1%                           | 90550075302020 | Generic |
| HYDROCORTISONE<br>BUTYRATE                 | HYDROCORTISONE BUTYRATE CREAM 0.1%                          | 90550075303705 | Generic |
| HYDROCORTISONE<br>BUTYRATE                 | HYDROCORTISONE BUTYRATE LOTION 0.1%                         | 90550075304120 | Generic |
| HYDROCORTISONE<br>BUTYRATE                 | HYDROCORTISONE BUTYRATE OINT 0.1%                           | 90550075304205 | Generic |
| HYDROCORTISONE<br>BUTYRATE (LIPID)         | HYDROCORTISONE BUTYRATE<br>HYDROPHILIC LIPO BASE CREAM 0.1% | 90550075323705 | Generic |
| HYDROCORTISONE<br>BUTYRATE<br>(LIPOPHILIC) | HYDROCORTISONE BUTYRATE<br>HYDROPHILIC LIPO BASE CREAM 0.1% | 90550075323705 | Generic |
| PANDEL                                     | HYDROCORTISONE PROBUTATE CREAM 0.1%                         | 90550075273720 | Brand   |
| HYDROCORTISONE<br>VALERATE                 | HYDROCORTISONE VALERATE OINT 0.2%                           | 90550075204205 | Generic |
| HYDROCORTISONE<br>VALERATE                 | HYDROCORTISONE VALERATE CREAM 0.2%                          | 90550075203705 | Generic |
| TRIAMCINOLONE<br>ACETONIDE                 | TRIAMCINOLONE ACETONIDE AEROSOL<br>SOLN 0.147 MG/GM         | 90550085103400 | Generic |

**1** - Trial and failure, contraindication, or intolerance of a preferred topical steroid in comparable potency and/or formulation

| Approval Length | 12 month(s)                              |
|-----------------|--|
| Therapy Stage   | Reauthorization                          |
| Guideline Type  | Prior Authorization-IL and MN Plans Only |

| Product Name             | Generic Name  | GPI            | Brand/Generic |
|--------------------------|---|----------------|---------------|
| AMCINONIDE               | AMCINONIDE OINT 0.1%  | 90550010004205 | Generic       |
| SERNIVO                  | BETAMETHASONE DIPROPIONATE SPRAY<br>EMULSION 0.05% (BASE EQUIV) | 90550020001620 | Brand         |
| IMPOYZ                   | CLOBETASOL PROPIONATE CREAM 0.025%                              | 90550025103703 | Brand         |
| CLOCORTOLONE<br>PIVALATE | CLOCORTOLONE PIVALATE CREAM 0.1%                                | 90550030103705 | Generic       |
| DESONIDE                 | DESONIDE CREAM 0.05%  | 90550035003705 | Generic       |
| VERDESO                  | DESONIDE FOAM 0.05%   | 90550035003920 | Brand         |
| DESOXIMETASONE           | DESOXIMETASONE SPRAY 0.25%                                      | 90550040000910 | Generic       |
| DESOXIMETASONE           | DESOXIMETASONE CREAM 0.05%                                      | 90550040003705 | Generic       |
| DESOXIMETASONE           | DESOXIMETASONE CREAM 0.25%                                      | 90550040003710 | Generic       |
| DESOXIMETASONE           | DESOXIMETASONE GEL 0.05%  | 90550040004005 | Generic       |
| DESOXIMETASONE           | DESOXIMETASONE OINT 0.05%                                       | 90550040004203 | Generic       |
| DESOXIMETASONE           | DESOXIMETASONE OINT 0.25%                                       | 90550040004205 | Generic       |
| DIFLORASONE<br>DIACETATE | DIFLORASONE DIACETATE CREAM 0.05%                               | 90550050103705 | Generic       |
| DIFLORASONE<br>DIACETATE | DIFLORASONE DIACETATE OINT 0.05%                                | 90550050104205 | Generic       |
| APEXICON E               | DIFLORASONE DIACETATE EMOLLIENT<br>BASE CREAM 0.05%             | 90550050153705 | Brand         |
| FLUOCINONIDE             | FLUOCINONIDE CREAM 0.1%   | 90550060003710 | Generic       |
| FLURANDRENOLIDE          | FLURANDRENOLIDE CREAM 0.05%                                     | 90550065003710 | Generic       |
| FLURANDRENOLIDE          | FLURANDRENOLIDE LOTION 0.05%                                    | 90550065004105 | Generic       |
| HALCINONIDE              | HALCINONIDE CREAM 0.1%  | 90550070003710 | Generic       |
| HALOG                    | HALCINONIDE OINT 0.1%   | 90550070004205 | Brand         |

| ULTRAVATE                                  | HALOBETASOL PROPIONATE LOTION 0.05%                         | 90550073104110 | Brand   |
|--|---|----------------|---------|
| - CITOTOTAL                                | TIMEGBETAGGET NOT TOTALLE EGITION 0.00%                     | 90550073104110 | Diana   |
| TEXACORT                                   | HYDROCORTISONE SOLN 2.5%                                    | 90550075002020 | Brand   |
| HYDROCORTISONE<br>BUTYRATE                 | HYDROCORTISONE BUTYRATE SOLN 0.1%                           | 90550075302020 | Generic |
| HYDROCORTISONE<br>BUTYRATE                 | HYDROCORTISONE BUTYRATE CREAM 0.1%                          | 90550075303705 | Generic |
| HYDROCORTISONE<br>BUTYRATE                 | HYDROCORTISONE BUTYRATE LOTION 0.1%                         | 90550075304120 | Generic |
| HYDROCORTISONE<br>BUTYRATE                 | HYDROCORTISONE BUTYRATE OINT 0.1%                           | 90550075304205 | Generic |
| HYDROCORTISONE<br>BUTYRATE (LIPID)         | HYDROCORTISONE BUTYRATE<br>HYDROPHILIC LIPO BASE CREAM 0.1% | 90550075323705 | Generic |
| HYDROCORTISONE<br>BUTYRATE<br>(LIPOPHILIC) | HYDROCORTISONE BUTYRATE<br>HYDROPHILIC LIPO BASE CREAM 0.1% | 90550075323705 | Generic |
| PANDEL                                     | HYDROCORTISONE PROBUTATE CREAM 0.1%                         | 90550075273720 | Brand   |
| HYDROCORTISONE<br>VALERATE                 | HYDROCORTISONE VALERATE OINT 0.2%                           | 90550075204205 | Generic |
| HYDROCORTISONE<br>VALERATE                 | HYDROCORTISONE VALERATE CREAM 0.2%                          | 90550075203705 | Generic |
| TRIAMCINOLONE<br>ACETONIDE                 | TRIAMCINOLONE ACETONIDE AEROSOL<br>SOLN 0.147 MG/GM         | 90550085103400 | Generic |

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug.

| Notes | *Members new to the plan (as evidenced by coverage effective date of       |
|-------|--|
|       | less than or equal to 90 days) must meet the initial criteria for coverage |

| Approval Length          |     | 12/31/2039   |                |               |
|--------------------------|-----|--|----------------|---------------|
| Guideline Type           |     | Prior Authorization-All plans except IL and MN             |                |               |
| Product Name             | Ge  | neric Name   | GPI            | Brand/Generic |
| AMCINONIDE               | AMO | CINONIDE OINT 0.1%   | 90550010004205 | Generic       |
| SERNIVO                  |     | AMETHASONE DIPROPIONATE SPRAY<br>JLSION 0.05% (BASE EQUIV) | 90550020001620 | Brand         |
| IMPOYZ                   | CLC | DBETASOL PROPIONATE CREAM 0.025%                           | 90550025103703 | Brand         |
| CLOCORTOLONE<br>PIVALATE | CLC | OCORTOLONE PIVALATE CREAM 0.1%                             | 90550030103705 | Generic       |

| DESONIDE                                   | DESONIDE CREAM 0.05%  | 90550035003705 | Generic |
|--|---|----------------|---------|
| VERDESO                                    | DESONIDE FOAM 0.05%   | 90550035003920 | Brand   |
| DESOXIMETASONE                             | DESOXIMETASONE SPRAY 0.25%                                  | 90550040000910 | Generic |
| DESOXIMETASONE                             | DESOXIMETASONE CREAM 0.05%                                  | 90550040003705 | Generic |
| DESOXIMETASONE                             | DESOXIMETASONE CREAM 0.25%                                  | 90550040003710 | Generic |
| DESOXIMETASONE                             | DESOXIMETASONE GEL 0.05%                                    | 90550040004005 | Generic |
| DESOXIMETASONE                             | DESOXIMETASONE OINT 0.05%                                   | 90550040004203 | Generic |
| DESOXIMETASONE                             | DESOXIMETASONE OINT 0.25%                                   | 90550040004205 | Generic |
| DIFLORASONE<br>DIACETATE                   | DIFLORASONE DIACETATE CREAM 0.05%                           | 90550050103705 | Generic |
| DIFLORASONE<br>DIACETATE                   | DIFLORASONE DIACETATE OINT 0.05%                            | 90550050104205 | Generic |
| APEXICON E                                 | DIFLORASONE DIACETATE EMOLLIENT<br>BASE CREAM 0.05%         | 90550050153705 | Brand   |
| FLUOCINONIDE                               | FLUOCINONIDE CREAM 0.1%                                     | 90550060003710 | Generic |
| FLURANDRENOLIDE                            | FLURANDRENOLIDE CREAM 0.05%                                 | 90550065003710 | Generic |
| FLURANDRENOLIDE                            | FLURANDRENOLIDE LOTION 0.05%                                | 90550065004105 | Generic |
| HALCINONIDE                                | HALCINONIDE CREAM 0.1%                                      | 90550070003710 | Generic |
| HALOG                                      | HALCINONIDE OINT 0.1%                                       | 90550070004205 | Brand   |
| ULTRAVATE                                  | HALOBETASOL PROPIONATE LOTION 0.05%                         | 90550073104110 | Brand   |
| TEXACORT                                   | HYDROCORTISONE SOLN 2.5%                                    | 90550075002020 | Brand   |
| HYDROCORTISONE<br>BUTYRATE                 | HYDROCORTISONE BUTYRATE SOLN 0.1%                           | 90550075302020 | Generic |
| HYDROCORTISONE<br>BUTYRATE                 | HYDROCORTISONE BUTYRATE CREAM 0.1%                          | 90550075303705 | Generic |
| HYDROCORTISONE<br>BUTYRATE                 | HYDROCORTISONE BUTYRATE LOTION 0.1%                         | 90550075304120 | Generic |
| HYDROCORTISONE<br>BUTYRATE                 | HYDROCORTISONE BUTYRATE OINT 0.1%                           | 90550075304205 | Generic |
| HYDROCORTISONE<br>BUTYRATE (LIPID)         | HYDROCORTISONE BUTYRATE<br>HYDROPHILIC LIPO BASE CREAM 0.1% | 90550075323705 | Generic |
| HYDROCORTISONE<br>BUTYRATE<br>(LIPOPHILIC) | HYDROCORTISONE BUTYRATE<br>HYDROPHILIC LIPO BASE CREAM 0.1% | 90550075323705 | Generic |
| PANDEL                                     | HYDROCORTISONE PROBUTATE CREAM 0.1%                         | 90550075273720 | Brand   |
| HYDROCORTISONE<br>VALERATE                 | HYDROCORTISONE VALERATE OINT 0.2%                           | 90550075204205 | Generic |
| HYDROCORTISONE<br>VALERATE                 | HYDROCORTISONE VALERATE CREAM 0.2%                          | 90550075203705 | Generic |

| TRIAMCINOLONE<br>ACETONIDE | TRIAMCINOLONE ACETONIDE AEROSOL<br>SOLN 0.147 MG/GM | 90550085103400 | Generic |
|----------------------------|---|----------------|---------|
|----------------------------|---|----------------|---------|

**1** - Trial and failure, contraindication, or intolerance of a preferred topical steroid in comparable potency and/or formulation

| Date       | Notes       |
|------------|-------------|
| 10/31/2023 | New Program |

| Non-Sedating Antihistamine   |  |  |
|--|--|--|
| (3) hadroness and mission had not be trained and a state of the first hadroness according and the first hadroness according to t |  |  |

| Guideline ID          | GL-129167                  |
|-----------------------|----------------------------|
| <b>Guideline Name</b> | Non-Sedating Antihistamine |
| Formulary             | Quartz                     |

## **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

### Note:

Member new to the plan (as evidenced by coverage effective date of less than or equal to 90 days) who initiated therapy using a manufacturer-sponsored free drug program, provider samples, and/or vouchers will go through initial criteria, otherwise for continuation of therapy for new to plan, reauthorization criteria applies.

### 1. Criteria

| Product Name: Generic desloratadine, Clarinex D (desloratadine/pseudoephedrine) |       |  |                |               |
|---|-------|--|----------------|---------------|
| Diagnosis Allergic Rhinitis   |       | Allergic Rhinitis                                      |                |               |
| Approval Length   |       | 12/31/2039   |                |               |
| Guideline Type  |       | Prior Authorization - All Plans except IL and MN Plans |                |               |
| Product Name  | Gene  | ric Name   | GPI            | Brand/Generic |
| DESLORATADINE   | DESLO | RATADINE TAB 5 MG                                      | 41550021000320 | Generic       |
| CLARINEX-D 12<br>HOUR   |       | RATADINE & PSEUDOEPHEDRINE TAB<br>HR 2.5-120 MG        | 43993002627420 | Brand         |

| DESLORATADINE ODT    | DESLORATADINE TAB ORALLY<br>DISINTEGRATING 2.5 MG | 41550021007210 | Generic |
|----------------------|---|----------------|---------|
| DESLORATADINE<br>ODT | DESLORATADINE TAB ORALLY<br>DISINTEGRATING 5 MG   | 41550021007220 | Generic |

1 - Diagnosis of allergic rhinitis

#### **AND**

- **2** Trial and failure, contraindication, or intolerance to ALL of the following over the counter (OTC) agents:
  - Cetirizine
  - Fexofenadine
  - Levocetirizine
  - Loratadine

### **AND**

**3** - Trial and failure, contraindication, or intolerance to one nasal steroid\* (e.g., fluticasone)

| Notes | *Note: The nasal steroid criterion does not apply in the case of predicta |
|-------|---|
|       | ble situational exposures where nasal steroids would not be the best cli  |
|       | nical choice or for children 12 years of age or younger.                  |

| Product Name: Generic desloratadine, Clarinex D (desloratadine/pseudoephedrine) |                                       |  |
|---|---------------------------------------|--|
| Diagnosis   | Allergic Rhinitis                     |  |
| Approval Length   | 12 month(s)                           |  |
| Therapy Stage   | Initial Authorization                 |  |
| Guideline Type  | Prior Authorization - IL and MN Plans |  |

| Product Name          | Generic Name  | GPI            | Brand/Generic |
|-----------------------|---|----------------|---------------|
| DESLORATADINE         | DESLORATADINE TAB 5 MG                                    | 41550021000320 | Generic       |
| CLARINEX-D 12<br>HOUR | DESLORATADINE & PSEUDOEPHEDRINE TAB<br>ER 12HR 2.5-120 MG | 43993002627420 | Brand         |
| DESLORATADINE ODT     | DESLORATADINE TAB ORALLY<br>DISINTEGRATING 2.5 MG         | 41550021007210 | Generic       |

| DESLORATADINE DESLORATADINE TAB ORALLY DISINTEGRATING 5 MG | 41550021007220 | Generic |
|--|----------------|---------|
|--|----------------|---------|

1 - Diagnosis of allergic rhinitis

### AND

- **2** Trial and failure, contraindication, or intolerance to ALL of the following over the counter (OTC) agents:
  - Cetirizine
  - Fexofenadine
  - Levocetirizine
  - Loratadine

### AND

**3** - Trial and failure, contraindication, or intolerance to one nasal steroid\* (e.g., fluticasone)

| Notes | *Note: The nasal steroid criterion does not apply in the case of predicta |
|-------|---|
|       | ble situational exposures where nasal steroids would not be the best cli  |
|       | nical choice or for children 12 years of age or younger.                  |

| Product Name: Generic desloratadine, Clarinex D (desloratadine/pseudoephedrine) |  |  |
|---|--|--|
| Diagnosis   | Urticarial Disease                                     |  |
| Approval Length   | 12/31/2039   |  |
| Guideline Type  | Prior Authorization - All Plans except IL and MN Plans |  |

| Product Name          | Generic Name  | GPI            | Brand/Generic |
|-----------------------|---|----------------|---------------|
| DESLORATADINE         | DESLORATADINE TAB 5 MG                                    | 41550021000320 | Generic       |
| CLARINEX-D 12<br>HOUR | DESLORATADINE & PSEUDOEPHEDRINE TAB<br>ER 12HR 2.5-120 MG | 43993002627420 | Brand         |
| DESLORATADINE ODT     | DESLORATADINE TAB ORALLY<br>DISINTEGRATING 2.5 MG         | 41550021007210 | Generic       |
| DESLORATADINE<br>ODT  | DESLORATADINE TAB ORALLY<br>DISINTEGRATING 5 MG           | 41550021007220 | Generic       |

1 - Diagnosis of urticarial disease

#### **AND**

- **2** Trial and failure, contraindication, or intolerance to ALL of the following over the counter (OTC) agents:
  - Cetirizine
  - Fexofenadine
  - Levocetirizine
  - Loratadine

| Product Name: Generic desloratadine, Clarinex D (desloratadine/pseudoephedrine) |                                       |  |
|---|---------------------------------------|--|
| Diagnosis   | Urticarial Disease                    |  |
| Approval Length   | 12 month(s)                           |  |
| Therapy Stage   | Initial Authorization                 |  |
| Guideline Type  | Prior Authorization - IL and MN Plans |  |

| Product Name          | Generic Name  | GPI            | Brand/Generic |
|-----------------------|---|----------------|---------------|
| DESLORATADINE         | DESLORATADINE TAB 5 MG                                    | 41550021000320 | Generic       |
| CLARINEX-D 12<br>HOUR | DESLORATADINE & PSEUDOEPHEDRINE TAB<br>ER 12HR 2.5-120 MG | 43993002627420 | Brand         |
| DESLORATADINE<br>ODT  | DESLORATADINE TAB ORALLY<br>DISINTEGRATING 2.5 MG         | 41550021007210 | Generic       |
| DESLORATADINE<br>ODT  | DESLORATADINE TAB ORALLY<br>DISINTEGRATING 5 MG           | 41550021007220 | Generic       |

### **Approval Criteria**

1 - Diagnosis of urticarial disease

### AND

2 - Trial and failure, contraindication, or intolerance to ALL of the following over the counter

## (OTC) agents:

- Cetirizine
- Fexofenadine
- Levocetirizine
- Loratadine

| Product Name: Generic desloratadine, Clarinex D (desloratadine/pseudoephedrine) |  |  |
|---|--|--|
| Diagnosis All Indications   |  |  |
| Approval Length 12 month(s)   |  |  |
| Therapy Stage Reauthorization   |  |  |
| Guideline Type Prior Authorization - IL and MN Plans                            |  |  |

| Product Name          | Generic Name  | GPI            | Brand/Generic |
|-----------------------|---|----------------|---------------|
| DESLORATADINE         | DESLORATADINE TAB 5 MG                                    | 41550021000320 | Generic       |
| CLARINEX-D 12<br>HOUR | DESLORATADINE & PSEUDOEPHEDRINE TAB<br>ER 12HR 2.5-120 MG | 43993002627420 | Brand         |
| DESLORATADINE<br>ODT  | DESLORATADINE TAB ORALLY<br>DISINTEGRATING 2.5 MG         | 41550021007210 | Generic       |
| DESLORATADINE<br>ODT  | DESLORATADINE TAB ORALLY<br>DISINTEGRATING 5 MG           | 41550021007220 | Generic       |

## **Approval Criteria**

**1** - Prescriber provides clinical documentation from the past 12 months that the member is continuing therapy on the requested drug

| Date      | Notes                   |
|-----------|-------------------------|
| 9/27/2023 | 2024 New Implementation |

| Non-solid Dosage Forms   |
|--|
| The State Strange come to Angles on The State State State Commission and State |
|  |

| Guideline ID          | GL-132813              |
|-----------------------|------------------------|
| <b>Guideline Name</b> | Non-solid Dosage Forms |
| Formulary             | Quartz                 |

## **Guideline Note:**

| Effective Date: |
|-----------------|
|-----------------|

### 1. Criteria

Product Name: Generic Famotidine Suspension 40 mg/5mL, Generic Naproxen Suspension 125 mg/ 5mL, Generic Sevelamer packet, Brand Valsartan solution 4 mg, mL, Atorvaliq, Generic Baclofen solution 5 mg/5mL, Thyquidity, Flolipid, Zonisade, Norliqva, Katerzia, generic esomeprazole gran, Nexium gran, generic lansoprazole ODT, Prilosec Powder, Aspruzyo

| Approval Length   | 12 month(s)           |
|---|-----------------------|
| Therapy Stage   | Initial Authorization |
| Guideline Type Prior Authorization - IL and MN plans only |                       |

| Product Name  | Generic Name                      | GPI            | Brand/Generic |
|---|-----------------------------------|----------------|---------------|
| FAMOTIDINE  | FAMOTIDINE FOR SUSP 40 MG/5ML     | 49200030001920 | Generic       |
| NAPROXEN  | NAPROXEN SUSP 125 MG/5ML          | 66100060001805 | Generic       |
| SEVELAMER SEVELAMER CARBONATE PACKET 0.8 GM CARBONATE |                                   | 52800070053020 | Generic       |
| SEVELAMER<br>CARBONATE                                | SEVELAMER CARBONATE PACKET 2.4 GM | 52800070053040 | Generic       |

| VALSARTAN                 | VALSARTAN ORAL SOLN 4 MG/ML                                     | 36150080002025 | Brand   |
|---------------------------|---|----------------|---------|
| ATORVALIQ                 | ATORVASTATIN CALCIUM SUSP 20 MG/5ML<br>(4MG/ML) (BASE EQUIV)    | 39400010101810 | Brand   |
| BACLOFEN                  | BACLOFEN ORAL SOLN 5 MG/5ML                                     | 75100010002070 | Generic |
| THYQUIDITY                | LEVOTHYROXINE SODIUM ORAL SOLUTION 100 MCG/5ML                  | 28100010102023 | Brand   |
| FLOLIPID                  | SIMVASTATIN SUSP 20 MG/5ML (4 MG/ML)                            | 39400075001810 | Brand   |
| FLOLIPID                  | SIMVASTATIN SUSP 40 MG/5ML (8 MG/ML)                            | 39400075001820 | Brand   |
| ZONISADE                  | ZONISAMIDE ORAL SUSP 100 MG/5ML (20<br>MG/ML)                   | 72600090001820 | Brand   |
| NORLIQVA                  | AMLODIPINE BESYLATE ORAL SOLN 1 MG/ML (BASE EQUIVALENT)         | 34000003102020 | Brand   |
| KATERZIA                  | AMLODIPINE BENZOATE ORAL SUSP 1 MG/ML (BASE EQUIVALENT)         | 34000003081820 | Brand   |
| ESOMEPRAZOLE<br>MAGNESIUM | ESOMEPRAZOLE MAGNESIUM FOR DELAYED<br>RELEASE SUSP PACKET 10 MG | 49270025103010 | Generic |
| ESOMEPRAZOLE<br>MAGNESIUM | ESOMEPRAZOLE MAGNESIUM FOR DELAYED RELEASE SUSP PACKET 20 MG    | 49270025103020 | Generic |
| ESOMEPRAZOLE<br>MAGNESIUM | ESOMEPRAZOLE MAGNESIUM FOR DELAYED RELEASE SUSP PACKET 40 MG    | 49270025103040 | Generic |
| NEXIUM                    | ESOMEPRAZOLE MAGNESIUM FOR DELAYED RELEASE SUSP PACK 2.5 MG     | 49270025103004 | Brand   |
| NEXIUM                    | ESOMEPRAZOLE MAGNESIUM FOR DELAYED RELEASE SUSP PACKET 5 MG     | 49270025103007 | Brand   |
| LANSOPRAZOLE<br>ODT       | LANSOPRAZOLE TAB DELAYED RELEASE<br>ORALLY DISINTEGRATING 15 MG | 4927004000H315 | Generic |
| LANSOPRAZOLE<br>ODT       | LANSOPRAZOLE TAB DELAYED RELEASE<br>ORALLY DISINTEGRATING 30 MG | 4927004000H330 | Generic |
| PRILOSEC                  | OMEPRAZOLE MAGNESIUM FOR DELAYED<br>RELEASE SUSP PACKET 2.5 MG  | 49270060103020 | Brand   |
| PRILOSEC                  | OMEPRAZOLE MAGNESIUM FOR DELAYED<br>RELEASE SUSP PACKET 10 MG   | 49270060103030 | Brand   |
| ASPRUZYO<br>SPRINKLE      | RANOLAZINE ER GRANULES PACKET 500 MG                            | 32200040003020 | Brand   |
| ASPRUZYO<br>SPRINKLE      | RANOLAZINE ER GRANULES PACKET 1000 MG                           | 32200040003040 | Brand   |

1 - Unable to tolerate solid dose form

OR

2 - Age is less than 12 years old\*

#### OR

**3** - Minnesota Plans Only - Member has stage four metastatic cancer and the requested drug is being used as supportive care to treat symptoms directly related to their cancer or chemotherapy regimen

| Notes | *Age edit does not apply to Zonisamide oral suspension because Zonis |
|-------|--|
|       | amide is only approved for age 16 and older.                         |

Product Name: Generic Famotidine Suspension 40 mg/5mL, Generic Naproxen Suspension 125 mg/ 5mL, Generic Sevelamer packet, Brand Valsartan solution 4 mg, mL, Atorvaliq, Generic Baclofen solution 5 mg/5mL, Thyquidity, Flolipid, Zonisade, Norliqva, Katerzia, generic esomeprazole gran, Nexium gran, generic lansoprazole ODT, Prilosec Powder, Aspruzyo

| Approval Length   | 12 month(s)     |
|---|-----------------|
| Therapy Stage   | Reauthorization |
| Guideline Type Prior Authorization - IL and MN plans only |                 |

| Product Name           | Product Name Generic Name                                    |                | Brand/Generic |
|------------------------|--|----------------|---------------|
| FAMOTIDINE             | FAMOTIDINE FOR SUSP 40 MG/5ML                                | 49200030001920 | Generic       |
| NAPROXEN               | NAPROXEN SUSP 125 MG/5ML                                     | 66100060001805 | Generic       |
| SEVELAMER<br>CARBONATE | SEVELAMER CARBONATE PACKET 0.8 GM                            | 52800070053020 | Generic       |
| SEVELAMER<br>CARBONATE | SEVELAMER CARBONATE PACKET 2.4 GM                            | 52800070053040 | Generic       |
| VALSARTAN              | VALSARTAN ORAL SOLN 4 MG/ML                                  | 36150080002025 | Brand         |
| ATORVALIQ              | ATORVASTATIN CALCIUM SUSP 20 MG/5ML<br>(4MG/ML) (BASE EQUIV) | 39400010101810 | Brand         |
| BACLOFEN               | BACLOFEN ORAL SOLN 5 MG/5ML                                  | 75100010002070 | Generic       |
| THYQUIDITY             | LEVOTHYROXINE SODIUM ORAL SOLUTION 100 MCG/5ML               | 28100010102023 | Brand         |
| FLOLIPID               | SIMVASTATIN SUSP 20 MG/5ML (4 MG/ML)                         | 39400075001810 | Brand         |
| FLOLIPID               | SIMVASTATIN SUSP 40 MG/5ML (8 MG/ML)                         | 39400075001820 | Brand         |
| ZONISADE               | ZONISAMIDE ORAL SUSP 100 MG/5ML (20 MG/ML)                   | 72600090001820 | Brand         |
| NORLIQVA               | AMLODIPINE BESYLATE ORAL SOLN 1 MG/ML (BASE EQUIVALENT)      | 34000003102020 | Brand         |

| KATERZIA                  | AMLODIPINE BENZOATE ORAL SUSP 1 MG/ML (BASE EQUIVALENT)         | 34000003081820 | Brand   |
|---------------------------|---|----------------|---------|
| ESOMEPRAZOLE<br>MAGNESIUM | ESOMEPRAZOLE MAGNESIUM FOR DELAYED<br>RELEASE SUSP PACKET 10 MG | 49270025103010 | Generic |
| ESOMEPRAZOLE<br>MAGNESIUM | ESOMEPRAZOLE MAGNESIUM FOR DELAYED RELEASE SUSP PACKET 20 MG    | 49270025103020 | Generic |
| ESOMEPRAZOLE<br>MAGNESIUM | ESOMEPRAZOLE MAGNESIUM FOR DELAYED RELEASE SUSP PACKET 40 MG    | 49270025103040 | Generic |
| NEXIUM                    | ESOMEPRAZOLE MAGNESIUM FOR DELAYED RELEASE SUSP PACK 2.5 MG     | 49270025103004 | Brand   |
| NEXIUM                    | ESOMEPRAZOLE MAGNESIUM FOR DELAYED<br>RELEASE SUSP PACKET 5 MG  | 49270025103007 | Brand   |
| LANSOPRAZOLE<br>ODT       | LANSOPRAZOLE TAB DELAYED RELEASE<br>ORALLY DISINTEGRATING 15 MG | 4927004000H315 | Generic |
| LANSOPRAZOLE<br>ODT       | LANSOPRAZOLE TAB DELAYED RELEASE<br>ORALLY DISINTEGRATING 30 MG | 4927004000H330 | Generic |
| PRILOSEC                  | OMEPRAZOLE MAGNESIUM FOR DELAYED<br>RELEASE SUSP PACKET 2.5 MG  | 49270060103020 | Brand   |
| PRILOSEC                  | OMEPRAZOLE MAGNESIUM FOR DELAYED<br>RELEASE SUSP PACKET 10 MG   | 49270060103030 | Brand   |
| ASPRUZYO<br>SPRINKLE      | RANOLAZINE ER GRANULES PACKET 500 MG                            | 32200040003020 | Brand   |
| ASPRUZYO<br>SPRINKLE      | RANOLAZINE ER GRANULES PACKET 1000 MG                           | 32200040003040 | Brand   |

**1** - Clinical documentation from the previous 12 months demonstrating a positive response to therapy

| Notes | *Age edit does not apply to Zonisamide oral suspension because Zonis |
|-------|--|
|       | amide is only approved for age 16 and older.                         |

Product Name: Generic Famotidine Suspension 40 mg/5mL, Generic Naproxen Suspension 125 mg/ 5mL, Generic Sevelamer packet, Brand Valsartan solution 4 mg, mL, Atorvaliq, Generic Baclofen solution 5 mg/5mL, Thyquidity, Flolipid, Zonisade, Norliqva, Katerzia, generic esomeprazole gran, Nexium gran, generic lansoprazole ODT, Prilosec Powder, Aspruzyo

| Approval Length | 12/31/2039                                       |
|-----------------|--|
| Guideline Type  | Prior Authorization - All plans except IL and MN |

| Product Name | Generic Name                  | GPI            | Brand/Generic |
|--------------|-------------------------------|----------------|---------------|
| FAMOTIDINE   | FAMOTIDINE FOR SUSP 40 MG/5ML | 49200030001920 | Generic       |
| NAPROXEN     | NAPROXEN SUSP 125 MG/5ML      | 66100060001805 | Generic       |

| SEVELAMER<br>CARBONATE    | SEVELAMER CARBONATE PACKET 0.8 GM                               | 52800070053020 | Generic |
|---------------------------|---|----------------|---------|
| SEVELAMER<br>CARBONATE    | SEVELAMER CARBONATE PACKET 2.4 GM                               | 52800070053040 | Generic |
| VALSARTAN                 | VALSARTAN ORAL SOLN 4 MG/ML                                     | 36150080002025 | Brand   |
| ATORVALIQ                 | ATORVASTATIN CALCIUM SUSP 20 MG/5ML<br>(4MG/ML) (BASE EQUIV)    | 39400010101810 | Brand   |
| BACLOFEN                  | BACLOFEN ORAL SOLN 5 MG/5ML                                     | 75100010002070 | Generic |
| THYQUIDITY                | LEVOTHYROXINE SODIUM ORAL SOLUTION 100 MCG/5ML                  | 28100010102023 | Brand   |
| FLOLIPID                  | SIMVASTATIN SUSP 20 MG/5ML (4 MG/ML)                            | 39400075001810 | Brand   |
| FLOLIPID                  | SIMVASTATIN SUSP 40 MG/5ML (8 MG/ML)                            | 39400075001820 | Brand   |
| ZONISADE                  | ZONISAMIDE ORAL SUSP 100 MG/5ML (20 MG/ML)                      | 72600090001820 | Brand   |
| NORLIQVA                  | AMLODIPINE BESYLATE ORAL SOLN 1 MG/ML (BASE EQUIVALENT)         | 34000003102020 | Brand   |
| KATERZIA                  | AMLODIPINE BENZOATE ORAL SUSP 1 MG/ML (BASE EQUIVALENT)         | 34000003081820 | Brand   |
| ESOMEPRAZOLE<br>MAGNESIUM | ESOMEPRAZOLE MAGNESIUM FOR DELAYED RELEASE SUSP PACKET 10 MG    | 49270025103010 | Generic |
| ESOMEPRAZOLE<br>MAGNESIUM | ESOMEPRAZOLE MAGNESIUM FOR DELAYED RELEASE SUSP PACKET 20 MG    | 49270025103020 | Generic |
| ESOMEPRAZOLE<br>MAGNESIUM | ESOMEPRAZOLE MAGNESIUM FOR DELAYED<br>RELEASE SUSP PACKET 40 MG | 49270025103040 | Generic |
| NEXIUM                    | ESOMEPRAZOLE MAGNESIUM FOR DELAYED RELEASE SUSP PACK 2.5 MG     | 49270025103004 | Brand   |
| NEXIUM                    | ESOMEPRAZOLE MAGNESIUM FOR DELAYED RELEASE SUSP PACKET 5 MG     | 49270025103007 | Brand   |
| LANSOPRAZOLE<br>ODT       | LANSOPRAZOLE TAB DELAYED RELEASE<br>ORALLY DISINTEGRATING 15 MG | 4927004000H315 | Generic |
| LANSOPRAZOLE<br>ODT       | LANSOPRAZOLE TAB DELAYED RELEASE<br>ORALLY DISINTEGRATING 30 MG | 4927004000H330 | Generic |
| PRILOSEC                  | OMEPRAZOLE MAGNESIUM FOR DELAYED<br>RELEASE SUSP PACKET 2.5 MG  | 49270060103020 | Brand   |
| PRILOSEC                  | OMEPRAZOLE MAGNESIUM FOR DELAYED<br>RELEASE SUSP PACKET 10 MG   | 49270060103030 | Brand   |
| ASPRUZYO<br>SPRINKLE      | RANOLAZINE ER GRANULES PACKET 500 MG                            | 32200040003020 | Brand   |
| ASPRUZYO<br>SPRINKLE      | RANOLAZINE ER GRANULES PACKET 1000 MG                           | 32200040003040 | Brand   |

| 1 - Unable to tolerate solid dose form |   |  |
|--|---|--|
|  | OR  |  |
| 2 - Age is less than 12 years old*     |   |  |
| Notes                                  | *Age edit does not apply to Zonisamide oral suspension because Zonis amide is only approved for age 16 and older. |  |

| Date       | Notes       |
|------------|-------------|
| 11/28/2023 | New Program |

| Nonpreferred Bowel Preparations  |  |
|--|--|
| (2) Indicating and indicate high to find and a state and a state of the state of th |  |
|  |  |

| Guideline ID          | GL-131403                       |
|-----------------------|---------------------------------|
| <b>Guideline Name</b> | Nonpreferred Bowel Preparations |
| Formulary             | Quartz                          |

# **Guideline Note:**

| Effective Date: |
|-----------------|
|-----------------|

# 1. Criteria

| Product Name: Clenpiq, Plenvu, Sodium sulfate/Potassium sulfate/Magnesium sulfate |   |  |               |  |
|---|---|--|---------------|--|
| Approval Length   | 12 month(s)   |  |               |  |
| Therapy Stage   | Initial Authorization   |  |               |  |
| Guideline Type  | Prior Authorization-IL and MN Plans                             | Prior Authorization-IL and MN Plans Only |               |  |
| Product Name  | Generic Name  | GPI                                      | Brand/Generic |  |
| CLENPIQ   | SOD PICOSULFATE-MG OX-CITRIC AC SOL 10 MG-3.5 GM-12 GM/160ML    | 46992003452020                           | Brand         |  |
| CLENPIQ   | SOD PICOSULFATE-MG OX-CITRIC AC SOL<br>10 MG-3.5 GM-12 GM/175ML | 46992003452030                           | Brand         |  |
| SODIUM<br>SULFATE/POTASSIUM<br>SULFATE/MAGNESIUM<br>SULFATE                       | SOD SULFATE-POT SULF-MG SULF ORAL<br>SOL 17.5-3.13-1.6 GM/177ML | 46992003602020                           | Generic       |  |
| PLENVU  | PEG 3350-KCL-NACL-NA SULFATE-NA<br>ASCORBATE-C FOR SOLN 140 GM  | 46992006302135                           | Brand         |  |

1 - Trial and failure, contraindication or intolerance to a preferred bowel preparation

| Product Name: Clenpiq, Plenvu, Sodium sulfate/Potassium sulfate/Magnesium sulfate |                               |  |  |
|---|-------------------------------|--|--|
| Approval Length   | 12 month(s)                   |  |  |
| Therapy Stage   | Therapy Stage Reauthorization |  |  |
| Guideline Type Prior Authorization-IL and MN Plans Only                           |                               |  |  |
|   |                               |  |  |

| Product Name  | Generic Name  | GPI            | Brand/Generic |
|---|---|----------------|---------------|
| CLENPIQ   | SOD PICOSULFATE-MG OX-CITRIC AC SOL<br>10 MG-3.5 GM-12 GM/160ML | 46992003452020 | Brand         |
| CLENPIQ   | SOD PICOSULFATE-MG OX-CITRIC AC SOL<br>10 MG-3.5 GM-12 GM/175ML | 46992003452030 | Brand         |
| SODIUM<br>SULFATE/POTASSIUM<br>SULFATE/MAGNESIUM<br>SULFATE | SOD SULFATE-POT SULF-MG SULF ORAL<br>SOL 17.5-3.13-1.6 GM/177ML | 46992003602020 | Generic       |
| PLENVU  | PEG 3350-KCL-NACL-NA SULFATE-NA<br>ASCORBATE-C FOR SOLN 140 GM  | 46992006302135 | Brand         |

## **Approval Criteria**

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug.

| Product Name: Clenpiq, Plenvu, Sodium sulfate/Potassium sulfate/Magnesium sulfate |  |               |       |
|---|--|---------------|-------|
| Approval Length   | 12/31/2039   |               |       |
| Guideline Type  | Prior Authorization-All plans except IL and MN                       |               |       |
| Product Name Generic Name GPI Brai  |  | Brand/Generic |       |
| CLENDIO   | NI ENIDIO SOD DICOSTILI EATE MC OVICITDIC AC SOL TRANSPORTE PROPERTY |               | Brand |

| Product Name  | Generic Name  | GPI            | Brand/Generic |
|---|---|----------------|---------------|
| CLENPIQ   | SOD PICOSULFATE-MG OX-CITRIC AC SOL<br>10 MG-3.5 GM-12 GM/160ML | 46992003452020 | Brand         |
| CLENPIQ   | SOD PICOSULFATE-MG OX-CITRIC AC SOL<br>10 MG-3.5 GM-12 GM/175ML | 46992003452030 | Brand         |
| SODIUM<br>SULFATE/POTASSIUM<br>SULFATE/MAGNESIUM<br>SULFATE | SOD SULFATE-POT SULF-MG SULF ORAL<br>SOL 17.5-3.13-1.6 GM/177ML | 46992003602020 | Generic       |

| PLENVU            | PEG 3350-KCL-NACL-NA SULFATE-NA<br>ASCORBATE-C FOR SOLN 140 GM | 46992006302135 | Brand |
|-------------------|--|----------------|-------|
|                   |  |                |       |
| Approval Criteria |  |                |       |

1 - Trial and failure, contraindication or intolerance to a preferred bowel preparation

| Date       | Notes       |
|------------|-------------|
| 10/24/2023 | New program |

| Nonpreferred insulin   |  |  |  |  |
|--|--|--|--|--|
| Substitution process to shape. To the two factors many, comply, a tilled to the fact the process for consolius and the c |  |  |  |  |
|  |  |  |  |  |

| Guideline ID          | GL-131426            |  |
|-----------------------|----------------------|--|
| <b>Guideline Name</b> | Nonpreferred insulin |  |
| Formulary             | Quartz               |  |

# **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

# 1. Criteria

| Product Name: Apidra, Humalog Mix 50:50                 |  |  |
|---|--|--|
| Approval Length 12 month(s)                             |  |  |
| Therapy Stage Initial Authorization                     |  |  |
| Guideline Type Prior Authorization-IL and MN Plans Only |  |  |

| Product<br>Name                 | Generic Name  | GPI            | Brand/Generic |
|---------------------------------|---|----------------|---------------|
| HUMALOG<br>MIX 50/50            | INSULIN LISPRO PROTAMINE & LISPRO INJ 100<br>UNIT/ML (50-50)    | 27104080001840 | Brand         |
| APIDRA<br>SOLOSTAR              | INSULIN GLULISINE SOLN PEN-INJECTOR INJ 100<br>UNIT/ML          | 2710400400D220 | Brand         |
| HUMALOG<br>MIX 50/50<br>KWIKPEN | INSULIN LISPRO PROT & LISPRO SUS PEN-INJ 100<br>UNIT/ML (50-50) | 2710408000D340 | Brand         |
| APIDRA                          | INSULIN GLULISINE INJ 100 UNIT/ML                               | 27104004002022 | Brand         |

1 - Diagnosis of diabetes mellitus

### AND

**2** - Trial and failure, contraindication or intolerance to use of insulin aspart (Novolog, Novolog Mix) including dose adjustments

| Product Name: Apidra, Humalog Mix 50:50 |  |  |
|---|--|--|
| Approval Length 12 month(s)             |  |  |
| Therapy Stage                           | Reauthorization                          |  |
| Guideline Type                          | Prior Authorization-IL and MN Plans Only |  |

| Product<br>Name                 | Generic Name  | GPI            | Brand/Generic |
|---------------------------------|---|----------------|---------------|
| HUMALOG<br>MIX 50/50            | INSULIN LISPRO PROTAMINE & LISPRO INJ 100<br>UNIT/ML (50-50)    | 27104080001840 | Brand         |
| APIDRA<br>SOLOSTAR              | INSULIN GLULISINE SOLN PEN-INJECTOR INJ 100<br>UNIT/ML          | 2710400400D220 | Brand         |
| HUMALOG<br>MIX 50/50<br>KWIKPEN | INSULIN LISPRO PROT & LISPRO SUS PEN-INJ 100<br>UNIT/ML (50-50) | 2710408000D340 | Brand         |
| APIDRA                          | INSULIN GLULISINE INJ 100 UNIT/ML                               | 27104004002022 | Brand         |

### **Approval Criteria**

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug.

| Product Name: Apidra, Humalog Mix 50:50 |  |  |     |               |
|---|--|--|-----|---------------|
| Approval Length                         |  | 12/31/2039                                     |     |               |
| Guideline Type                          |  | Prior Authorization-All plans except IL and MN |     |               |
| Product Generic Na<br>Name              |  | me   | GPI | Brand/Generic |

| HUMALOG<br>MIX 50/50            | INSULIN LISPRO PROTAMINE & LISPRO INJ 100<br>UNIT/ML (50-50) | 27104080001840 | Brand |
|---------------------------------|--|----------------|-------|
| APIDRA<br>SOLOSTAR              | INSULIN GLULISINE SOLN PEN-INJECTOR INJ 100<br>UNIT/ML       | 2710400400D220 | Brand |
| HUMALOG<br>MIX 50/50<br>KWIKPEN | MIX 50/50 UNIT/ML (50-50)                                    |                | Brand |
| APIDRA                          | INSULIN GLULISINE INJ 100 UNIT/ML                            | 27104004002022 | Brand |

1 - Diagnosis of diabetes mellitus

### AND

**2** - Trial and failure, contraindication or intolerance to use of insulin aspart (Novolog, Novolog Mix) including dose adjustments

| Date      | Notes       |
|-----------|-------------|
| 10/9/2023 | New Program |

| Nonsteroidal Anti-inflammatory (NSAID) Combinatio |  |  |  |
|---|--|--|--|
| •   | Polandings and religion. The he will be small usually allow the late he has been discussed as reads. |  |  |

| Guideline ID          | GL-131404   |  |
|-----------------------|---|--|
| <b>Guideline Name</b> | Nonsteroidal Anti-inflammatory (NSAID) Combinations |  |
| Formulary             | Quartz  |  |

# Guideline Note:

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

## 1. Criteria

| Product Name: Generic Ibuprofen/famotidine, Naproxen/esomeprazole |  |  |
|---|--|--|
| Approval Length   | 12 month(s)                              |  |
| Therapy Stage   | Initial Authorization                    |  |
| Guideline Type  | Prior Authorization-IL and MN Plans Only |  |

| Product Name                       | Generic Name  | GPI            | Brand/Generic |
|------------------------------------|---|----------------|---------------|
| IBUPROFEN/FAMOTIDINE               | IBUPROFEN-FAMOTIDINE TAB 800-<br>26.6 MG            | 66109902320340 | Generic       |
| NAPROXEN/ESOMEPRAZOLE<br>MAGNESIUM | NAPROXEN-ESOMEPRAZOLE<br>MAGNESIUM TAB DR 375-20 MG | 66109902440620 | Generic       |
| NAPROXEN/ESOMEPRAZOLE<br>MAGNESIUM | NAPROXEN-ESOMEPRAZOLE<br>MAGNESIUM TAB DR 500-20 MG | 66109902440640 | Generic       |

## **Approval Criteria**

**1** - Diagnosis of osteoarthritis, rheumatoid arthritis, or other pain-related condition requiring chronic NSAID use

#### **AND**

2 - Diagnosis of current or past gastric ulcer

#### **AND**

**3** - Trial and failure after an adequate trial of the equivalent NSAID and histamine blocker or proton pump inhibitor as separate products

#### **AND**

**4** - Prescriber supplies published literature to support the requested combination product will produce different clinical results than using the equivalent agents as separate products

#### OR

- 5 For Minnesota Plans Only
- **5.1** Diagnosis of stage four metastatic cancer and the requested drug is being used to treat cancer-related pain

| Product Name: Generic Ibuprofen/famotidine, Naproxen/esomeprazole |  |   |                |               |
|---|--|---|----------------|---------------|
| Approval Length   | 12                                       | 12 month(s)   |                |               |
| Therapy Stage   | Rea                                      | Reauthorization                                     |                |               |
| Guideline Type  | Prior Authorization-IL and MN Plans Only |   |                |               |
| Product Name  |  | Generic Name  | GPI            | Brand/Generic |
| IBUPROFEN/FAMOTIDINE  |  | IBUPROFEN-FAMOTIDINE TAB 800-<br>26.6 MG            | 66109902320340 | Generic       |
| NAPROXEN/ESOMEPRAZOLE<br>MAGNESIUM                                |  | NAPROXEN-ESOMEPRAZOLE<br>MAGNESIUM TAB DR 375-20 MG | 66109902440620 | Generic       |
| NAPROXEN/ESOMEPRAZOLE<br>MAGNESIUM                                |  | NAPROXEN-ESOMEPRAZOLE<br>MAGNESIUM TAB DR 500-20 MG | 66109902440640 | Generic       |

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug.

| Notes | *Members new to the plan (as evidenced by coverage effective date of       |
|-------|--|
|       | less than or equal to 90 days) must meet the initial criteria for coverage |

| Product Name: Generic Ibuprofen/famotidine, Naproxen/esomeprazole |  |
|---|--|
| Approval Length 12/31/2039  |  |
| Guideline Type  | Prior Authorization-All plans except IL and MN |

| Product Name                       | Generic Name  | GPI            | Brand/Generic |
|------------------------------------|---|----------------|---------------|
| IBUPROFEN/FAMOTIDINE               | IBUPROFEN-FAMOTIDINE TAB 800-<br>26.6 MG            | 66109902320340 | Generic       |
| NAPROXEN/ESOMEPRAZOLE<br>MAGNESIUM | NAPROXEN-ESOMEPRAZOLE<br>MAGNESIUM TAB DR 375-20 MG | 66109902440620 | Generic       |
| NAPROXEN/ESOMEPRAZOLE<br>MAGNESIUM | NAPROXEN-ESOMEPRAZOLE<br>MAGNESIUM TAB DR 500-20 MG | 66109902440640 | Generic       |

## **Approval Criteria**

**1** - Diagnosis of osteoarthritis, rheumatoid arthritis, or other pain-related condition requiring chronic NSAID use

#### **AND**

2 - Diagnosis of current or past gastric ulcer

### **AND**

**3** - Trial and failure after an adequate trial of the equivalent NSAID and histamine blocker or proton pump inhibitor as separate products

#### AND

**4** - Prescriber supplies published literature to support the requested combination product will produce different clinical results than using the equivalent agents as separate products

## 2. Revision History

| Date       | Notes       |
|------------|-------------|
| 10/27/2023 | New program |

| Northera (droxidopa)   |  |  |  |  |  |
|--|--|--|--|--|--|
| The State of the S |  |  |  |  |  |
|  |  |  |  |  |  |

## **Prior Authorization Guideline**

| Guideline ID          | GL-129157            |  |
|-----------------------|----------------------|--|
| <b>Guideline Name</b> | Northera (droxidopa) |  |
| Formulary             | Quartz               |  |

## **Guideline Note:**

| Effective Date: | 1/1/2023 |
|-----------------|----------|
|-----------------|----------|

## 1. Criteria

| Product Name: Generic Droxidopa*                                      |  |
|---|--|
| Approval Length See note*   |  |
| Therapy Stage Initial Authorization                                   |  |
| Guideline Type Prior Authorization - All Plans except IL and MN Plans |  |

| Product<br>Name | Generic Name         | GPI            | Brand/Generic |
|-----------------|----------------------|----------------|---------------|
| DROXIDOPA       | DROXIDOPA CAP 100 MG | 38700030000130 | Generic       |
| DROXIDOPA       | DROXIDOPA CAP 200 MG | 38700030000140 | Generic       |
| DROXIDOPA       | DROXIDOPA CAP 300 MG | 38700030000150 | Generic       |

## **Approval Criteria**

**1** - Diagnosis of symptomatic neurogenic orthostatic hypotension caused by primary autonomic failure (Parkinson's disease, multiple system atrophy, and pure autonomic failure), dopamine beta-hydroxylase deficiency, or nondiabetic autonomic neuropathy

#### **AND**

2 - Prescribed by, or in consultation with, a Neurologist

### **AND**

3 - Trial and failure, contraindication, or intolerance to both midodrine and fludrocortisone

| Notes | * 2 months with partial fill |
|-------|------------------------------|
|       | (max 15 days/prescription)   |

| Product Name: Generic Droxidopa                                       |  |
|---|--|
| Approval Length 12/31/2039  |  |
| Therapy Stage Reauthorization   |  |
| Guideline Type Prior Authorization - All Plans except IL and MN Plans |  |

| Product<br>Name | Generic Name         | GPI            | Brand/Generic |
|-----------------|----------------------|----------------|---------------|
| DROXIDOPA       | DROXIDOPA CAP 100 MG | 38700030000130 | Generic       |
| DROXIDOPA       | DROXIDOPA CAP 200 MG | 38700030000140 | Generic       |
| DROXIDOPA       | DROXIDOPA CAP 300 MG | 38700030000150 | Generic       |

## **Approval Criteria**

**1** - Prescriber provides clinical documentation from the previous two months of demonstrated ongoing beneficial response to therapy.

| Product Name: Generic Droxidopa     |                                       |  |  |
|-------------------------------------|---------------------------------------|--|--|
| Approval Length                     | proval Length 12 month(s)             |  |  |
| Therapy Stage Initial Authorization |                                       |  |  |
| Guideline Type                      | Prior Authorization - IL and MN Plans |  |  |

| Product<br>Name | Generic Name         | GPI            | Brand/Generic |
|-----------------|----------------------|----------------|---------------|
| DROXIDOPA       | DROXIDOPA CAP 100 MG | 38700030000130 | Generic       |
| DROXIDOPA       | DROXIDOPA CAP 200 MG | 38700030000140 | Generic       |
| DROXIDOPA       | DROXIDOPA CAP 300 MG | 38700030000150 | Generic       |

**1** - Diagnosis of symptomatic neurogenic orthostatic hypotension caused by primary autonomic failure (Parkinson's disease, multiple system atrophy, and pure autonomic failure), dopamine beta-hydroxylase deficiency, or nondiabetic autonomic neuropathy

#### **AND**

2 - Prescribed by, or in consultation with, a Neurologist

#### **AND**

3 - Trial and failure, contraindication, or intolerance to both midodrine and fludrocortisone

| Product Name: Generic Droxidopa                      |                           |  |  |
|--|---------------------------|--|--|
| Approval Length                                      | oproval Length 12/31/2039 |  |  |
| Therapy Stage  | Reauthorization           |  |  |
| Guideline Type Prior Authorization - IL and MN Plans |                           |  |  |

| Product<br>Name | Generic Name         | GPI            | Brand/Generic |
|-----------------|----------------------|----------------|---------------|
| DROXIDOPA       | DROXIDOPA CAP 100 MG | 38700030000130 | Generic       |
| DROXIDOPA       | DROXIDOPA CAP 200 MG | 38700030000140 | Generic       |
| DROXIDOPA       | DROXIDOPA CAP 300 MG | 38700030000150 | Generic       |

## **Approval Criteria**

**1** - Prescriber provides clinical documentation from the previous twelve months of demonstrated ongoing beneficial response to therapy.

## 2. Revision History

| Date      | Notes       |
|-----------|-------------|
| 9/20/2023 | New Program |

| Nucala (mepolizumab)   |
|--|
| The interest and interest to the last the second course a search delicated provide contribution of the con |

## **Prior Authorization Guideline**

| Guideline ID          | GL-137266            |
|-----------------------|----------------------|
| <b>Guideline Name</b> | Nucala (mepolizumab) |
| Formulary             | Quartz               |

## **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

## Note:

\*\*\*Member new to the plan (as evidenced by coverage effective date of less than or equal to 90 days) who initiated therapy using a manufacturer-sponsored free drug program, provider samples, and/or vouchers will go through initial criteria, otherwise for continuation of therapy for new to plan, reauthorization criteria applies

## 1. Criteria

| Product Name: Nucala             |  |  |                |               |
|----------------------------------|--|--|----------------|---------------|
| Diagnosis                        |  | Eosinophilic Asthma                                    |                |               |
| Approval Length 12/31/2039       |  | 12/31/2039   |                |               |
| Guideline Type                   |  | Prior Authorization - ALL Plans Except IL and MN Plans |                |               |
| Product<br>Name                  |  |  | GPI            | Brand/Generic |
| NUCALA MEPOLIZUM,<br>INJECTOR 10 |  | AB SUBCUTANEOUS SOLUTION AUTO-<br>00 MG/ML             | 4460405500D530 | Brand         |

| NUCALA | MEPOLIZUMAB SUBCUTANEOUS SOLUTION PREF<br>SYRINGE 40 MG/0.4ML | 4460405500E520 | Brand |
|--------|---|----------------|-------|
| NUCALA | MEPOLIZUMAB SUBCUTANEOUS SOLUTION PREF<br>SYRINGE 100 MG/ML   | 4460405500E530 | Brand |

| 1 | _ | Medication   | must he  | self_adn  | ninistered     |
|---|---|--------------|----------|-----------|----------------|
|   | - | ivieuication | HIUSL DE | Sell-auli | III II SICI CU |

AND

2 - Diagnosis of eosinophilic asthma

**AND** 

**3** - Submission of medical records (e.g., chart notes) documenting that the blood eosinophil count is greater than or equal to 150 cells/mm3

#### AND

**4** - Other causes of eosinophilia such as hypereosinophilic syndromes, neoplastic disease, or parasitic disease have been ruled out

## **AND**

- **5** One of the following:
- **5.1** Symptoms are not well controlled or poorly controlled (Table 1) despite adherence\* to a greater than or equal to a 3-month trial of medium to high-dose inhaled corticosteroids in combination with a long-acting bronchodilator, long-acting muscarinic antagonist, or leukotriene modifier

#### OR

**5.2** Member has an intolerance to medium to high dose inhaled corticosteroids in combination with a long-acting bronchodilator or leukotriene modifier. Exceptions based on adverse effects from medium to high dose ICS or comorbid conditions increasing long-term risks of adverse

effects from high dose ICS or oral corticosteroids include one of the following:

- Cataracts in members older than 40 years of age
- Glaucoma
- Recurrent thrush
- Dysphonia
- Growth inhibition, after consultation with an endocrinologist
- Diagnosis of osteoporosis, whose treatment is resistant to FDA approved osteoporosis treatment

#### AND

**6** - Member is 6 years of age or older

### **AND**

**7** - Prescribed by or in consultation with an asthma specialist (i.e., allergist, immunologist, pulmonologist)

| Notes *Adherence to treatment is defined as a medication possession ratio (   |
|---|
| MPR) greater than or equal to 70%, based on the previous 120 days of prescription claims  **IL-5 inhibitor drugs in combination with omalizumab will be considered on a case-by-case basis if each individual agent with combination high dose ICS/LABA did not control symptoms. Tezepelumab, in combination with other biologics, has not been studied and coverage is not allowed except in xtenuating circumstances (applies to both eosinophilic or non-eosinophilic asthma populations) |

| Product Name: Nucala          |                                       |
|-------------------------------|---------------------------------------|
| Diagnosis Eosinophilic Asthma |                                       |
| Approval Length               | 12 month(s)                           |
| Therapy Stage                 | Initial Authorization                 |
| Guideline Type                | Prior Authorization - IL and MN Plans |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| NUCALA          | MEPOLIZUMAB SUBCUTANEOUS SOLUTION AUTO-<br>INJECTOR 100 MG/ML | 4460405500D530 | Brand         |
| NUCALA          | MEPOLIZUMAB SUBCUTANEOUS SOLUTION PREF<br>SYRINGE 40 MG/0.4ML | 4460405500E520 | Brand         |

| NUCALA | MEPOLIZUMAB SUBCUTANEOUS SOLUTION PREF<br>SYRINGE 100 MG/ML | 4460405500E530 | Brand |
|--------|---|----------------|-------|
|        |   |                |       |

1 - Medication must be self-administered

AND

2 - Diagnosis of eosinophilic asthma

**AND** 

**3** - Submission of medical records (e.g., chart notes) documenting that the blood eosinophil count is greater than or equal to 150 cells/mm3

AND

**4** - Other causes of eosinophilia such as hypereosinophilic syndromes, neoplastic disease, or parasitic disease have been ruled out

AND

- 5 One of the following:
- **5.1** Symptoms are not well controlled or poorly controlled (Table 1) despite adherence\* to a greater than or equal to a 3-month trial of medium to high-dose inhaled corticosteroids in combination with a long-acting bronchodilator, long-acting muscarinic antagonist, or leukotriene modifier

OR

**5.2** Member has an intolerance to medium to high dose inhaled corticosteroids in combination with a long-acting bronchodilator or leukotriene modifier. Exceptions based on adverse effects from medium to high dose ICS or comorbid conditions increasing long-term risks of adverse effects from high dose ICS or oral corticosteroids include one of the following:

- Cataracts in members older than 40 years of age
- Glaucoma
- Recurrent thrush
- Dysphonia
- Growth inhibition, after consultation with an endocrinologist
- Diagnosis of osteoporosis, whose treatment is resistant to FDA approved osteoporosis treatment

#### **AND**

6 - Member is 6 years of age or older

### **AND**

**7** - Prescribed by or in consultation with an asthma specialist (i.e., allergist, immunologist, pulmonologist)

| Notes | *Adherence to treatment is defined as a medication possession ratio (    |
|-------|--|
|       | MPR) greater than or equal to 70%, based on the previous 120 days of     |
|       | , , ,  |
|       | prescription claims  |
|       | ** IL-5 inhibitor drugs in combination with omalizumab will be considere |
|       | d on a case-by-case basis if each individual                             |
|       | agent with combination high dose ICS/LABA did not control symptoms.      |
|       | Tezepelumab, in combination with other                                   |
|       |  |
|       | biologics, has not been studied and coverage is not allowed except in e  |
|       | xtenuating circumstances (applies to both                                |
|       | eosinophilic or non-eosinophilic asthma populations)                     |
|       | eosinophilic of flori-eosinophilic astrilla populations)                 |

| Product Name: Nucala          |                                       |
|-------------------------------|---------------------------------------|
| Diagnosis Eosinophilic Asthma |                                       |
| Approval Length               | 12 month(s)                           |
| Therapy Stage                 | Reauthorization                       |
| Guideline Type                | Prior Authorization - IL and MN Plans |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| NUCALA          | MEPOLIZUMAB SUBCUTANEOUS SOLUTION AUTO-<br>INJECTOR 100 MG/ML | 4460405500D530 | Brand         |
| NUCALA          | MEPOLIZUMAB SUBCUTANEOUS SOLUTION PREF<br>SYRINGE 40 MG/0.4ML | 4460405500E520 | Brand         |

| NUCALA | MEPOLIZUMAB SUBCUTANEOUS SOLUTION PREF<br>SYRINGE 100 MG/ML | 4460405500E530 | Brand |
|--------|---|----------------|-------|
|--------|---|----------------|-------|

- **1** Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member has responded to therapy as evidenced by one of the following:
  - Decreased frequency of use of, or ability to lower the chronic daily dose, of oral corticosteroids to treat/prevent exacerbations
  - Decreased frequency of use of unscheduled emergency department/urgent care visits for exacerbations
  - Reduction in reported symptoms such as chest tightness, coughing, shortness of breath, nocturnal awakenings, nasal congestion, obstruction, etc.
  - Sustained (at least six months) improvement in Asthma Control Test (ACT) scores

| **Continuation of case-by case-approved IgE inhibitor and IL-5 inhibitor, or tezepelumab combination therapy will only be considered if ICS/LA |
|--|
| BA therapy was also continued AND there was reduction in oral steroid dose, exacerbations, or hospitalizations                                 |

| Product Name: Nucala                                   |  |
|--|--|
| Diagnosis Eosinophilic Granulomatosis with Polyangitis |  |
| Approval Length 12/31/2039                             |  |
| Guideline Type   | Prior Authorization - ALL Plans Except IL and MN Plans |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| NUCALA          | MEPOLIZUMAB SUBCUTANEOUS SOLUTION AUTO-<br>INJECTOR 100 MG/ML | 4460405500D530 | Brand         |
| NUCALA          | MEPOLIZUMAB SUBCUTANEOUS SOLUTION PREF<br>SYRINGE 40 MG/0.4ML | 4460405500E520 | Brand         |
| NUCALA          | MEPOLIZUMAB SUBCUTANEOUS SOLUTION PREF<br>SYRINGE 100 MG/ML   | 4460405500E530 | Brand         |

## **Approval Criteria**

1 - Medication must be self-administered

| AND  |
|--|
| 2 - Diagnosis of eosinophilic granulomatosis with polyangitis  |
| AND  |
|  |
| 3 - Disease is one of the following:   |
| <ul><li>Relapsed</li><li>Refractory</li></ul>  |
| AND  |
|  |
| 4 - All of the following:  |
| <b>4.1</b> Blood eosinophil level greater than or equal to 10% or an absolute eosinophil count greater than 1000 cells/µL with other causes ruled out (i.e. hypereosinophilic syndromes, neoplastic disease, or parasitic disease) |
| AND  |
| <b>4.2</b> At least TWO of the following organ systems or features of EGPA disease:  |
| 4.2.1 Histopathological evidence of one of the following:  |
| eosinophilic vasculitis (i.e. bleeding under skin, red rash, petechiae, fibrinoid degeneration, bleed elete)   |
| degeneration, blood clots)  • perivascular eosinophilic infiltration (i.e. inflammatory cells around blood vessels,  |
| lichenoid infiltration)  • eosinophil-rich granulomatosis inflammation (i.e. nodules, thick aggregation of histiocytes)  |
|  |
| OR   |
| 4.2.2 Neuropathy (i.e. mono or polyneuropathy, mononeuritis multiplex)   |
| OR   |
|  |

| <b>4.2.3</b> Pulmonary infiltrates (i.e. asthma, chronic pneumonia, hemoptysis, cough)        |
|---|
| OR  |
| 4.2.4 Sino-nasal abnormality (i.e. sinusitis, allergic rhinitis, polyposis)                   |
| OR  |
| 4.2.5 Cardiomyopathy (i.e. heart failure, myocarditis, pericarditis, subendocardial fibrosis) |
| OR  |
| 4.2.6 Glomerulonephritis (i.e. hematuria, red cell casts, proteinuria)                        |
| OR  |
| 4.2.7 Alveolar hemorrhage (by bronchoalveolar lavage)   |
| OR  |
| 4.2.8 Palpable purpura (i.e. skin nodules, urticarial rash, digital ischemia)                 |
| OR  |
| 4.2.9 Positive antineutrophil cytoplasmic antibody [ANCA]                                     |
| AND   |
| 5 - Member is 18 years of age or older  |
| AND   |
|   |

- **6** Trial and failure, intolerance, or contraindication to an adequate 3-month trial of both of the following:
  - prednisone
  - At least ONE additional immunosuppressive agent (i.e. cyclophosphamide, azathioprine, or methotrexate)

#### **AND**

**7** - Submission of medical records (e.g., chart notes) documenting baseline disease severity assessment with an objective measure/tool (i.e. chronic oral corticosteroid dose, number of intermittent steroid bursts, Birmingham Vasculitis Activity Score BVAS, number urgent care, emergency room visits or hospitalizations etc.)

#### AND

**8** - Prescribed by, or in consultation with, a provider experienced in the treatment EGPA (i.e. Allergist, Pulmonologist, or Rheumatologist)

| Product Name: Nucala |  |  |
|----------------------|--|--|
| Diagnosis            | Eosinophilic Granulomatosis with Polyangitis |  |
| Approval Length      | 12 month(s)                                  |  |
| Therapy Stage        | Initial Authorization                        |  |
| Guideline Type       | Prior Authorization - IL and MN Plans        |  |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| NUCALA          | MEPOLIZUMAB SUBCUTANEOUS SOLUTION AUTO-<br>INJECTOR 100 MG/ML | 4460405500D530 | Brand         |
| NUCALA          | MEPOLIZUMAB SUBCUTANEOUS SOLUTION PREF<br>SYRINGE 40 MG/0.4ML | 4460405500E520 | Brand         |
| NUCALA          | MEPOLIZUMAB SUBCUTANEOUS SOLUTION PREF<br>SYRINGE 100 MG/ML   | 4460405500E530 | Brand         |

## **Approval Criteria**

1 - Medication must be self-administered

| AND  |  |  |  |  |
|--|--|--|--|--|
| 2 - Diagnosis of eosinophilic granulomatosis with polyangitis  |  |  |  |  |
| AND  |  |  |  |  |
| 3 - Disease is one of the following:   |  |  |  |  |
| <ul><li>Relapsed</li><li>Refractory</li></ul>  |  |  |  |  |
| AND  |  |  |  |  |
| 4 - All of the following:  |  |  |  |  |
| <b>4.1</b> Blood eosinophil level greater than or equal to 10% or an absolute eosinophil count greater than 1000 cells/μL with other causes ruled out (i.e. hypereosinophilic syndromes, neoplastic disease, or parasitic disease) |  |  |  |  |
| AND  |  |  |  |  |
| <b>4.2</b> At least TWO of the following organ systems or features of EGPA disease:  |  |  |  |  |
| 4.2.1 Histopathological evidence of one of the following:  |  |  |  |  |
| <ul> <li>eosinophilic vasculitis (i.e. bleeding under skin, red rash, petechiae, fibrinoid degeneration, blood clots)</li> </ul>   |  |  |  |  |
| <ul> <li>perivascular eosinophilic infiltration (i.e. inflammatory cells around blood vessels, lichenoid infiltration)</li> </ul>  |  |  |  |  |
| <ul> <li>eosinophil-rich granulomatosis inflammation (i.e. nodules, thick aggregation of histiocytes)</li> </ul>   |  |  |  |  |
| OR   |  |  |  |  |
|  |  |  |  |  |
| 4.2.2 Neuropathy (i.e. mono or polyneuropathy, mononeuritis multiplex)   |  |  |  |  |
| OR   |  |  |  |  |
|  |  |  |  |  |

| <b>4.2.3</b> Pulmonary infiltrates (i.e. asthma, chronic pneumonia, hemoptysis, cough)        |
|---|
| OR  |
| 4.2.4 Sino-nasal abnormality (i.e. sinusitis, allergic rhinitis, polyposis)                   |
| OR  |
| 4.2.5 Cardiomyopathy (i.e. heart failure, myocarditis, pericarditis, subendocardial fibrosis) |
| OR  |
| 4.2.6 Glomerulonephritis (i.e. hematuria, red cell casts, proteinuria)                        |
| OR  |
| 4.2.7 Alveolar hemorrhage (by bronchoalveolar lavage)   |
| OR  |
| 4.2.8 Palpable purpura (i.e. skin nodules, urticarial rash, digital ischemia)                 |
| OR  |
| 4.2.9 Positive antineutrophil cytoplasmic antibody [ANCA]                                     |
| AND   |
| 5 - Member is 18 years of age or older  |
| AND   |
|   |

- **6** Trial and failure, intolerance, or contraindication to an adequate 3-month trial of both of the following:
  - prednisone
  - At least ONE additional immunosuppressive agent (i.e. cyclophosphamide, azathioprine, or methotrexate)

#### **AND**

**7** - Submission of medical records (e.g., chart notes) documenting baseline disease severity assessment with an objective measure/tool (i.e. chronic oral corticosteroid dose, number of intermittent steroid bursts, Birmingham Vasculitis Activity Score BVAS, number urgent care, emergency room visits or hospitalizations etc.)

#### AND

**8** - Prescribed by, or in consultation with, a provider experienced in the treatment EGPA (i.e. Allergist, Pulmonologist, or Rheumatologist)

| Product Name: Nucala |  |  |
|----------------------|--|--|
| Diagnosis            | Eosinophilic Granulomatosis with Polyangitis |  |
| Approval Length      | 12 month(s)                                  |  |
| Therapy Stage        | Reauthorization                              |  |
| Guideline Type       | Prior Authorization - IL and MN Plans        |  |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| NUCALA          | MEPOLIZUMAB SUBCUTANEOUS SOLUTION AUTO-<br>INJECTOR 100 MG/ML | 4460405500D530 | Brand         |
| NUCALA          | MEPOLIZUMAB SUBCUTANEOUS SOLUTION PREF<br>SYRINGE 40 MG/0.4ML | 4460405500E520 | Brand         |
| NUCALA          | MEPOLIZUMAB SUBCUTANEOUS SOLUTION PREF<br>SYRINGE 100 MG/ML   | 4460405500E530 | Brand         |

### **Approval Criteria**

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is showing a response to therapy based upon at least ONE of the following objective measures:

**1.1** Birmingham Vasculitis Activity Score (BVAS version 3) improvement from baseline (i.e. a clinically significant score improvement for vasculitis is 16 units or greater)

OR

**1.2** Reduction in the total daily dose of prednisolone/prednisone (50-75% reduction in dose from baseline) or reduction in intermittent steroid bursts

OR

**1.3** Improvement in the duration of remission or improvement in rate of relapses, urgent care, emergency room visits or hospitalizations

| Product Name: Nucala |  |
|----------------------|--|
| Diagnosis            | Hypereosinophilic Syndrome                             |
| Approval Length      | 12/31/2039   |
| Guideline Type       | Prior Authorization - All Plans Except IL and MN Plans |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| NUCALA          | MEPOLIZUMAB SUBCUTANEOUS SOLUTION AUTO-<br>INJECTOR 100 MG/ML | 4460405500D530 | Brand         |
| NUCALA          | MEPOLIZUMAB SUBCUTANEOUS SOLUTION PREF<br>SYRINGE 40 MG/0.4ML | 4460405500E520 | Brand         |
| NUCALA          | MEPOLIZUMAB SUBCUTANEOUS SOLUTION PREF<br>SYRINGE 100 MG/ML   | 4460405500E530 | Brand         |

## **Approval Criteria**

1 - Medication must be self-administered

#### AND

**2** - Diagnosis of hypereosinophilic syndrome for greater than or equal to 6 months without an identifiable non-hematologic secondary cause (i.e. cancer, imatinib-sensitive conditions, etc.)

### AND

3 - Blood eosinophil count of greater than or equal to 1,000 cells/mc on at least two occasions

#### **AND**

**4** - Trial and failure, contraindication, or intolerance to the use of at least one steroid-sparing preventive treatments for at least 4 weeks (e.g., hydroxyurea, interferon-alfa, cyclosporine, etc.)

### **AND**

- **5** Prescribed by or in consultation with one of the following:
  - hematologist
  - allergist
  - other specialist in the treatment of Hypereosinophilic Syndrome

| Product Name: Nucala |                                       |
|----------------------|---------------------------------------|
| Diagnosis            | Hypereosinophilic Syndrome            |
| Approval Length      | 12 month(s)                           |
| Therapy Stage        | Initial Authorization                 |
| Guideline Type       | Prior Authorization - IL and MN Plans |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| NUCALA          | MEPOLIZUMAB SUBCUTANEOUS SOLUTION AUTO-<br>INJECTOR 100 MG/ML | 4460405500D530 | Brand         |
| NUCALA          | MEPOLIZUMAB SUBCUTANEOUS SOLUTION PREF<br>SYRINGE 40 MG/0.4ML | 4460405500E520 | Brand         |
| NUCALA          | MEPOLIZUMAB SUBCUTANEOUS SOLUTION PREF<br>SYRINGE 100 MG/ML   | 4460405500E530 | Brand         |

## **Approval Criteria**

1 - Medication must be self-administered

#### AND

**2** - Diagnosis of hypereosinophilic syndrome for greater than or equal to 6 months without an identifiable non-hematologic secondary cause (i.e. cancer, imatinib-sensitive conditions, etc.)

#### AND

3 - Blood eosinophil count of greater than or equal to 1,000 cells/mc on at least two occasions

#### **AND**

**4** - Trial and failure, contraindication, or intolerance to the use of at least one steroid-sparing preventive treatments for at least 4 weeks (e.g., hydroxyurea, interferon-alfa, cyclosporine, etc.)

#### AND

- **5** Prescribed by or in consultation with one of the following:
  - hematologist
  - allergist
  - other specialist in the treatment of Hypereosinophilic Syndrome

| Product Name: Nucala |                                       |  |
|----------------------|---------------------------------------|--|
| Diagnosis            | Hypereosinophilic Syndrome            |  |
| Approval Length      | 12 month(s)                           |  |
| Therapy Stage        | Reauthorization                       |  |
| Guideline Type       | Prior Authorization - IL and MN Plans |  |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| NUCALA          | MEPOLIZUMAB SUBCUTANEOUS SOLUTION AUTO-<br>INJECTOR 100 MG/ML | 4460405500D530 | Brand         |
| NUCALA          | MEPOLIZUMAB SUBCUTANEOUS SOLUTION PREF<br>SYRINGE 40 MG/0.4ML | 4460405500E520 | Brand         |
| NUCALA          | MEPOLIZUMAB SUBCUTANEOUS SOLUTION PREF<br>SYRINGE 100 MG/ML   | 4460405500E530 | Brand         |

**1** - Submission of medical records (e.g., chart notes) documenting the member's response to therapy within the past 12 months including individual improvements in functional status

| ** Continuation of case-by case-approved IgE inhibitor and IL-5 inhibitor, or tezepelumab combination therapy will only be considered if ICS/L |
|--|
| ABA therapy was also continued AND there was reduction in oral steroid dose, exacerbations, or hospitalizations                                |

| Product Name: Nucala  |              |  |
|---|--------------|--|
| Diagnosis   | Nasal Polyps |  |
| Approval Length   | 12/31/2039   |  |
| Guideline Type Prior Authorization - All Plans Except IL and MN Plans |              |  |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| NUCALA          | MEPOLIZUMAB SUBCUTANEOUS SOLUTION AUTO-<br>INJECTOR 100 MG/ML | 4460405500D530 | Brand         |
| NUCALA          | MEPOLIZUMAB SUBCUTANEOUS SOLUTION PREF<br>SYRINGE 40 MG/0.4ML | 4460405500E520 | Brand         |
| NUCALA          | MEPOLIZUMAB SUBCUTANEOUS SOLUTION PREF<br>SYRINGE 100 MG/ML   | 4460405500E530 | Brand         |

## **Approval Criteria**

1 - Medication must be self-administered

#### **AND**

- 2 Diagnosis of chronic rhinosinusitis with nasal polyposis including all of the following:
  - At least eight weeks of moderate to severe nasal congestion/blockage/obstruction OR diminished sense of smell or rhinorrhea
  - Submission of medical records (e.g., chart notes) documenting nasal polyps by direct exam, endoscopy, or sinus CT scan (i.e. nasal polyp score five out of eight)
  - No chronic or acute infection requiring systemic treatment within two weeks before therapy initiation

#### AND

- 3 One of the following:
  - Trial and failure, contraindication, or intolerance to oral corticosteroids for nasal polyps
  - Prior to surgery for nasal polyps greater than six months ago
  - Trial and failure, contraindication, or intolerance to 2 or more nasal steroid sprays (i.e. failed two nasal sprays)
  - Trial and failure, contraindication, or intolerance to IM injections for polyps with one previous nasal spray

#### **AND**

4 - Will be used in combination with a nasal corticosteroid medication

#### **AND**

**5** - Will not be used in combination with other biologics (e.g., dupilumab, omalizumab, benralizumab, or reslizumab)

#### **AND**

**6** - Prescribed by, or in consultation with a specialist experienced in the treatment of nasal polyps (i.e., otolaryngologist, allergist)

| Product Name: Nucala |                                       |  |
|----------------------|---------------------------------------|--|
| Diagnosis            | Nasal Polyps                          |  |
| Approval Length      | 12 month(s)                           |  |
| Therapy Stage        | Initial Authorization                 |  |
| Guideline Type       | Prior Authorization - IL and MN Plans |  |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| NUCALA          | MEPOLIZUMAB SUBCUTANEOUS SOLUTION AUTO-<br>INJECTOR 100 MG/ML | 4460405500D530 | Brand         |
| NUCALA          | MEPOLIZUMAB SUBCUTANEOUS SOLUTION PREF<br>SYRINGE 40 MG/0.4ML | 4460405500E520 | Brand         |
| NUCALA          | MEPOLIZUMAB SUBCUTANEOUS SOLUTION PREF                        | 4460405500E530 | Brand         |

|                   | SYRINGE 100 MG/ML  |                       |           |
|-------------------|--|-----------------------|-----------|
|                   |  |                       |           |
| Approv            | al Criteria  |                       |           |
| <b>1</b> - Medi   | ication must be self-administered  |                       |           |
|                   | AND  |                       |           |
| <b>2</b> - Diag   | nosis of chronic rhinosinusitis with nasal polyposis in  | cluding all of the fo | ollowing: |
| • \$              | diminished sense of smell or rhinorrhea  • Submission of medical records (e.g., chart notes) documenting nasal polyps by direct exam, endoscopy, or sinus CT scan (i.e. nasal polyp score five out of eight)   |                       |           |
|                   | AND  |                       |           |
| <b>3</b> - One    | of the following:  |                       |           |
| • F               | <ul> <li>Trial and failure, contraindication, or intolerance to oral corticosteroids for nasal polyps</li> <li>Prior to surgery for nasal polyps greater than six months ago</li> <li>Trial and failure, contraindication, or intolerance to 2 or more nasal steroid sprays (i.e. failed two nasal sprays)</li> <li>Trial and failure, contraindication, or intolerance to IM injections for polyps with one previous nasal spray</li> </ul> |                       |           |
|                   | AND  |                       |           |
| <b>4</b> - Will I | pe used in combination with a nasal corticosteroid me  | edication             |           |
|                   | AND  |                       |           |

**5** - Will not be used in combination with other biologics (e.g., dupilumab, omalizumab, benralizumab, or reslizumab)

## **AND**

| <b>6</b> - Prescribed by, or in consultation with a specialist experienced in the treatment of nasal polyps (i.e., otolaryngologist, allergist) |  |  |  |
|---|--|--|--|
| Notes   | **Continuation of case-by case-approved IgE inhibitor and IL-5 inhibitor , or tezepelumab combination therapy will only be considered if ICS/LA BA therapy was also continued AND there was reduction in oral steroid dose, exacerbations, or hospitalizations |  |  |

| Product Name: Nucala                                 |                 |  |
|--|-----------------|--|
| Diagnosis Nasal Polyps                               |                 |  |
| Approval Length                                      | 12 month(s)     |  |
| Therapy Stage  | Reauthorization |  |
| Guideline Type Prior Authorization - IL and MN Plans |                 |  |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| NUCALA          | MEPOLIZUMAB SUBCUTANEOUS SOLUTION AUTO-<br>INJECTOR 100 MG/ML | 4460405500D530 | Brand         |
| NUCALA          | MEPOLIZUMAB SUBCUTANEOUS SOLUTION PREF<br>SYRINGE 40 MG/0.4ML | 4460405500E520 | Brand         |
| NUCALA          | MEPOLIZUMAB SUBCUTANEOUS SOLUTION PREF<br>SYRINGE 100 MG/ML   | 4460405500E530 | Brand         |

**1** - Submission of medical records (e.g., chart notes), documenting the member's response to therapy within the past 12 months including individual improvements in functional status

## 2. Background

| Benefit/Coverage/Program Information                     |                          |                            |  |  |
|--|--------------------------|----------------------------|--|--|
| TABLE 1 - Outcome Measure values for uncontrolled asthma |                          |                            |  |  |
| Measure  | Not Well Controlled      | Very Poorly Controlled     |  |  |
| Baseline symptoms (outside of exacerbation)              | Greater than 2 days/week | Throughout the day         |  |  |
| Nighttime awakening                                      | 1-3 times/week           | Greater than or equal to 4 |  |  |

|  |                                   | times/week                               |
|--|-----------------------------------|--|
| Interference with normal activity  | Some limitation                   | Extremely limited                        |
| Short acting beta agonist use for symptom control  | Greater than 2 days/week          | Several times per day                    |
| FEV1   | 60-80% predicted or personal best | Less than 60% predicted or personal best |
| Asthma exacerbations requiring oral steroids greater than or equal to 2 times in the past year | Yes                               | Yes                                      |
| Asthma Control Test (ACT)  | 16 - 19                           | Less than or equal to 15                 |

## 3. Definitions

| Definition                      | Description   |
|---------------------------------|---|
| Relapsing EGPA                  | At least one confirmed EGPA relapse while the person was on prednisolone dose of greater than or equal to 7.5 mg (or equivalent) within the past 2 years that required an increase in oral corticosteroid dose, initiation/increased immunosuppressive therapy dose, or hospitalization.  |
| Refractory EGPA                 | 1) Failure to attain remission (BVAS = 0 and oral steroid dose less than or equal to 7.5 mg/day prednisolone or equivalent) within the last 6 months following induction treatment with a standard regimen (e.g., cyclophosphamide, methotrexate, azathioprine, mycophenolate, high dose steroids) administered for at least 3 months OR 2) within 6 months prior to initiation, recurrence of symptoms of EGPA while tapering oral steroids, occurring at any dose level greater than or equal to 7.5 mg/day prednisolone or equivalent. |
| Failure of an immunosuppressant | Defined as EGPA symptoms are not resolving or flare occurring with a prednisone dose change, hospitalization, OR contraindications/clinical inappropriateness to immunosuppressants (i.e., liver disease, fertility etc.).  |

# 4. Revision History

| Date      | Notes                   |
|-----------|-------------------------|
| 12/1/2023 | 2024 New Implementation |

| Nuplazid   | (Pimavanserin Tartrate)  |  |
|--|--|--|
| The list and longer current for displayed. The file may have been record | , count, or dated lenif, detail is grain his securific and harden. |  |
|  |  |  |

## **Prior Authorization Guideline**

| Guideline ID          | GL-131415                        |  |
|-----------------------|----------------------------------|--|
| <b>Guideline Name</b> | Nuplazid (Pimavanserin Tartrate) |  |
| Formulary             | Quartz                           |  |

## **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

## Note:

Member new to the plan who are being treated for Parkinson's disease psychosis and are established on therapy will have coverage under their drug benefit with documentation of symptom improvement or disease stability.

## 1. Criteria

NUPLAZID

**EQUIVALENT**)

PIMAVANSERIN TARTRATE TAB 10 MG (BASE

| Product Name: Nuplazid |                                       |  |                |               |
|------------------------|---------------------------------------|--|----------------|---------------|
| Approval Le            | ength                                 | 12 month(s)                              |                |               |
| Therapy St             | age                                   | Initial Authorization                    |                |               |
| Guideline Type         |                                       | Prior Authorization-IL and MN Plans Only |                |               |
| Product<br>Name        | Generic Name                          |  | GPI            | Brand/Generic |
| NUPLAZID               | PIMAVANSERIN TARTRATE CAP 34 MG (BASE |  | 59400028200120 | Brand         |

Brand

59400028200310

| EQUIVALENT) |  |
|-------------|--|

1 - Diagnosis of Parkinson's disease psychosis with documented hallucinations or delusions

### **AND**

2 - Drug is prescribed by, or in consultation with, a Neurologist

### **AND**

**3** - Dose reductions and alterations in scheduling of dopaminergic agents led to increased Parkinson's symptoms

| Product Name: Nuplazid                                  |                 |  |
|---|-----------------|--|
| Approval Length 12 month(s)                             |                 |  |
| Therapy Stage   | Reauthorization |  |
| Guideline Type Prior Authorization-IL and MN Plans Only |                 |  |

| Product<br>Name | Generic Name                                      | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| NUPLAZID        | PIMAVANSERIN TARTRATE CAP 34 MG (BASE EQUIVALENT) | 59400028200120 | Brand         |
| NUPLAZID        | PIMAVANSERIN TARTRATE TAB 10 MG (BASE EQUIVALENT) | 59400028200310 | Brand         |

## **Approval Criteria**

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug.

| Product Name: Nuplazid              |  |
|-------------------------------------|--|
| Approval Length 12/31/2039          |  |
| Therapy Stage Initial Authorization |  |

| Guideline Type  |   | Prior Authorization-All plans except IL and MN |                |               |
|-----------------|---|--|----------------|---------------|
| Product<br>Name | Generic Name                                      |  | GPI            | Brand/Generic |
| NUPLAZID        | PIMAVANSERIN TARTRATE CAP 34 MG (BASE EQUIVALENT) |  | 59400028200120 | Brand         |
| NUPLAZID        | PIMAVANSERIN TARTRATE TAB 10 MG (BASE EQUIVALENT) |  | 59400028200310 | Brand         |

1 - Diagnosis of Parkinson's disease psychosis with documented hallucinations or delusions

## **AND**

2 - Drug is prescribed by, or in consultation with, a Neurologist

### **AND**

**3** - Dose reductions and alterations in scheduling of dopaminergic agents led to increased Parkinson's symptoms

## 2. Revision History

| Date      | Notes       |
|-----------|-------------|
| 10/9/2023 | New program |

| Nuzyra                                    | Nuzyra (omadacycline)   |  |  |  |
|---|---|--|--|--|
| The blad ingrunned technique. The file of | my ban han manuf, warant, or differ. You find to be probe the covered and harden. |  |  |  |
|   |   |  |  |  |

## **Prior Authorization Guideline**

| Guideline ID          | GL-129176             |
|-----------------------|-----------------------|
| <b>Guideline Name</b> | Nuzyra (omadacycline) |
| Formulary             | Quartz                |

## **Guideline Note:**

| Effective Date: |
|-----------------|
|-----------------|

## 1. Criteria

| Product Name: Nuzyra |  |  |                |       |
|----------------------|--|--|----------------|-------|
| Approval Le          | ength 1 Time Approval                                      |  |                |       |
| Guideline T          | ype Prior Authorization - ALL Plans Except IL and MN Plans |  |                |       |
| Product<br>Name      | Generic Name GPI Brand                                     |  | Brand/Generic  |       |
| NUZYRA               | OMADACYCLINE TOSYLATE TAB 150 MG (BASE EQUIVALENT)         |  | 04200050200320 | Brand |

## **Approval Criteria**

- **1** One of the following:
- **1.1** Member has been receiving drug during hospitalization and needs to complete the course of therapy as an outpatient

OR

- 1.2 ALL of the following:
- **1.2.1** Submission of medical records (e.g., chart notes) documenting BOTH of the following:
  - Outpatient treatment of bacterial resistant strains
  - Report of susceptibilities resistant to preferred alternatives

#### **AND**

1.2.2 Prescribed by or in consultation with an Infectious Disease Specialist

| Product Name: Nuzyra |                                 |  |
|----------------------|---------------------------------|--|
| Approval Length      | 12 month(s)                     |  |
| Therapy Stage        | Initial Authorization           |  |
| Guideline Type       | Prior Authorization - IL Plans* |  |

| Product<br>Name | Generic Name                                       | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| NUZYRA          | OMADACYCLINE TOSYLATE TAB 150 MG (BASE EQUIVALENT) | 04200050200320 | Brand         |

## **Approval Criteria**

- **1** One of the following:
- **1.1** Member has been receiving drug during hospitalization and needs to complete the course of therapy as an outpatient

OR

- **1.2** ALL of the following:
- **1.2.1** Submission of medical records (e.g., chart notes) documenting BOTH of the following:
  - Outpatient treatment of bacterial resistant strains

• Report of susceptibilities resistant to preferred alternatives

#### **AND**

1.2.2 Prescribed by or in consultation with an Infectious Disease Specialist

### OR

**1.3** The requested FDA approved drug is being used for the long-term treatment of tick-borne disease

| *Members who are established on therapy will have coverage eir drug benefit for the remainder of the current treatment course  *Member new to the plan (as evidenced by coverage effective ess than or equal to 90 days) and were not previously approverage whose therapy was initiated using a manufacturer-spore drug program, provider samples, and/or vouchers will go the uthorization criteria |
|---|
|---|

| Product Name: Nuzyra |                                 |
|----------------------|---------------------------------|
| Approval Length      | 12 month(s)                     |
| Therapy Stage        | Reauthorization                 |
| Guideline Type       | Prior Authorization - IL Plans* |

| Product<br>Name | Generic Name                                       | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| NUZYRA          | OMADACYCLINE TOSYLATE TAB 150 MG (BASE EQUIVALENT) | 04200050200320 | Brand         |

## **Approval Criteria**

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug

#### **AND**

2 - Drug is being used for the long-term treatment of tick borne disease

| Notes | *Members who are established on therapy will have coverage under the eir drug benefit for the remainder of the current treatment course  *Member new to the plan (as evidenced by coverage effective date of I ess than or equal to 90 days) and were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers will go through real transfer or effective extension or extension. |
|-------|---|
|       | uthorization criteria   |

| Product Name: Nuzyra |  |  |                |       |
|----------------------|--|--|----------------|-------|
| Approval Le          | ength 12 month(s)  |  |                |       |
| Guideline T          | ype Prior Authorization - MN Plans*                        |  |                |       |
| Product<br>Name      | Generic Name GPI Brand/0                                   |  | Brand/Generic  |       |
| NUZYRA               | OMADACYCLINE TOSYLATE TAB 150 MG (BASE EQUIVALENT) 0420005 |  | 04200050200320 | Brand |

- **1** One of the following:
- 1.1 Member has been receiving drug during hospitalization and needs to complete the course of therapy as an outpatient

OR

- 1.2 ALL of the following:
- **1.2.1** Submission of medical records (e.g., chart notes) documenting BOTH of the following:

  - Outpatient treatment of bacterial resistant strains
    Report of susceptibilities resistant to preferred alternatives

### AND

1.2.2 Prescribed by or in consultation with an Infectious Disease Specialist

| *Members who are established on therapy will have coverage under the eir drug benefit for the remainder of the |
|--|
| current treatment course   |

## 2. Revision History

| Date      | Notes                   |
|-----------|-------------------------|
| 9/20/2023 | 2024 New Implementation |

| Ocaliva (obeticholic acid)  |  |  |  |  |
|---|--|--|--|--|
| [3] The Marketing and Stability is Table to the count, a stable and support to the count of an extension of the count of a stability process to a count of a stability. |  |  |  |  |
|   |  |  |  |  |

| Guideline ID   | GL-131406                  |
|----------------|----------------------------|
| Guideline Name | Ocaliva (obeticholic acid) |
| Formulary      | Quartz                     |

# **Guideline Note:**

| Effective Date: |
|-----------------|
|-----------------|

# 1. Criteria

| Product Name: Ocaliva |  |
|-----------------------|--|
| Approval Length       | 12 month(s)                              |
| Therapy Stage         | Initial Authorization                    |
| Guideline Type        | Prior Authorization-IL and MN Plans Only |

| Product<br>Name | Generic Name               | GPI            | Brand/Generic |
|-----------------|----------------------------|----------------|---------------|
| OCALIVA         | OBETICHOLIC ACID TAB 5 MG  | 52750060000320 | Brand         |
| OCALIVA         | OBETICHOLIC ACID TAB 10 MG | 52750060000330 | Brand         |

# **Approval Criteria**

1 - Diagnosis of primary biliary cholangitis

#### AND

**2** - Alkaline phosphatase level > 1.6 times the upper limit of normal (ULN) OR total bilirubin between 1-2 times the ULN

#### **AND**

**3** - Obeticholic acid will be used in combination with ursodeoxycholic acid (UDCA or ursodiol) OR there is trial and failure, contraindication or intolerance to ursodeoxycholic acid

#### AND

**4** - Person does not have compensated cirrhosis with portal hypertension or a history of decompensated cirrhosis

| Product Name: Ocaliva                                   |             |
|---|-------------|
| Approval Length   | 12 month(s) |
| Therapy Stage Reauthorization                           |             |
| Guideline Type Prior Authorization-IL and MN Plans Only |             |

| Product<br>Name | Generic Name               | GPI            | Brand/Generic |
|-----------------|----------------------------|----------------|---------------|
| OCALIVA         | OBETICHOLIC ACID TAB 5 MG  | 52750060000320 | Brand         |
| OCALIVA         | OBETICHOLIC ACID TAB 10 MG | 52750060000330 | Brand         |

### **Approval Criteria**

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug.

| Product Name: Ocaliva   |  |
|---|--|
| Approval Length 12/31/2039                                    |  |
| Guideline Type Prior Authorization-All plans except IL and MN |  |

| Product<br>Name | Generic Name               | GPI            | Brand/Generic |
|-----------------|----------------------------|----------------|---------------|
| OCALIVA         | OBETICHOLIC ACID TAB 5 MG  | 52750060000320 | Brand         |
| OCALIVA         | OBETICHOLIC ACID TAB 10 MG | 52750060000330 | Brand         |

1 - Diagnosis of primary biliary cholangitis

#### **AND**

**2** - Alkaline phosphatase level > 1.6 times the upper limit of normal (ULN) OR total bilirubin between 1-2 times the ULN

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**3** - Obeticholic acid will be used in combination with ursodeoxycholic acid (UDCA or ursodiol) OR there is trial and failure, contraindication or intolerance to ursodeoxycholic acid

#### **AND**

**4** - Person does not have compensated cirrhosis with portal hypertension or a history of decompensated cirrhosis

| Date      | Notes       |
|-----------|-------------|
| 10/9/2023 | New program |

| Off Label Administrative   |  |  |  |  |
|--|--|--|--|--|
| The National Action of the State of the Stat |  |  |  |  |

| Guideline ID          | GL-135255                |
|-----------------------|--------------------------|
| <b>Guideline Name</b> | Off Label Administrative |
| Formulary             | Quartz                   |

# **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

# 1. Criteria

| Product Name: A drug used for an off-label indication or non-FDA approved indication |             |     |               |
|--|-------------|-----|---------------|
| Diagnosis Off-label indication   |             |     |               |
| Approval Length  | 12 month(s) |     |               |
| Guideline Type Administrative  |             |     |               |
| Product Name Generic Name  |             | GPI | Brand/Generic |

### **Approval Criteria**

- 1 ONE of the following:
- **1.1** Diagnosis is supported as a use in American Hospital Formulary Service Drug Information (AHFS DI)

| <i>,</i> 16 | , |
|-------------|---|
| ·           |   |

**1.2** Diagnosis is supported in the FDA Uses/Non-FDA Uses section in DRUGDEX Evaluation with a Strength of Recommendation rating of IIb or better (see DRUGDEX Strength of Recommendation table in Background section)

#### OR

**1.3** Provider submits two articles from major peer reviewed medical journals that present data supporting the proposed off-label use or uses as generally safe and effective unless there is clear and convincing contradictory evidence presented in a major peer-reviewed medical journal

#### **AND**

- 2 ONE of the following:
- **2.1** Trial and failure, contraindication or intolerance to an adequate trial of all formulary and/or over the counter (OTC) alternatives

#### OR

**2.2** (Minnesota plans only) person with stage four metastatic cancer and the requested drug is being used as supportive care to treat symptoms directly related to their cancer or chemotherapy regimen

#### OR

**2.3** (Illinois Plans only) The requested FDA approved drug is being used for the long-term treatment of tick-borne disease

## 2. Background

#### **Clinical Practice Guidelines**

| Class                  | Recommendation                | Description   |
|------------------------|-------------------------------|---|
| Class I                | Recommended                   | The given test or treatment has been proven useful, and should be performed or administered.      |
| Class IIa              | Recommended, In<br>Most Cases | The given test or treatment is generally considered to be useful, and is indicated in most cases. |
| Class IIb              | Recommended, in Some Cases    | The given test or treatment may be useful, and is indicated in some, but not most, cases.         |
| Class III              | Not Recommended               | The given test or treatment is not useful, and should be avoided                                  |
| Class<br>Indeterminate | Evidence Inconclusive         |   |

| Category | Level of Consensus   |
|----------|--|
| 1        | Based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate.    |
| 2A       | Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.   |
| 2B       | Based upon lower-level evidence, there is NCCN consensus that the intervention is appropriate.           |
| 3        | Based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate. |

### NCCN Categories of Evidence and Consensus [A]

Lexi-Drugs: Strength of Recommendation for Inclusion in Lexi-Drugs for Oncology Off-Label Use and Level of Evidence Scale for Oncology Off-Label Use [5] Strength of Recommendation for Inclusion

| Strong (for proposed off-label use) | The evidence persuasively supports the off-label use (ie, Level of Evidence A). |
|-------------------------------------|---|
|                                     |   |

| Equivocal (for proposed off-label use) | may be necessary to further define the role of this medication for the off-label use.   |  |
|--|---|--|
| Against proposed off-<br>label use     | The evidence either advocates against the off-label use or suggests a lack of support for the off-label use (independent of Level of Evidence). Additional studies are necessary to define the role of this medication for the off-label use. |  |

# Level of Evidence Scale for Oncology Off-Label Use

| A | Consistent evidence from well-performed randomized, controlled trials or overwhelming evidence of some other form (eg, results of the introduction of penicillin treatment) to support off-label use. Further research is unlikely to change confidence in the estimate of benefit.   |
|---|---|
| В | Evidence from randomized, controlled trials with important limitations (eg, inconsistent results, methodologic flaws, indirect, imprecise); or very strong evidence of some other research design. Further research (if performed) is likely to have an impact on confidence in the estimate of benefit and risk and may change the estimate. |
| С | Evidence from observational studies (eg, retrospective case series/reports providing significant impact on patient care); unsystematic clinical experience; or potentially flawed randomized, controlled trials (eg, when limited options exist for condition). Any estimate of effect is uncertain.  |
| G | Use has been substantiated by inclusion in at least one evidence-based or consensus-based clinical practice guideline.  |

| Date      | Notes                   |
|-----------|-------------------------|
| 12/8/2023 | 2024 New Implementation |

| O        | mnipod   | d Insulin  | i Deliver         | y System | 1 |
|----------|--|--|-------------------|----------|---|
| The bina | ad inage countri he diquique. The file may have have a | mod, warmed, or allebed likely that the list points in the a | entile activities |          |   |

| Guideline ID          | GL-139181                       |  |
|-----------------------|---------------------------------|--|
| <b>Guideline Name</b> | Omnipod Insulin Delivery System |  |
| Formulary             | Quartz                          |  |

### **Guideline Note:**

| Effective Date: | 1/19/2024 |
|-----------------|-----------|
|-----------------|-----------|

### Note:

Member new to the plan (as evidenced by coverage effective date of less than or equal to 90 days) who initiated therapy using a manufacturer-sponsored free drug program, provider samples, and/or vouchers will go through initial criteria, otherwise for continuation of therapy for new to plan, reauthorization criteria applies

### 1. Criteria

| Product Name: Omnipod Dash, Omnipod 5 |   |                       |                |               |  |
|---------------------------------------|---|-----------------------|----------------|---------------|--|
| Approval Length                       |   | 12 month(s)           |                |               |  |
| Therapy St                            | age   | Initial Authorization |                |               |  |
| Guideline Type                        |   | Prior Authorization   |                |               |  |
| Product<br>Name                       |   |                       | GPI            | Brand/Generic |  |
| OMNIPOD<br>DASH<br>PODS               | *INSULIN INFUSION DISPOSABLE PUMP<br>RESERVOIR*** |                       | 97201030506300 | Brand         |  |

| (GEN 4)                                 |   |                |       |
|---|---|----------------|-------|
| OMNIPOD<br>5 G6 PODS<br>(GEN 5)         | *INSULIN INFUSION DISPOSABLE PUMP<br>RESERVOIR*** | 97201030506300 | Brand |
| OMNIPOD<br>5 G6<br>INTRO KIT<br>(GEN 5) | *INSULIN INFUSION DISPOSABLE PUMP KIT***          | 97201030506400 | Brand |

**1** - Prescribed by or in consultation with an Endocrinologist or other provider with expertise in the management of diabetes (e.g., Certified Diabetic Educator [CDE])

#### **AND**

- 2 One of the following:
- 2.1 Diagnosis of type 1 diabetes mellitus or other type of insulin-deficient diabetes

OR

- **2.2** Both of the following:
- **2.2.1** Diagnosis of gestational diabetes

AND

**2.2.2** Member is on an intensive insulin therapy regimen of at least 3 insulin injections per day with frequent self-adjustments of insulin dose

OR

- **2.3** All of the following:
- 2.3.1 Diagnosis of type 2 diabetes mellitus

**AND** 

**2.3.2** Evidence of adherence to an intensive insulin therapy regimen with at least three insulin injections per day, requiring frequent self-adjustments of insulin for at least 6 months

#### **AND**

- **2.3.3** At least ONE of the following criteria while on the intensive insulin therapy regimen:
  - Hemoglobin A1c greater than 7%
  - Recurrent hypoglycemia (less than 70mg/dL)
  - Dawn phenomenon (recurrent morning FBG greater than 200 mg/dL)
  - History of severe glycemic excursions
  - Fluctuations in blood sugar before mealtimes

| Notes | QL = 10 cartridges per 30 days |
|-------|--------------------------------|
|-------|--------------------------------|

| Product Name: Omnipod Dash, Omnipod 5 |                     |  |
|---------------------------------------|---------------------|--|
| Approval Length                       | 12 month(s)         |  |
| Therapy Stage                         | Reauthorization     |  |
| Guideline Type                        | Prior Authorization |  |

| Product<br>Name                         | Generic Name                                      | GPI            | Brand/Generic |
|---|---|----------------|---------------|
| OMNIPOD<br>DASH<br>PODS<br>(GEN 4)      | *INSULIN INFUSION DISPOSABLE PUMP<br>RESERVOIR*** | 97201030506300 | Brand         |
| OMNIPOD<br>5 G6 PODS<br>(GEN 5)         | *INSULIN INFUSION DISPOSABLE PUMP<br>RESERVOIR*** | 97201030506300 | Brand         |
| OMNIPOD<br>5 G6<br>INTRO KIT<br>(GEN 5) | *INSULIN INFUSION DISPOSABLE PUMP KIT***          | 97201030506400 | Brand         |

#### **Approval Criteria**

**1** - Member has been evaluated within the past 12 months by an Endocrinologist or other diabetes specialist

| AND   |                                |  |  |
|---|--------------------------------|--|--|
| 2 - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the pump |                                |  |  |
| Notes   | QL = 10 cartridges per 30 days |  |  |

| Date      | Notes            |
|-----------|------------------|
| 1/18/2024 | Update Guideline |

| Opioid Risk Management Program   | / Day Opioid First Fill Exception |
|--|-----------------------------------|
| (3) The first proposed the finished. The first is precised assess a second set of the first first proposed in contradicts. |                                   |
|  |                                   |

| Guideline ID          | GL-134592  |  |
|-----------------------|--|--|
| <b>Guideline Name</b> | Opioid Risk Management Program 7 Day Opioid First Fill Exception |  |
| Formulary             | Quartz   |  |

### **Guideline Note:**

| Effective Date: |
|-----------------|
|-----------------|

### 1. Criteria

| Product Name: all opioids, including opioid containing cold products |   |   |  |
|--|---|---|--|
| Approval Length  | 14 Day(s)   |   |  |
| Guideline Type   | DUR - Reject 88: Excd 7DS, review CDC guide effective dose and shortest duration at start. Su |   |  |
| Description Alexander Companie Name                                  |   | D |  |

|  | Product Name | Generic Name | GPI | Brand/Generic |  |
|--|--------------|--------------|-----|---------------|--|
|--|--------------|--------------|-----|---------------|--|

### **Approval Criteria**

- 1 One of the following:
  - Long-term care resident
  - Receiving hospice, palliative, or other end-of-life care
  - Treatment of cancer-related pain or sickle cell-related pain
  - Prescriber attests that the current prescription is a continuation of a stable, on-going

opioid treatment regimen

| Date       | Notes       |
|------------|-------------|
| 11/27/2023 | New Program |

| Opioid Risk Management Program: Opioid Concurrent Use Edi |  |  |  |  |  |  |
|---|--|--|--|--|--|--|
| The brind in  | age and the large. The last terms are all a season and the last terms are an extended at the last terms. |  |  |  |  |  |

| Guideline ID  | GL-134593 |
|---|-----------|
| Guideline Name Opioid Risk Management Program: Opioid Concurrent Use Ed |           |
| Formulary   | Quartz    |

# **Guideline Note:**

| Effective Date: |
|-----------------|
|-----------------|

### 1. Criteria

| Product Name: all opioids, including opioid containing cold products                                  |  |          |                 |               |
|---|--|----------|-----------------|---------------|
| Diagnosis Opioid Dependency Stopped   |  |          |                 |               |
| Approval Length 12 month(s)   |  |          |                 |               |
| Guideline Type  DUR - Reject 88: Buprenorphine Hx:Call MD,Enter O/R. Co-prescrit Naloxone for safety. |  |          | R. Co-prescribe |               |
| Product Name Gener  |  | ric Name | GPI             | Brand/Generic |

### **Approval Criteria**

**1** - Prescriber attests that the person has stopped opioid dependency treatment with a buprenorphine containing drug and is resuming other opioid treatment

| Product Name: all opioids, including opioid containing cold products |  |  |  |
|--|--|--|--|
| Diagnosis Opioid Dependency Continued                                |  |  |  |
| 1 fill (14 days)   |  |  |  |
| Guideline Type Prior Authorization                                   |  |  |  |
|  |  |  |  |

| Product Name | Generic Name | GPI | Brand/Generic |
|--------------|--------------|-----|---------------|
|--------------|--------------|-----|---------------|

**1** - Prescriber attests that the person is continuing opioid dependency treatment with a buprenorphine containing drug but requires acute opioid treatment

| Date       | Notes       |
|------------|-------------|
| 11/27/2023 | New Program |

| Opioid Risk Management: Opioid dose greater than 120 Morphine Milligram Equivalents (MME) |  |  |  |  |  |
|---|--|--|--|--|--|
|   | (3) Third in the state of the s |  |  |  |  |

| Guideline ID | GL-134594   |  |  |
|--------------|---|--|--|
|              | Opioid Risk Management: Opioid dose greater than 120 Morphine Milligram Equivalents (MME) |  |  |
| Formulary    | Quartz  |  |  |

### **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

### 1. Criteria

| Product Name: all opioids, including opioid containing cold products  |  |          |     |               |
|---|--|----------|-----|---------------|
| Approval Length 12/31/2039  |  |          |     |               |
| Guideline Type  DUR - Reject 88: MED 120mg Exceeded; Ttl MME MED <total calculated="" cumulative="" med="">MG TO O/R, ENTER PSS CODE OR MALL HD</total> |  |          |     |               |
| Product Name Gene   |  | ric Name | GPI | Brand/Generic |

### **Approval Criteria**

- **1** One of the following:
  - Long-term care resident
  - Receiving hospice, palliative, or other end of life care

- Treatment of cancer-related pain
- Treatment of sickle cell-related pain

| Product Name: all opioids, including opioid containing cold products |   |  |  |
|--|---|--|--|
| Approval Length  | 12 month(s)   |  |  |
| Guideline Type   | DUR - Reject 88: MED 120mg Exceeded; Ttl MME MED <total calculated="" cumulative="" med="">MG TO O/R, ENTER PSS CODE OR MALL HD</total> |  |  |
|  |   |  |  |

| Product Name | Generic Name | GPI | Brand/Generic |
|--------------|--------------|-----|---------------|
|--------------|--------------|-----|---------------|

- **1** All of the following:
  - Prescriber states the opioid dose requested is medically necessary
  - Documentation that the state prescription drug monitoring program (PDMP) site has been checked in the past month
  - Documentation of a current pain contract
  - Documentation that use of naloxone has been discussed
  - Documentation of urine compliance screen in the previous 12 months

| Product Name: all opioids, including opioid containing cold products  |       |           |     |               |
|---|-------|-----------|-----|---------------|
| Approval Length   |       | 14 Day(s) |     |               |
| Guideline Type  DUR - Reject 88: MED 120mg Exceeded; Ttl MME MED <total calculated="" cumulative="" med="">MG TO O/R, ENTER PSS CODE OR MALL HD</total> |       |           |     |               |
| Product Name  | Canal | ric Name  | CDI | Brand/Generic |

| Product Name   Generic Name   GPI   Brand/Generi |
|--|
|--|

### **Approval Criteria**

 ${f 1}$  - Person is changing medications and the new medication regimen does not exceed 120 MME

| Product Name: all opioids, including opioid containing cold products |  |  |
|--|--|--|
| Approval Length 3 month(s)   |  |  |

|              |       | DUR - Reject 88: MED 120mg Exceeded; Ttl M calculated cumulative MED >MG TO O/R, ENTI MALL HD |     |               |
|--------------|-------|---|-----|---------------|
| Product Name | Genei | ric Name  | GPI | Brand/Generic |

- **1** Member discharged from an inpatient stay after a severe, acute trauma with ALL of the following:
  - Prescriber states the opioid dose requested is medically necessary
  - Documentation that the state PDMP site has been checked prior to discharge
  - Documentation that use of naloxone has been discussed

OR

- **2** Both of the following:
- 2.1 Person has 2 or more fills of greater than 120 MME within the previous 6 months

**AND** 

2.2 Provider attests that continuation of therapy greater than 120 MME is medically necessary

| Date       | Notes       |
|------------|-------------|
| 11/27/2023 | New Program |

| Opze                                  | lura (ru   | kolitinib   | ) |  |
|---------------------------------------|--|---|---|--|
| The leth and image current the sliqui | guil. The firmsy have been neces, neurons, or debest. Serb | that he his points in the semantife and invation. |   |  |
|                                       |  |   |   |  |

| Guideline ID          | GL-136714              |  |
|-----------------------|------------------------|--|
| <b>Guideline Name</b> | Opzelura (ruxolitinib) |  |
| Formulary             | Quartz                 |  |

# **Guideline Note:**

| Effective Date: |
|-----------------|
|-----------------|

# 1. Criteria

| Product Name: Opzelura |                                    |  |
|------------------------|------------------------------------|--|
| Diagnosis              | Mild to moderate atopic dermatitis |  |
| Approval Length        | 12 month(s)                        |  |
| Therapy Stage          | Initial Authorization              |  |
| Guideline Type         | Prior Authorization                |  |

| Product<br>Name | Generic Name                     | GPI            | Brand/Generic |
|-----------------|----------------------------------|----------------|---------------|
| OPZELURA        | RUXOLITINIB PHOSPHATE CREAM 1.5% | 90272060503720 | Brand         |

# **Approval Criteria**

1 - Diagnosis of mild to moderate atopic dermatitis

#### **AND**

2 - Trial and failure of or contraindication to topical corticosteroid.

#### **AND**

3 - Trial and failure of or contraindication to calcineurin inhibitor (e.g. pimecrolimus, tacrolimus)

#### AND

**4** - Therapy will not be used in combination with other therapeutic biologics (e.g., dupilumab, omalizumab, Upadacitinib)

| Product Name: Opzelura |                       |  |
|------------------------|-----------------------|--|
| Diagnosis Vitiligo     |                       |  |
| Approval Length        | 12 month(s)           |  |
| Therapy Stage          | Initial Authorization |  |
| Guideline Type         | Prior Authorization   |  |

| Product<br>Name | Generic Name                     | GPI            | Brand/Generic |
|-----------------|----------------------------------|----------------|---------------|
| OPZELURA        | RUXOLITINIB PHOSPHATE CREAM 1.5% | 90272060503720 | Brand         |

### **Approval Criteria**

1 - Diagnosis of nonsegmental vitiligo

#### **AND**

2 - Prescribed by, or in consultation with, a Dermatologist

#### **AND**

| 3 - Area being treated does not exceed 10% body surface area (BSA)  |   |                     |                |
|---|---|---------------------|----------------|
|   | AND   |                     |                |
| 4 - Person meets one  | of the following:                           |                     |                |
| <b>4.1</b> Trial and failure  | of or contraindication to a medium-to-hi    | gh potency topical  | corticosteroid |
|   | OR  |                     |                |
| <b>4.2</b> Person is treatin genitalia  | g vitiligo affecting one of the following a | reas: face, skin fo | lds, and/or    |
|   | OR  |                     |                |
| <b>4.3</b> Person has sterd   | id-induced atrophy                          |                     |                |
|   | OR  |                     |                |
| <b>4.4</b> Person has a his   | tory of long-term topical steroid use       |                     |                |
|   | AND   |                     |                |
| <b>5</b> - Therapy will not be used in combination with other therapeutic biologics (e.g., dupilumab, omalizumab, Upadacitinib) |   |                     |                |
|   |   |                     |                |
| Product Name: Opzel   | ura   |                     |                |
| Diagnosis   | All diagnoses                               |                     |                |
| Approval Length   | 12 month(s)                                 |                     |                |
| Therapy Stage   | Reauthorization                             |                     |                |
| Guideline Type  | Prior Authorization                         |                     |                |
| Product   Generic Name   GPI   Brand/Generic Name   |   |                     |                |

| OPZELURA RUXOLITINIB PHOSPHATE CREAM 1.5% | 90272060503720 | Brand |
|---|----------------|-------|
|---|----------------|-------|

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug and with improvement in symptoms (e.g. reduction in body surface area affected, reduced itching, repigmentation.

| Date      | Notes                   |
|-----------|-------------------------|
| 12/1/2023 | 2024 New Implementation |

| Oral Calcitonin Gene-Related Peptide (CGRP) Inhibit   |  |  |  |  |
|---|--|--|--|--|
| [3] National and Analysis in National States and Analysis and Analysis produce and Analysis |  |  |  |  |

| Guideline ID          | GL-129229  |  |
|-----------------------|--|--|
| <b>Guideline Name</b> | Oral Calcitonin Gene-Related Peptide (CGRP) Inhibitors |  |
| Formulary             | Quartz   |  |

# **Guideline Note:**

| Effective Date: |
|-----------------|
|-----------------|

# 1. Criteria

| Product Name: Nurtec ODT, Ubrelvy                                    |  |  |
|--|--|--|
| Diagnosis Acute Migraine Treatment                                   |  |  |
| Approval Length 12/31/2039   |  |  |
| Guideline Type Prior Authorization- ALL Plans Except IL and MN Plans |  |  |

| Product<br>Name | Generic Name                        | GPI            | Brand/Generic |
|-----------------|-------------------------------------|----------------|---------------|
| NURTEC          | RIMEGEPANT SULFATE TAB DISINT 75 MG | 67701060707220 | Brand         |
| UBRELVY         | UBROGEPANT TAB 50 MG                | 67701080000320 | Brand         |
| UBRELVY         | UBROGEPANT TAB 100 MG               | 67701080000340 | Brand         |

### **Approval Criteria**

- 1 ONE of the following:
  - **1.1** Trial and failure or intolerance to at least two of the following:
    - sumatriptan
    - naratriptan
    - rizatriptan
    - eletriptan
    - zolmitriptan
    - almotriptan
    - frovatriptan

OR

- **1.2** Both of the following:
- 1.2.1 Contraindication to triptan use

AND

**1.2.2** Trial and failure, contraindication or intolerance to two non-triptan, prescription strength analgesics that are effective for treatment of migraines according to the American Headache Society treatment guidelines (e.g., nonsteroidal anti-inflammatory drugs (NSAIDs), ergotamine derivatives)

| Product Name: Nurtec ODT, Ubrelvy   |                                      |  |  |
|-------------------------------------|--------------------------------------|--|--|
| Diagnosis Acute Migraine Treatment  |                                      |  |  |
| Approval Length 12 month(s)         |                                      |  |  |
| Therapy Stage Initial Authorization |                                      |  |  |
| Guideline Type                      | Prior Authorization- IL and MN Plans |  |  |

| Product<br>Name | Generic Name                        | GPI            | Brand/Generic |
|-----------------|-------------------------------------|----------------|---------------|
| NURTEC          | RIMEGEPANT SULFATE TAB DISINT 75 MG | 67701060707220 | Brand         |
| UBRELVY         | UBROGEPANT TAB 50 MG                | 67701080000320 | Brand         |
| UBRELVY         | UBROGEPANT TAB 100 MG               | 67701080000340 | Brand         |

#### **Approval Criteria**

- **1** One of the following:
- **1.1** Trial and failure or intolerance to at least two of the following:
  - sumatriptan
  - naratriptan
  - rizatriptan
  - eletriptan
  - zolmitriptan
  - almotriptan
  - frovatriptan

OR

- 1.2 Both of the following
- **1.2.1** Contraindication to triptan use

#### **AND**

**1.2.2** Trial and failure, contraindication or intolerance to two non-triptan, prescription strength analgesics that are effective for treatment of migraines according to the American Headache Society treatment guidelines (e.g., nonsteroidal anti-inflammatory drugs (NSAIDs), ergotamine derivatives)

| Product Name: Nurtec ODT, Ubrelvy                   |                 |  |
|---|-----------------|--|
| Diagnosis Acute Migraine Treatment                  |                 |  |
| Approval Length                                     | 12 month(s)     |  |
| Therapy Stage                                       | Reauthorization |  |
| Guideline Type Prior Authorization- IL and MN Plans |                 |  |

| Product<br>Name | Generic Name                        | GPI            | Brand/Generic |
|-----------------|-------------------------------------|----------------|---------------|
| NURTEC          | RIMEGEPANT SULFATE TAB DISINT 75 MG | 67701060707220 | Brand         |
| UBRELVY         | UBROGEPANT TAB 50 MG                | 67701080000320 | Brand         |
| UBRELVY         | UBROGEPANT TAB 100 MG               | 67701080000340 | Brand         |

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug

| Product Name: Nurtec ODT, Qulipta                                    |            |  |
|--|------------|--|
| Diagnosis Prevention of Migraine                                     |            |  |
| Approval Length  | 12/31/2039 |  |
| Guideline Type Prior Authorization- ALL Plans Except IL and MN Plans |            |  |

| Product<br>Name | Generic Name                        | GPI            | Brand/Generic |
|-----------------|-------------------------------------|----------------|---------------|
| QULIPTA         | ATOGEPANT TAB 10 MG                 | 67701010000310 | Brand         |
| QULIPTA         | ATOGEPANT TAB 30 MG                 | 67701010000320 | Brand         |
| QULIPTA         | ATOGEPANT TAB 60 MG                 | 67701010000330 | Brand         |
| NURTEC          | RIMEGEPANT SULFATE TAB DISINT 75 MG | 67701060707220 | Brand         |

### **Approval Criteria**

**1** - Member has greater than or equal to 4 migraine days per month with submission of medical records (e.g., chart notes) documenting that headaches are disabling (e.g., unable to work/attend school, unable to participate in activities of daily living [ADLs], moderate to severe MIDAS score)

**AND** 

2 - Member is 18 years of age or older

AND

**3** - Trial and failure, contraindication or intolerance to two generic preventive migraine medications (e.g., anti-hypertensives, antiepileptics, antidepressants, botulinum toxin)

**AND** 

**4** - Trial and failure, contraindication or intolerance to both of the following:

- Aimovig
- Emgality

#### **AND**

**5** - Drug is not being used in combination with another CGRP inhibitor for the preventative treatment of migraines

| Product Name: Nurtec ODT, Qulipta                    |                       |  |
|--|-----------------------|--|
| Diagnosis Prevention of Migraine                     |                       |  |
| Approval Length                                      | 12 month(s)           |  |
| Therapy Stage  | Initial Authorization |  |
| Guideline Type Prior Authorization- IL and MN Plans* |                       |  |

| Product<br>Name | Generic Name                        | GPI            | Brand/Generic |
|-----------------|-------------------------------------|----------------|---------------|
| QULIPTA         | ATOGEPANT TAB 10 MG                 | 67701010000310 | Brand         |
| QULIPTA         | ATOGEPANT TAB 30 MG                 | 67701010000320 | Brand         |
| QULIPTA         | ATOGEPANT TAB 60 MG                 | 67701010000330 | Brand         |
| NURTEC          | RIMEGEPANT SULFATE TAB DISINT 75 MG | 67701060707220 | Brand         |

### **Approval Criteria**

**1** - Member has greater than or equal to 4 migraine days per month with submission of medical records (e.g., chart notes) documenting that headaches are disabling (e.g., unable to work/attend school, unable to participate in activities of daily living [ADLs], moderate to severe MIDAS score)

**AND** 

2 - Member is 18 years of age or older

**AND** 

**3** - Trial and failure, contraindication or intolerance to two generic preventive migraine medications (e.g., anti-hypertensives, antiepileptics, antidepressants, botulinum toxin)

#### AND

- **4** Trial and failure, contraindication or intolerance to both of the following:
  - Aimovig
  - Emgality

#### **AND**

**5** - Drug is not being used in combination with another CGRP inhibitor for the preventative treatment of migraines

| Notes | *Member new to the plan (as evidenced by coverage effective date of I ess than or equal to 90 days) and were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored fre e drug program, provider samples, and/or vouchers will go through rea |
|-------|--|
|       | uthorization criteria  |

| Product Name: Nurtec ODT, Qulipta |                                       |  |
|-----------------------------------|---------------------------------------|--|
| Diagnosis                         | Prevention of Migraine                |  |
| Approval Length                   | 12 month(s)                           |  |
| Therapy Stage                     | Reauthorization                       |  |
| Guideline Type                    | Prior Authorization- IL and MN Plans* |  |

| Product<br>Name | Generic Name                        | GPI            | Brand/Generic |
|-----------------|-------------------------------------|----------------|---------------|
| QULIPTA         | ATOGEPANT TAB 10 MG                 | 67701010000310 | Brand         |
| QULIPTA         | ATOGEPANT TAB 30 MG                 | 67701010000320 | Brand         |
| QULIPTA         | ATOGEPANT TAB 60 MG                 | 67701010000330 | Brand         |
| NURTEC          | RIMEGEPANT SULFATE TAB DISINT 75 MG | 67701060707220 | Brand         |
| UBRELVY         | UBROGEPANT TAB 50 MG                | 67701080000320 | Brand         |
| UBRELVY         | UBROGEPANT TAB 100 MG               | 67701080000340 | Brand         |

### **Approval Criteria**

1 - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member (as evidenced by coverage effective date of less than or equal to 90 days) is showing a response to therapy (e.g., symptom improvement such as decreased frequency or severity of headaches from baseline, reduced cluster headache frequency, improved ability to participate in therapies/ADLs, improved MIDAS score, less acute medication use, fewer ER/UC visits for migraine, ability to return to work/school)

#### **AND**

**2** - Drug is not being used in combination with another CGRP inhibitor for the preventative treatment of migraines

| Notes | *Member new to the plan (as evidenced by coverage effective date of I ess than or equal to 90 days) and were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers will go through rea |
|-------|---|
|       | uthorization criteria   |

| Product Name: Nurtec ODT, Ubrelvy              |   |  |
|--|---|--|
| Diagnosis Acute treatment – Quantity Exception |   |  |
| Approval Length                                | 12/31/2039  |  |
| Therapy Stage                                  | Reauthorization                                       |  |
| Guideline Type                                 | Quantity Exception - ALL Plans Except IL and MN Plans |  |

| Product<br>Name | Generic Name                        | GPI            | Brand/Generic |
|-----------------|-------------------------------------|----------------|---------------|
| NURTEC          | RIMEGEPANT SULFATE TAB DISINT 75 MG | 67701060707220 | Brand         |
| UBRELVY         | UBROGEPANT TAB 50 MG                | 67701080000320 | Brand         |
| UBRELVY         | UBROGEPANT TAB 100 MG               | 67701080000340 | Brand         |

#### **Approval Criteria**

**1** - Submission of medical records (e.g., chart notes) documenting that member has 2 or more headaches per week

#### **AND**

2 - Patient is on migraine headache prophylaxis treatment

| Product Name: Nurtec ODT, Ubrelvy              |                                      |  |
|--|--------------------------------------|--|
| Diagnosis Acute treatment – Quantity Exception |                                      |  |
| Approval Length                                | 12 month(s)                          |  |
| Therapy Stage                                  | Reauthorization                      |  |
| Guideline Type                                 | Quantity Exception - IL and MN Plans |  |

| Product<br>Name | Generic Name                        | GPI            | Brand/Generic |
|-----------------|-------------------------------------|----------------|---------------|
| NURTEC          | RIMEGEPANT SULFATE TAB DISINT 75 MG | 67701060707220 | Brand         |
| UBRELVY         | UBROGEPANT TAB 50 MG                | 67701080000320 | Brand         |
| UBRELVY         | UBROGEPANT TAB 100 MG               | 67701080000340 | Brand         |

**1** - Submission of medical records (e.g., chart notes) documenting that member has 2 or more headaches per week

### AND

2 - Patient is on migraine headache prophylaxis treatment

| Date       | Notes                   |
|------------|-------------------------|
| 10/25/2023 | 2024 New Implementation |

| ( | Orencia (abatacept)  |   |  |  |  |  |
|---|--|---|--|--|--|--|
| • | The listed image current the elephysis. The file may have need to elephysis. | ham record, seramed, or diched, Welly Shall Re Sri. | politic to that acceptable and limiters. |  |  |  |
|   |  |   |  |  |  |  |

| Guideline ID          | GL-137207           |  |
|-----------------------|---------------------|--|
| <b>Guideline Name</b> | Orencia (abatacept) |  |
| Formulary             | Quartz              |  |

# **Guideline Note:**

| Effective Date: |
|-----------------|
|-----------------|

# 1. Criteria

| Product Name: Orencia               |  |  |
|-------------------------------------|--|--|
| Diagnosis Psoriatic Arthritis (PsA) |  |  |
| Approval Length                     | 12/31/2039   |  |
| Guideline Type                      | Prior Authorization – All Plans except IL and MN Plans |  |

| Product<br>Name      | Generic Name  | GPI            | Brand/Generic |
|----------------------|---|----------------|---------------|
| ORENCIA<br>CLICKJECT | ABATACEPT SUBCUTANEOUS SOLN AUTO-INJECTOR 125 MG/ML         | 6640001000D520 | Brand         |
| ORENCIA              | ABATACEPT SUBCUTANEOUS SOLN PREFILLED SYRINGE 50 MG/0.4ML   | 6640001000E510 | Brand         |
| ORENCIA              | ABATACEPT SUBCUTANEOUS SOLN PREFILLED SYRINGE 87.5 MG/0.7ML | 6640001000E515 | Brand         |
| ORENCIA              | ABATACEPT SUBCUTANEOUS SOLN PREFILLED<br>SYRINGE 125 MG/ML  | 6640001000E520 | Brand         |
|                      |   |                |               |

| Approval Criteria  |
|--|
| 1 - Diagnosis of moderate to severely active psoriatic arthritis (PsA)   |
| AND  |
| 2 - Prescribed by or in consultation with a dermatologist or rheumatologist  |
| AND  |
| <b>3</b> - Submission of medical records (e.g., chart notes) documenting at least ONE of the following:  |
| <ul> <li>actively inflamed joints</li> <li>axial disease</li> <li>active skin, nail, or scalp psoriasis involvement</li> <li>dactylitis</li> <li>enthesitis</li> </ul> |
| AND  |
| <b>4</b> - Not used in combination with other biologic DMARDs (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)                                 |
| AND  |
| 5 - Medication will be self-administered   |
| AND  |
| <b>6</b> - Trial and failure, contraindication, or intolerance to TWO of the following:  |
| <ul> <li>Adalimumab</li> <li>Etanercept</li> <li>Certolizumab</li> <li>Golimumab</li> <li>Risankizumab</li> </ul>  |

- Upadacitinib
- Guselkumab
- Tofacitinib/Tofacitinib XR
- Ustekinumab

| Product Name: Orencia |                                       |  |
|-----------------------|---------------------------------------|--|
| Diagnosis             | Psoriatic Arthritis (PsA)             |  |
| Approval Length       | 12 month(s)                           |  |
| Therapy Stage         | Initial Authorization                 |  |
| Guideline Type        | Prior Authorization – IL and MN Plans |  |

| Product<br>Name      | Generic Name  | GPI            | Brand/Generic |
|----------------------|---|----------------|---------------|
| ORENCIA<br>CLICKJECT | ABATACEPT SUBCUTANEOUS SOLN AUTO-INJECTOR 125 MG/ML         | 6640001000D520 | Brand         |
| ORENCIA              | ABATACEPT SUBCUTANEOUS SOLN PREFILLED SYRINGE 50 MG/0.4ML   | 6640001000E510 | Brand         |
| ORENCIA              | ABATACEPT SUBCUTANEOUS SOLN PREFILLED SYRINGE 87.5 MG/0.7ML | 6640001000E515 | Brand         |
| ORENCIA              | ABATACEPT SUBCUTANEOUS SOLN PREFILLED<br>SYRINGE 125 MG/ML  | 6640001000E520 | Brand         |

1 - Diagnosis of moderate to severely active psoriatic arthritis (PsA)

#### **AND**

**2** - Prescribed by or in consultation with a dermatologist or rheumatologist

### **AND**

- ${\bf 3}$  Submission of medical records (e.g., chart notes) documenting at least ONE of the following:
  - actively inflamed joints
  - axial disease
  - active skin, nail, or scalp psoriasis involvement

- dactylitis
- enthesitis

#### AND

**4** - Not used in combination with other biologic DMARDs (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

#### **AND**

5 - Medication will be self-administered

#### **AND**

- **6** Trial and failure, contraindication, or intolerance to TWO of the following:
  - Adalimumab
  - Etanercept
  - Certolizumab
  - Golimumab
  - Risankizumab
  - Upadacitinib
  - Guselkumab
  - Tofacitinib/Tofacitinib XR
  - Ustekinumab

| Product Name: Orencia   |  |  |
|---|--|--|
| Diagnosis Moderate to Severely Active Rheumatoid Arthritis (RA)       |  |  |
| Approval Length 12/31/2039  |  |  |
| Guideline Type Prior Authorization – All Plans except IL and MN Plans |  |  |

| Product<br>Name      | Generic Name  | GPI            | Brand/Generic |
|----------------------|---|----------------|---------------|
| ORENCIA<br>CLICKJECT | ABATACEPT SUBCUTANEOUS SOLN AUTO-INJECTOR 125 MG/ML       | 6640001000D520 | Brand         |
| ORENCIA              | ABATACEPT SUBCUTANEOUS SOLN PREFILLED SYRINGE 50 MG/0.4ML | 6640001000E510 | Brand         |

| ORENCIA | ABATACEPT SUBCUTANEOUS SOLN PREFILLED SYRINGE 87.5 MG/0.7ML | 6640001000E515 | Brand |
|---------|---|----------------|-------|
| ORENCIA | ABATACEPT SUBCUTANEOUS SOLN PREFILLED SYRINGE 125 MG/ML     | 6640001000E520 | Brand |

1 - Diagnosis of moderate to severely active rheumatoid arthritis (RA)

#### **AND**

- **2** Submission of medical records (e.g., chart notes) documenting a 3-month trial and failure, intolerance, or contraindication to ONE of the following:
  - Methotrexate (MTX)\*
  - Leflunomide
  - Hydroxychloroquine
  - Sulfasalazine

#### **AND**

- 3 Trial and failure, contraindication, or intolerance to TWO of the following:
  - Adalimumab
  - Certolizumab
  - Etanercept
  - Golimumab
  - Tofactinib (ER)
  - Upadacitinib

#### **AND**

**4** - Medication will be self-administered (not in clinic or provider office)

#### **AND**

**5** - Prescribed by or in consultation with a rheumatologist

| AND  |   |  |  |
|--|---|--|--|
| <b>6</b> - Not used in combination with other biologic DMARDs (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.) |   |  |  |
| Notes  | * Absolute contraindications to methotrexate are pregnancy, nursing, al coholism, alcoholic liver disease or other chronic liver disease, immuno deficiency syndromes, bone marrow hyperplasia, leukopenia, thromboc ytopenia or significant anemia, or hypersensitivity to methotrexate. |  |  |

| Product Name: Orencia |   |  |
|-----------------------|---|--|
| Diagnosis             | Moderate to Severely Active Rheumatoid Arthritis (RA) |  |
| Approval Length       | 12 month(s)   |  |
| Therapy Stage         | Initial Authorization                                 |  |
| Guideline Type        | Prior Authorization – IL and MN Plans                 |  |

| Product<br>Name      | Generic Name  | GPI            | Brand/Generic |
|----------------------|---|----------------|---------------|
| ORENCIA<br>CLICKJECT | ABATACEPT SUBCUTANEOUS SOLN AUTO-INJECTOR 125 MG/ML         | 6640001000D520 | Brand         |
| ORENCIA              | ABATACEPT SUBCUTANEOUS SOLN PREFILLED SYRINGE 50 MG/0.4ML   | 6640001000E510 | Brand         |
| ORENCIA              | ABATACEPT SUBCUTANEOUS SOLN PREFILLED SYRINGE 87.5 MG/0.7ML | 6640001000E515 | Brand         |
| ORENCIA              | ABATACEPT SUBCUTANEOUS SOLN PREFILLED SYRINGE 125 MG/ML     | 6640001000E520 | Brand         |

1 - Diagnosis of moderate to severely active rheumatoid arthritis (RA)

### **AND**

- **2** Submission of medical records (e.g., chart notes) documenting a 3-month trial and failure, intolerance, or contraindication to ONE of the following:
  - Methotrexate (MTX)\*
  - Leflunomide
  - Hydroxychloroquine Sulfasalazine

- **3** Trial and failure, contraindication, or intolerance to TWO of the following:
  - Adalimumab
  - Certolizumab
  - Etanercept
  - Golimumab
  - Tofactinib (ER)
  - Upadacitinib

#### **AND**

4 - Medication will be self-administered (not in clinic or provider office)

#### **AND**

**5** - Prescribed by or in consultation with a rheumatologist

#### AND

**6** - Not used in combination with other biologic DMARDs (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

| Notes | * Absolute contraindications to methotrexate are pregnancy, nursing, al  |
|-------|--|
|       | coholism, alcoholic liver disease or other chronic liver disease, immuno |
|       | deficiency syndromes, bone marrow hyperplasia, leukopenia, thromboc      |
|       | ytopenia or significant anemia, or hypersensitivity to methotrexate.     |

| Product Name: Orencia |  |
|-----------------------|--|
| Diagnosis             | Juvenile Idiopathic Arthritis (JIA)                    |
| Approval Length       | 12/31/2039   |
| Guideline Type        | Prior Authorization – All Plans except IL and MN Plans |

| Product<br>Name      | Generic Name  | GPI            | Brand/Generic |
|----------------------|---|----------------|---------------|
| ORENCIA<br>CLICKJECT | ABATACEPT SUBCUTANEOUS SOLN AUTO-INJECTOR 125 MG/ML | 6640001000D520 | Brand         |

| ORENCIA | ABATACEPT SUBCUTANEOUS SOLN PREFILLED SYRINGE 50 MG/0.4ML   | 6640001000E510 | Brand |
|---------|---|----------------|-------|
| ORENCIA | ABATACEPT SUBCUTANEOUS SOLN PREFILLED SYRINGE 87.5 MG/0.7ML | 6640001000E515 | Brand |
| ORENCIA | ABATACEPT SUBCUTANEOUS SOLN PREFILLED SYRINGE 125 MG/ML     | 6640001000E520 | Brand |

1 - Diagnosis of juvenile idiopathic arthritis

#### **AND**

**2** - Prescribed by or in consultation with a rheumatologist

#### **AND**

- **3** Minimum 3-month trial and failure, contraindication, or intolerance to ONE of the following:
  - Methotrexate (MTX)\*
  - Leflunomide
  - Hydroxychloroquine
  - Sulfasalazine

### AND

- 4 Trial and failure, contraindication, or intolerance to TWO of the following:
  - Adalimumab
  - Etanercept
  - Tofacitinib/Tofacitinib XR

#### **AND**

**5** - Not used in combination with other biologic DMARDs (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

| AND                       |   |
|---------------------------|---|
| 6 - Medication will be se | elf-administered  |
| Notes                     | * Absolute contraindications to methotrexate are pregnancy, nursing, al coholism, alcoholic liver disease or other chronic liver disease, immuno deficiency syndromes, bone marrow hyperplasia, leukopenia, thromboc ytopenia or significant anemia, or hypersensitivity to methotrexate. |

| Product Name: Orencia |                                       |
|-----------------------|---------------------------------------|
| Diagnosis             | Juvenile Idiopathic Arthritis (JIA)   |
| Approval Length       | 12 month(s)                           |
| Therapy Stage         | Initial Authorization                 |
| Guideline Type        | Prior Authorization – IL and MN Plans |

| Product<br>Name      | Generic Name  | GPI            | Brand/Generic |
|----------------------|---|----------------|---------------|
| ORENCIA<br>CLICKJECT | ABATACEPT SUBCUTANEOUS SOLN AUTO-INJECTOR 125 MG/ML         | 6640001000D520 | Brand         |
| ORENCIA              | ABATACEPT SUBCUTANEOUS SOLN PREFILLED SYRINGE 50 MG/0.4ML   | 6640001000E510 | Brand         |
| ORENCIA              | ABATACEPT SUBCUTANEOUS SOLN PREFILLED SYRINGE 87.5 MG/0.7ML | 6640001000E515 | Brand         |
| ORENCIA              | ABATACEPT SUBCUTANEOUS SOLN PREFILLED SYRINGE 125 MG/ML     | 6640001000E520 | Brand         |

1 - Diagnosis of juvenile idiopathic arthritis

### **AND**

2 - Prescribed by or in consultation with a rheumatologist

### **AND**

**3** - Minimum 3-month trial and failure, contraindication, or intolerance to ONE of the following:

- Methotrexate (MTX)\*
- Leflunomide
- Hydroxychloroquine
- Sulfasalazine

- 4 Trial and failure, contraindication, or intolerance to TWO of the following:
  - Adalimumab
  - Etanercept
  - Tofacitinib/Tofacitinib XR

#### **AND**

**5** - Not used in combination with other biologic DMARDs (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

#### **AND**

6 - Medication will be self-administered

| Notes | * Absolute contraindications to methotrexate are pregnancy, nursing, al  |
|-------|--|
|       | coholism, alcoholic liver disease or other chronic liver disease, immuno |
|       | deficiency syndromes, bone marrow hyperplasia, leukopenia, thromboc      |
|       | ytopenia or significant anemia, or hypersensitivity to methotrexate.     |

| Product Name: Orencia |                                       |
|-----------------------|---------------------------------------|
| Diagnosis             | All Indications                       |
| Approval Length       | 12 month(s)                           |
| Therapy Stage         | Reauthorization                       |
| Guideline Type        | Prior Authorization – IL and MN Plans |

| Product<br>Name      | Generic Name  | GPI            | Brand/Generic |
|----------------------|---|----------------|---------------|
| ORENCIA<br>CLICKJECT | ABATACEPT SUBCUTANEOUS SOLN AUTO-INJECTOR 125 MG/ML       | 6640001000D520 | Brand         |
| ORENCIA              | ABATACEPT SUBCUTANEOUS SOLN PREFILLED SYRINGE 50 MG/0.4ML | 6640001000E510 | Brand         |

| ORENCIA | ABATACEPT SUBCUTANEOUS SOLN PREFILLED SYRINGE 87.5 MG/0.7ML | 6640001000E515 | Brand |
|---------|---|----------------|-------|
| ORENCIA | ABATACEPT SUBCUTANEOUS SOLN PREFILLED SYRINGE 125 MG/ML     | 6640001000E520 | Brand |

**1** - Prescriber provides clinical documentation from the previous 12 months of the member's response to therapy including individual improvements in functional status related to therapeutic response

| Date      | Notes                   |
|-----------|-------------------------|
| 12/4/2023 | 2024 New Implementation |

| ORFADIN (Nitisin   | one), Nityr (Nitisinone |
|--|-------------------------|
| (2) The Manufacture and Angles of The Rose, has been most, counted, a black body but he is active the annual of the second of th | artisan.                |
|  |                         |

| Guideline ID          | GL-129653                                |
|-----------------------|--|
| <b>Guideline Name</b> | ORFADIN (Nitisinone), Nityr (Nitisinone) |
| Formulary             | Quartz                                   |

# **Guideline Note:**

| Effective Date: |
|-----------------|
|-----------------|

| Product Name: Orfadin solution, Generic Nitisinone, Brand Nityr |  |
|---|--|
| 12 month(s)   |  |
| Initial Authorization   |  |
| Prior Authorization - IL and MN Plans                           |  |
|   |  |

| Product<br>Name | Generic Name            | GPI            | Brand/Generic |
|-----------------|-------------------------|----------------|---------------|
| NITISINONE      | NITISINONE CAP 2 MG     | 30904045000110 | Generic       |
| NITISINONE      | NITISINONE CAP 5 MG     | 30904045000120 | Generic       |
| NITISINONE      | NITISINONE CAP 10 MG    | 30904045000130 | Generic       |
| NITISINONE      | NITISINONE CAP 20 MG    | 30904045000140 | Generic       |
| ORFADIN         | NITISINONE SUSP 4 MG/ML | 30904045001820 | Brand         |
| NITYR           | NITISINONE TAB 2 MG     | 30904045000310 | Brand         |

| NITYR | NITISINONE TAB 5 MG  | 30904045000320 | Brand |
|-------|----------------------|----------------|-------|
| NITYR | NITISINONE TAB 10 MG | 30904045000330 | Brand |

1 - Diagnosis of hereditary tyrosinemia type I.

#### **AND**

2 - Detectable succinylacetone blood or urine levels.

| Product Name: Orfadin solution, Generic Nitisinone, Brand Nityr |                                       |
|---|---------------------------------------|
| Approval Length   | 12 month(s)                           |
| Therapy Stage   | Reauthorization                       |
| Guideline Type  | Prior Authorization - IL and MN Plans |

| Product<br>Name | Generic Name            | GPI            | Brand/Generic |
|-----------------|-------------------------|----------------|---------------|
| NITISINONE      | NITISINONE CAP 2 MG     | 30904045000110 | Generic       |
| NITISINONE      | NITISINONE CAP 5 MG     | 30904045000120 | Generic       |
| NITISINONE      | NITISINONE CAP 10 MG    | 30904045000130 | Generic       |
| NITISINONE      | NITISINONE CAP 20 MG    | 30904045000140 | Generic       |
| ORFADIN         | NITISINONE SUSP 4 MG/ML | 30904045001820 | Brand         |
| NITYR           | NITISINONE TAB 2 MG     | 30904045000310 | Brand         |
| NITYR           | NITISINONE TAB 5 MG     | 30904045000320 | Brand         |
| NITYR           | NITISINONE TAB 10 MG    | 30904045000330 | Brand         |

# **Approval Criteria**

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug.

Product Name: Orfadin solution, Generic Nitisinone, Brand Nityr

| Approval Length | 12/31/2039                                       |
|-----------------|--|
| Guideline Type  | Prior Authorization - All plans except IL and MN |

| Product<br>Name | Generic Name            | GPI            | Brand/Generic |
|-----------------|-------------------------|----------------|---------------|
| NITISINONE      | NITISINONE CAP 2 MG     | 30904045000110 | Generic       |
| NITISINONE      | NITISINONE CAP 5 MG     | 30904045000120 | Generic       |
| NITISINONE      | NITISINONE CAP 10 MG    | 30904045000130 | Generic       |
| NITISINONE      | NITISINONE CAP 20 MG    | 30904045000140 | Generic       |
| ORFADIN         | NITISINONE SUSP 4 MG/ML | 30904045001820 | Brand         |
| NITYR           | NITISINONE TAB 2 MG     | 30904045000310 | Brand         |
| NITYR           | NITISINONE TAB 5 MG     | 30904045000320 | Brand         |
| NITYR           | NITISINONE TAB 10 MG    | 30904045000330 | Brand         |

1 - Diagnosis of hereditary tyrosinemia type I.

### AND

**2** - Detectable succinylacetone blood or urine levels.

| Date       | Notes       |
|------------|-------------|
| 10/25/2023 | New Program |

| Otezla (apremilast)  |
|--|
| (2) The hardware continues to be the section continues and a continue with production production and the section and the secti |
|  |
|  |

| Guideline ID          | GL-137227          |  |
|-----------------------|--------------------|--|
| <b>Guideline Name</b> | tezla (apremilast) |  |
| Formulary             | Quartz             |  |

# **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

# Note:

Member new to the plan (as evidenced by coverage effective date of less than or equal to 90 days) who initiated therapy using a manufacturer-sponsored free drug program, provider samples, and/or vouchers will go through initial criteria, otherwise for continuation of therapy for new to plan, reauthorization criteria applies.

| Product Name: Otezla |   |                                     |                |               |
|----------------------|---|-------------------------------------|----------------|---------------|
| Diagnosis            |   | Plaque Psoriasis                    |                |               |
| Approval Lo          | ength   | 12/31/2039                          |                |               |
| Guideline T          | Type Prior Authorization – All Plans except IL and MN Plans |                                     |                |               |
| Product<br>Name      | Generic Name  |                                     | GPI            | Brand/Generic |
| OTEZLA               | APREMILAST<br>20 MG & 30 N                                  | TAB STARTER THERAPY PACK 10 MG & MG | 6670001500B720 | Brand         |

| OTEZLA | APREMILAST TAB 30 MG | 66700015000330 | Brand |
|--------|----------------------|----------------|-------|
|--------|----------------------|----------------|-------|

1 - Diagnosis of mild to severe plaque psoriasis

#### **AND**

2 - Prescribed by or in consultation with a dermatologist

#### **AND**

**3** - Trial and failure, contraindication, or intolerance to topical treatment (e.g. topical corticosteroids, calcipotriene, retinoids)

#### **AND**

**4** - Not used in combination with other biologic disease modifying anti-rheumatic drugs (DMARDs) (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

| Product Name: Otezla |                                       |  |
|----------------------|---------------------------------------|--|
| Diagnosis            | Plaque Psoriasis                      |  |
| Approval Length      | 12 month(s)                           |  |
| Therapy Stage        | Initial Authorization                 |  |
| Guideline Type       | Prior Authorization – IL and MN Plans |  |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| OTEZLA          | APREMILAST TAB STARTER THERAPY PACK 10 MG & 20 MG & 30 MG | 6670001500B720 | Brand         |
| OTEZLA          | APREMILAST TAB 30 MG                                      | 66700015000330 | Brand         |

#### **Approval Criteria**

| 1 - Dia | gnosis | of | mild | to | severe | plac | ue | psorias | sis |
|---------|--------|----|------|----|--------|------|----|---------|-----|
|---------|--------|----|------|----|--------|------|----|---------|-----|

2 - Prescribed by or in consultation with a dermatologist

#### **AND**

**3** - Trial and failure, contraindication, or intolerance to topical treatment (e.g. topical corticosteroids, calcipotriene, retinoids)

#### **AND**

**4** - Not used in combination with other biologic disease modifying anti-rheumatic drugs (DMARDs) (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

| Product Name: Otezla |  |
|----------------------|--|
| Diagnosis            | Psoriatic Arthritis (PsA)                              |
| Approval Length      | 12/31/2039   |
| Guideline Type       | Prior Authorization – All Plans except IL and MN Plans |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| OTEZLA          | APREMILAST TAB STARTER THERAPY PACK 10 MG & 20 MG & 30 MG | 6670001500B720 | Brand         |
| OTEZLA          | APREMILAST TAB 30 MG                                      | 66700015000330 | Brand         |

### **Approval Criteria**

1 - Diagnosis of moderate to severely active psoriatic arthritis (PsA)

#### **AND**

2 - Prescribed by or in consultation with a dermatologist or rheumatologist

- **3** Submission of medical records (e.g., chart notes) documenting at least ONE of the following:
  - actively inflamed joints
  - axial disease
  - active skin, nail, or scalp psoriasis involvement
  - dactylitis
  - enthesitis

#### **AND**

**4** - Not used in combination with other biologic DMARDs (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

| Product Name: Otezla |                                       |
|----------------------|---------------------------------------|
| Diagnosis            | Psoriatic Arthritis (PsA)             |
| Approval Length      | 12 month(s)                           |
| Therapy Stage        | Initial Authorization                 |
| Guideline Type       | Prior Authorization – IL and MN Plans |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| OTEZLA          | APREMILAST TAB STARTER THERAPY PACK 10 MG & 20 MG & 30 MG | 6670001500B720 | Brand         |
| OTEZLA          | APREMILAST TAB 30 MG                                      | 66700015000330 | Brand         |

# **Approval Criteria**

1 - Diagnosis of moderate to severely active psoriatic arthritis (PsA)

#### **AND**

2 - Prescribed by or in consultation with a dermatologist or rheumatologist

- **3** Submission of medical records (e.g., chart notes) documenting at least ONE of the following:
  - actively inflamed joints
  - axial disease
  - active skin, nail, or scalp psoriasis involvement
  - dactylitis
  - enthesitis

### AND

**4** - Not used in combination with other biologic DMARDs (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

| Product Name: Otezla |  |
|----------------------|--|
| Diagnosis            | Oral Ulcers Associated with Behçet's Disease           |
| Approval Length      | 12/31/2039   |
| Guideline Type       | Prior Authorization – All Plans except IL and MN Plans |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| OTEZLA          | APREMILAST TAB STARTER THERAPY PACK 10 MG & 20 MG & 30 MG | 6670001500B720 | Brand         |
| OTEZLA          | APREMILAST TAB 30 MG                                      | 66700015000330 | Brand         |

### **Approval Criteria**

1 - Diagnosis of Behçet's Disease with active oral ulcers

#### **AND**

2 - Prescribed by or in consultation with a rheumatologist

**3** - Not used in combination with other biologic DMARDs (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

| Product Name: Otezla |  |  |
|----------------------|--|--|
| Diagnosis            | Oral Ulcers Associated with Behçet's Disease |  |
| Approval Length      | 12 month(s)                                  |  |
| Therapy Stage        | Initial Authorization                        |  |
| Guideline Type       | Prior Authorization – IL and MN Plans        |  |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| OTEZLA          | APREMILAST TAB STARTER THERAPY PACK 10 MG & 20 MG & 30 MG | 6670001500B720 | Brand         |
| OTEZLA          | APREMILAST TAB 30 MG                                      | 66700015000330 | Brand         |

# **Approval Criteria**

1 - Diagnosis of Behçet's Disease with active oral ulcers

#### **AND**

2 - Prescribed by or in consultation with a rheumatologist

#### **AND**

**3** - Not used in combination with other biologic DMARDs (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

| Product Name: Otezla |                                       |  |
|----------------------|---------------------------------------|--|
| Diagnosis            | All Indications                       |  |
| Approval Length      | 12 month(s)                           |  |
| Therapy Stage        | Reauthorization                       |  |
| Guideline Type       | Prior Authorization – IL and MN Plans |  |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| OTEZLA          | APREMILAST TAB STARTER THERAPY PACK 10 MG & 20 MG & 30 MG | 6670001500B720 | Brand         |
| OTEZLA          | APREMILAST TAB 30 MG                                      | 66700015000330 | Brand         |

**1** - Prescriber provides clinical documentation from the previous 12 months of the member's response to therapy including individual improvements in functional status related to therapeutic response

| Date      | Notes                   |
|-----------|-------------------------|
| 12/4/2023 | 2024 New Implementation |

| Oxazolidinone Antibiotic   |  |  |
|--|--|--|
| The third region and adoption below to the control and a control and the position control and adoption to the cont |  |  |

| Guideline ID          | GL-131477                |
|-----------------------|--------------------------|
| <b>Guideline Name</b> | Oxazolidinone Antibiotic |
| Formulary             | Quartz                   |

# **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

### Note:

Member new to the plan (as evidenced by coverage effective date of less than or equal to 90 days) who initiated therapy using a manufacturer-sponsored free drug program, provider samples, and/or vouchers will go through initial criteria, otherwise for continuation of therapy for new to plan, reauthorization criteria applies.

| Product Name: Sivextro  |                |                      |                |               |
|---|----------------|----------------------|----------------|---------------|
| Approval Length   |                | 14 Day (s)*          |                |               |
| Guideline Type Prior Authorization - All Plans except IL and MN |                |                      |                |               |
| Product<br>Name   | Generic Name G |                      | GPI            | Brand/Generic |
| SIVEXTRO  | TEDIZOLID F    | PHOSPHATE TAB 200 MG | 16230070200320 | Brand         |
|   |                |                      |                |               |
|   |                |                      |                |               |

- 1 One of the following:
- **1.1** Submission of medical records (e.g., chart notes, paid claims) supporting use of the drug during the current hospitalization and needs to complete the course of therapy as an outpatient

OR

- **1.2** All of the following:
- 1.2.1 Used for outpatient treatment of resistant bacterial strains

#### **AND**

1.2.2 Report of susceptibilities documenting resistance to alternatives including linezolid

#### **AND**

1.2.3 Prescribed by, or in consultation with, an Infectious Disease specialist

OR

- **1.3** Both of the following:
- **1.3.1** Linezolid is the only viable alternative due to resistance

#### **AND**

**1.3.2** Member is taking serotonergic agents (e.g. SSRI, tricyclic antidepressants, triptans, etc.)

| Notes | *Approval duration: Approve for the duration of treatment (usual course |
|-------|---|
|       | 6-14 days, or 14 to 28 days for Vancomycin-resistant enterococcus)      |

| Product Name: Sivextro |             |
|------------------------|-------------|
| Approval Length        | 12 month(s) |

| Guideline T     | уре         | Prior Authorization - IL Plan and MN | Plans          |               |
|-----------------|-------------|--------------------------------------|----------------|---------------|
| Product<br>Name | Generic Na  | me                                   | GPI            | Brand/Generic |
| SIVEXTRO        | TEDIZOLID P | HOSPHATE TAB 200 MG                  | 16230070200320 | Brand         |

- 1 One of the following:
- **1.1** Submission of medical records (e.g., chart notes, paid claims) supporting use of the drug during the current hospitalization and needs to complete the course of therapy as an outpatient

OR

- **1.2** All of the following:
- **1.2.1** Used for outpatient treatment of resistant bacterial strains

#### **AND**

1.2.2 Report of susceptibilities documenting resistance to alternatives including linezolid

#### **AND**

**1.2.3** Prescribed by, or in consultation with, an Infectious Disease specialist

OR

- **1.3** Both of the following:
- 1.3.1 Linezolid is the only viable alternative due to resistance

#### **AND**

1.3.2 Member is taking serotonergic agents (e.g. SSRI, tricyclic antidepressants, triptans,

etc.)

OR

**1.4** For IL Plans ONLY: The requested drug is being used for the long-term treatment of tickborne disease

| Date      | Notes                   |
|-----------|-------------------------|
| 10/6/2023 | 2024 New Implementation |

| C      | Oxbryta (voxelotor)                            |  |  |  |  |  |
|--------|--|--|--|--|--|--|
| in the | selekat inggrunnst kediplysii. The fir ney han | n kann musel, seramel, er delderi. Verly that be | ink prints in the semantific and invalors. |  |  |  |
|        |  |  |  |  |  |  |
|        |  |  |  |  |  |  |

| Guideline ID          | GL-130600           |
|-----------------------|---------------------|
| <b>Guideline Name</b> | Oxbryta (voxelotor) |
| Formulary             | Quartz              |

# **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

# Note:

Member new to the plan (as evidenced by coverage effective date of less than or equal to 90 days) who initiated therapy using a manufacturer-sponsored free drug program, provider samples, and/or vouchers will go through initial criteria, otherwise for continuation of therapy for new to plan, reauthorization criteria applies

| Product Name: Oxbryta               |   |             |                |               |
|-------------------------------------|---|-------------|----------------|---------------|
| Approval Length 12 mg               |   | 12 month(s) |                |               |
| Therapy Stage Initial Authorization |   |             |                |               |
| Guideline Type Prior Authorization  |   |             |                |               |
| Product<br>Name                     | Generic Name                              |             | GPI            | Brand/Generic |
| OXBRYTA                             | VOXELOTOR TAB 300 MG                      |             | 82805080000310 | Brand         |
| OXBRYTA                             | VOXELOTOR TAB 500 MG 82805080000320 Brand |             | Brand          |               |

| OXBRYTA           | TA VOXELOTOR TAB FOR ORAL SUSP 300 MG 82805080007320 Brand |  |  |
|-------------------|--|--|--|
|                   |  |  |  |
| Approval Criteria |  |  |  |

- **1** Both of the following:
  - Diagnosis of sickle cell disease
  - Member has persistent anemia requiring transfusion within the past 12 months

- **2** Prescribed by or in consultation with one of the following:
  - Hematologist
  - Specialist with experience in the treatment of sickle cell disease

#### AND

- 3 One of the following:
  - Member is stable on hydroxyurea for at least 90 days
  - Submission of medical records (e.g., chart notes) documenting trial and failure, contraindication, or intolerance to hydroxyurea

#### **AND**

4 - Member's baseline hemoglobin (Hgb) is between 5.5 to 10.5 g/dL prior to use of Oxybryta

#### **AND**

**5** - Requested medication will not be used in combination with Adakveo (crizanlizumab)

| Notes | *Continuation of therapy/coverage criteria will not be applied to person |
|-------|--|
|       | s who were not previously approved for coverage whose therapy was i      |
|       | nitiated using a manufacturer-sponsored free drug program, provider s    |
|       | amples, and/or vouchers.   |

| Product Name: Oxbryta |                     |
|-----------------------|---------------------|
| Approval Length       | 12 month(s)         |
| Therapy Stage         | Reauthorization     |
| Guideline Type        | Prior Authorization |

| Product<br>Name | Generic Name                       | GPI            | Brand/Generic |
|-----------------|------------------------------------|----------------|---------------|
| OXBRYTA         | VOXELOTOR TAB 300 MG               | 82805080000310 | Brand         |
| OXBRYTA         | VOXELOTOR TAB 500 MG               | 82805080000320 | Brand         |
| OXBRYTA         | VOXELOTOR TAB FOR ORAL SUSP 300 MG | 82805080007320 | Brand         |

- **1** Submission of medical records (e.g., chart notes) documenting from the previous 12 months positive clinical response to therapy as evidenced by one of the following:
  - Decreased frequency of sickle cell hospitalizations or urgent care visits
  - Decreased frequency of vaso-occlusive crisis
  - Reduction in use of pain medications
  - Improved quality of life (e.g. decreased pain, fewer missed day of work/school, increase in activities, etc.)
  - Reduced need for transfusions

| *Continuation of therapy/coverage criteria will not be applied to person s who were not previously approved for coverage whose therapy was i |
|--|
| nitiated using a manufacturer-sponsored free drug program, provider s amples, and/or vouchers.   |

| Date      | Notes                   |
|-----------|-------------------------|
| 10/6/2023 | 2024 New Implementation |

| Oxervate (cenegermin)   |  |
|---|--|
| (2) Shakuruyuunahalalada Shikin hakun aada aada a daa ahii kalkati aadakka aada karikati. |  |
|   |  |

| Guideline ID   | GL-137246             |
|----------------|-----------------------|
| Guideline Name | Oxervate (cenegermin) |
| Formulary      | Quartz                |

# **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

# 1. Criteria

| Product Name: Oxervate |            |                        |     |               |
|------------------------|------------|------------------------|-----|---------------|
| Approval Le            | ength      | 8 Week(s) <sup>^</sup> |     |               |
| Guideline T            | уре        | Prior Authorization    |     |               |
| Product                | Generic Na | me                     | GPI | Brand/Generic |

| Product<br>Name | Generic Name                                  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| OXERVATE        | CENEGERMIN-BKBJ OPHTH SOLN 0.002% (20 MCG/ML) | 86770020202020 | Brand         |

# **Approval Criteria**

1 - Confirmed diagnosis of Stage 2\* or Stage 3\* Neurotrophic Keratitis

2 - Prescribed by, or in consultation with, an ophthalmologist

#### **AND**

**3** - Submission of medical records (e.g., chart notes) confirming decreased or loss of corneal sensitivity and corneal epithelium changes

#### **AND**

**4** - Underlying conditions are being treated, if appropriate (e.g., herpetic eye disease, diabetes, dry eye, multiple sclerosis, etc.)

#### AND

- **5** Failure to improve with conservative management after an adequate trial of one of the following for at least two weeks:
  - Ocular lubricants
  - Artificial tears

#### **AND**

6 - Discontinuation of ophthalmic steroids or avoidance of ophthalmic preservatives

| Notes | *Stage 2 (Moderate) = NK exhibits nonhealing persistent epithelial defe  |
|-------|--|
|       | Stage 3 (Severe) = NK exhibits corneal ulceration involving subepitheli  |
|       | al (stromal) tissue which may progress to corneal  |
|       | perforation.   |
|       | ^ Maximum coverage is limited to 56 days per lifetime approval. Oxerv  |
|       | ate is hard-coded with a quantity limit of 56 days of therapy per lifetime.  Subsequent request will be reviewed using the off-label guideline |
|       | Subsequent request will be reviewed using the on-label guideline   |

|   | Date | Notes |
|---|------|-------|
| ı |      |       |

| 12/6/2023 | New program |
|-----------|-------------|
|           |             |

| Oxymorphone Hydrochloride  |
|--|
| Substituting control banks to be the control control and the date of provide control and c |

| Guideline ID          | GL-129859                 |
|-----------------------|---------------------------|
| <b>Guideline Name</b> | Oxymorphone Hydrochloride |
| Formulary             | Quartz                    |

# **Guideline Note:**

| Effective Date: |
|-----------------|
|-----------------|

| rization          |
|-------------------|
| ization - IL Plan |
|                   |

| Product Name                       | Generic Name                       | GPI            | Brand/Generic |
|------------------------------------|------------------------------------|----------------|---------------|
| OXYMORPHONE<br>HYDROCHLORIDE       | OXYMORPHONE HCL TAB 5 MG           | 65100080100305 | Generic       |
| OXYMORPHONE<br>HYDROCHLORIDE       | OXYMORPHONE HCL TAB 10 MG          | 65100080100310 | Generic       |
| OXYMORPHONE<br>HYDROCHLORIDE<br>ER | OXYMORPHONE HCL TAB ER 12HR 5 MG   | 65100080107405 | Generic       |
| OXYMORPHONE<br>HYDROCHLORIDE<br>ER | OXYMORPHONE HCL TAB ER 12HR 7.5 MG | 65100080107407 | Generic       |

| OXYMORPHONE<br>HYDROCHLORIDE<br>ER | OXYMORPHONE HCL TAB ER 12HR 10 MG | 65100080107410 | Generic |
|------------------------------------|-----------------------------------|----------------|---------|
| OXYMORPHONE<br>HYDROCHLORIDE<br>ER | OXYMORPHONE HCL TAB ER 12HR 15 MG | 65100080107415 | Generic |
| OXYMORPHONE<br>HYDROCHLORIDE<br>ER | OXYMORPHONE HCL TAB ER 12HR 20 MG | 65100080107420 | Generic |
| OXYMORPHONE<br>HYDROCHLORIDE<br>ER | OXYMORPHONE HCL TAB ER 12HR 30 MG | 65100080107430 | Generic |
| OXYMORPHONE<br>HYDROCHLORIDEER     | OXYMORPHONE HCL TAB ER 12HR 40 MG | 65100080107440 | Generic |

**1** - For Oxymorphone IR requests ONLY: Trial and failure, contraindication, or intolerance to two generic immediate-release narcotics

#### OR

- **2** For Oxymorphone ER requests ONLY: Trial and failure, contraindication, or intolerance to BOTH of the following:
  - generic extended release morphine
  - extended release oxycodone

|  | *Member new to the plan (as evidenced by coverage effective date of I ess than or equal to 90 days) who initiated therapy using a manufactur er-sponsored free drug program, provider samples, and/or vouchers wil I go through initial criteria, otherwise for continuation of therapy for new to plan, reauthorization criteria applies |
|--|---|
|--|---|

| Product Name: Oxymorphone Immediate Release (IR), Oxymorphone Extended Release (ER) |                                 |                        |                |               |
|---|---------------------------------|------------------------|----------------|---------------|
| Approval Length   |                                 | 12 month(s)            |                |               |
| Therapy Stage   | apy Stage Initial Authorization |                        |                |               |
| Guideline Type  | Prior Authorization - MN Plan   |                        |                |               |
| Product Name G  |                                 | eneric Name            | GPI            | Brand/Generic |
| OXYMORPHONE OX<br>HYDROCHLORIDE   |                                 | YMORPHONE HCL TAB 5 MG | 65100080100305 | Generic       |

| OXYMORPHONE<br>HYDROCHLORIDE       | OXYMORPHONE HCL TAB 10 MG          | 65100080100310 | Generic |
|------------------------------------|------------------------------------|----------------|---------|
| OXYMORPHONE<br>HYDROCHLORIDE<br>ER | OXYMORPHONE HCL TAB ER 12HR 5 MG   | 65100080107405 | Generic |
| OXYMORPHONE<br>HYDROCHLORIDE<br>ER | OXYMORPHONE HCL TAB ER 12HR 7.5 MG | 65100080107407 | Generic |
| OXYMORPHONE<br>HYDROCHLORIDE<br>ER | OXYMORPHONE HCL TAB ER 12HR 10 MG  | 65100080107410 | Generic |
| OXYMORPHONE<br>HYDROCHLORIDE<br>ER | OXYMORPHONE HCL TAB ER 12HR 15 MG  | 65100080107415 | Generic |
| OXYMORPHONE<br>HYDROCHLORIDE<br>ER | OXYMORPHONE HCL TAB ER 12HR 20 MG  | 65100080107420 | Generic |
| OXYMORPHONE<br>HYDROCHLORIDE<br>ER | OXYMORPHONE HCL TAB ER 12HR 30 MG  | 65100080107430 | Generic |
| OXYMORPHONE<br>HYDROCHLORIDEER     | OXYMORPHONE HCL TAB ER 12HR 40 MG  | 65100080107440 | Generic |

- 1 For Oxymorphone IR requests ONLY, One of the following:
- **1.1** Trial and failure, contraindication, or intolerance to two generic immediate-release narcotics

OR

- 1.2 Both of the following
  - Member has stage four metastatic cancer
  - The requested drug is being used to treat cancer-related pain

OR

- 2 For Oxymorphone ER requests ONLY, one of the following:
  - **2.1** Trial and failure, contraindication, or intolerance to BOTH of the following:

- generic extended release morphine extended release oxycodone

#### OR

# **2.2** Both of the following:

- Member has stage four metastatic cancer
  The requested drug is being used to treat cancer-related pain

| Notes | *Member new to the plan (as evidenced by coverage effective date of I ess than or equal to 90 days) who initiated therapy using a manufactur er-sponsored free drug program, provider samples, and/or vouchers wil I go through initial criteria, otherwise for continuation of therapy for new |
|-------|---|
|       | to plan, reauthorization criteria applies   |

| Product Name: Oxymorphone Immediate Release (IR), Oxymorphone Extended Release (ER) |  |  |
|---|--|--|
| Approval Length 12 month(s)   |  |  |
| Therapy Stage Reauthorization   |  |  |
| Guideline Type Prior Authorization - IL and MN Plans                                |  |  |

| Product Name                       | Generic Name                       | GPI            | Brand/Generic |
|------------------------------------|------------------------------------|----------------|---------------|
| OXYMORPHONE<br>HYDROCHLORIDE       | OXYMORPHONE HCL TAB 5 MG           | 65100080100305 | Generic       |
| OXYMORPHONE<br>HYDROCHLORIDE       | OXYMORPHONE HCL TAB 10 MG          | 65100080100310 | Generic       |
| OXYMORPHONE<br>HYDROCHLORIDE<br>ER | OXYMORPHONE HCL TAB ER 12HR 5 MG   | 65100080107405 | Generic       |
| OXYMORPHONE<br>HYDROCHLORIDE<br>ER | OXYMORPHONE HCL TAB ER 12HR 7.5 MG | 65100080107407 | Generic       |
| OXYMORPHONE<br>HYDROCHLORIDE<br>ER | OXYMORPHONE HCL TAB ER 12HR 10 MG  | 65100080107410 | Generic       |
| OXYMORPHONE<br>HYDROCHLORIDE<br>ER | OXYMORPHONE HCL TAB ER 12HR 15 MG  | 65100080107415 | Generic       |
| OXYMORPHONE<br>HYDROCHLORIDE<br>ER | OXYMORPHONE HCL TAB ER 12HR 20 MG  | 65100080107420 | Generic       |
| OXYMORPHONE                        | OXYMORPHONE HCL TAB ER 12HR 30 MG  | 65100080107430 | Generic       |

| HYDROCHLORIDE<br>ER            |                                   |                |         |
|--------------------------------|-----------------------------------|----------------|---------|
| OXYMORPHONE<br>HYDROCHLORIDEER | OXYMORPHONE HCL TAB ER 12HR 40 MG | 65100080107440 | Generic |

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug

| Notes | *Member new to the plan (as evidenced by coverage effective date of I        |
|-------|--|
|       | ess than or equal to 90 days) who initiated therapy using a manufactur       |
|       | er-sponsored free drug program, provider samples, and/or vouchers wil        |
|       | I go through initial criteria, otherwise for continuation of therapy for new |
|       | to plan, reauthorization criteria applies                                    |

| Product Name: Oxymorphone Immediate Release (IR), Oxymorphone Extended Release (ER)  Approval Length 12/31/2039 |  |  |
|---|--|--|
|   |  |  |

| Product Name                       | Generic Name                       | GPI            | Brand/Generic |
|------------------------------------|------------------------------------|----------------|---------------|
| OXYMORPHONE<br>HYDROCHLORIDE       | OXYMORPHONE HCL TAB 5 MG           | 65100080100305 | Generic       |
| OXYMORPHONE<br>HYDROCHLORIDE       | OXYMORPHONE HCL TAB 10 MG          | 65100080100310 | Generic       |
| OXYMORPHONE<br>HYDROCHLORIDE<br>ER | OXYMORPHONE HCL TAB ER 12HR 5 MG   | 65100080107405 | Generic       |
| OXYMORPHONE<br>HYDROCHLORIDE<br>ER | OXYMORPHONE HCL TAB ER 12HR 7.5 MG | 65100080107407 | Generic       |
| OXYMORPHONE<br>HYDROCHLORIDE<br>ER | OXYMORPHONE HCL TAB ER 12HR 10 MG  | 65100080107410 | Generic       |
| OXYMORPHONE<br>HYDROCHLORIDE<br>ER | OXYMORPHONE HCL TAB ER 12HR 15 MG  | 65100080107415 | Generic       |
| OXYMORPHONE<br>HYDROCHLORIDE<br>ER | OXYMORPHONE HCL TAB ER 12HR 20 MG  | 65100080107420 | Generic       |
| OXYMORPHONE<br>HYDROCHLORIDE<br>ER | OXYMORPHONE HCL TAB ER 12HR 30 MG  | 65100080107430 | Generic       |
| OXYMORPHONE<br>HYDROCHLORIDEER     | OXYMORPHONE HCL TAB ER 12HR 40 MG  | 65100080107440 | Generic       |

**1** - For Oxymorphone IR requests ONLY: Trial and failure, contraindication, or intolerance to two generic immediate-release narcotics

OR

- **2** For Oxymorphone ER requests ONLY: Trial and failure, contraindication, or intolerance to BOTH of the following:
  - generic extended release morphine
  - extended release oxycodone

| Date      | Notes                   |
|-----------|-------------------------|
| 8/14/2023 | 2024 New Implementation |

| Palforzia (peanut powder)  |  |  |  |
|--|--|--|--|
| The Date of Supplement to Anglesge. The Bottom Control of State and State Stat |  |  |  |
|  |  |  |  |

| Guideline ID          | GL-129373                 |
|-----------------------|---------------------------|
| <b>Guideline Name</b> | Palforzia (peanut powder) |
| Formulary             | Quartz                    |

# **Guideline Note:**

| Effective Date: |
|-----------------|
|-----------------|

| Product Name: Palforzia                         |                       |
|---|-----------------------|
| Approval Length 12 month(s)                     |                       |
| Therapy Stage                                   | Initial Authorization |
| Guideline Type Prior Authorization - ALL Plans* |                       |

| Product Name                            | Generic Name   | GPI            | Brand/Generic |
|---|--|----------------|---------------|
| PALFORZIA<br>INITIAL DOSE<br>ESCALATION | PEANUT POWDER-DNFP STARTER PACK 0.5 & 1 & 1.5 & 3 & 6 MG     | 2010004020H510 | Brand         |
| PALFORZIA<br>LEVEL 1                    | PEANUT POWDER-DNFP CAP SPRINKLE PACK 3 X 1 MG (3 MG DOSE)    | 2010004020H525 | Brand         |
| PALFORZIA<br>LEVEL 2                    | PEANUT POWDER-DNFP CAP SPRINKLE PACK 6<br>X 1 MG (6 MG DOSE) | 2010004020H530 | Brand         |
| PALFORZIA<br>LEVEL 3                    | PEANUT POWDER-DNFP PACK 2 X 1 MG & 10 MG (12 MG DOSE)        | 2010004020H535 | Brand         |

| PALFORZIA<br>LEVEL 4                   | PEANUT POWDER-DNFP CAP SPRINKLE PACK<br>20 MG (20 MG DOSE)     | 2010004020H540 | Brand |
|--|--|----------------|-------|
| PALFORZIA<br>LEVEL 5                   | PEANUT POWDER-DNFP CAP SPRINKLE PACK 2<br>X 20 MG (40 MG DOSE) | 2010004020H545 | Brand |
| PALFORZIA<br>LEVEL 6                   | PEANUT POWDER-DNFP CAP SPRINKLE PACK 4<br>X 20 MG (80 MG DOSE) | 2010004020H550 | Brand |
| PALFORZIA<br>LEVEL 7                   | PEANUT POWDER-DNFP PACK 20 MG & 100 MG (120 MG DOSE)           | 2010004020H555 | Brand |
| PALFORZIA<br>LEVEL 8                   | PEANUT POWDER-DNFP PACK 3 X 20 MG & 100 MG (160 MG DOSE)       | 2010004020H560 | Brand |
| PALFORZIA<br>LEVEL 9                   | PEANUT POWDER-DNFP PACK 2 X 100 MG (200 MG DOSE)               | 2010004020H565 | Brand |
| PALFORZIA<br>LEVEL 10                  | PEANUT POWDER-DNFP PACK 2 X 20 MG & 2 X 100 MG (240 MG DOSE)   | 2010004020H570 | Brand |
| PALFORZIA<br>LEVEL 11<br>(TITRATION)   | PEANUT ALLERGEN POWDER-DNFP TITRATION PACKET 300 MG            | 20100040203030 | Brand |
| PALFORZIA<br>LEVEL 11<br>(MAINTENANCE) | PEANUT ALLERGEN POWDER-DNFP<br>MAINTENANCE PACKET 300 MG       | 20100040203050 | Brand |

**1** - Submission of medical records (e.g., chart notes) documenting systemic allergic reaction to peanuts (e.g., anaphylaxis, tongue/throat swelling, shortness of breath/wheezing the requires treatment, urticaria, angioedema, hypotension, and/or vomiting that occurs within 1-2 hours after ingestion of peanut)

#### **AND**

**2** - Submission of medical records (e.g., chart notes) documenting a positive skin prick test (wheal diameter greater than or equal to 3 mm) OR peanut specific IgE (greater than or equal to 0.35 kUA/L) within the past 12 months

#### **AND**

3 - Used in conjunction with a peanut-avoidance diet

#### AND

4 - Patient is 4 years of age or older, to less than or equal to 17 years of age

### AND

**5** - Prescribed by or in consultation with an allergist/immunologist

| Notes | *Member new to the plan (as evidenced by coverage effective date of I ess than or equal to 90 days) and were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or you chors will go through real |
|-------|---|
|       | e drug program, provider samples, and/or vouchers will go through rea<br>uthorization criteria  |

| Product Name: Palforzia                         |                 |  |
|---|-----------------|--|
| Approval Length 12 month(s)                     |                 |  |
| Therapy Stage                                   | Reauthorization |  |
| Guideline Type Prior Authorization - ALL Plans* |                 |  |
|   |                 |  |

| Product Name                            | Generic Name   | GPI            | Brand/Generic |
|---|--|----------------|---------------|
| PALFORZIA<br>INITIAL DOSE<br>ESCALATION | PEANUT POWDER-DNFP STARTER PACK 0.5 & 1 & 1.5 & 3 & 6 MG       | 2010004020H510 | Brand         |
| PALFORZIA<br>LEVEL 1                    | PEANUT POWDER-DNFP CAP SPRINKLE PACK 3 X 1 MG (3 MG DOSE)      | 2010004020H525 | Brand         |
| PALFORZIA<br>LEVEL 2                    | PEANUT POWDER-DNFP CAP SPRINKLE PACK 6 X 1 MG (6 MG DOSE)      | 2010004020H530 | Brand         |
| PALFORZIA<br>LEVEL 3                    | PEANUT POWDER-DNFP PACK 2 X 1 MG & 10 MG (12 MG DOSE)          | 2010004020H535 | Brand         |
| PALFORZIA<br>LEVEL 4                    | PEANUT POWDER-DNFP CAP SPRINKLE PACK<br>20 MG (20 MG DOSE)     | 2010004020H540 | Brand         |
| PALFORZIA<br>LEVEL 5                    | PEANUT POWDER-DNFP CAP SPRINKLE PACK 2<br>X 20 MG (40 MG DOSE) | 2010004020H545 | Brand         |
| PALFORZIA<br>LEVEL 6                    | PEANUT POWDER-DNFP CAP SPRINKLE PACK 4<br>X 20 MG (80 MG DOSE) | 2010004020H550 | Brand         |
| PALFORZIA<br>LEVEL 7                    | PEANUT POWDER-DNFP PACK 20 MG & 100 MG (120 MG DOSE)           | 2010004020H555 | Brand         |
| PALFORZIA<br>LEVEL 8                    | PEANUT POWDER-DNFP PACK 3 X 20 MG & 100 MG (160 MG DOSE)       | 2010004020H560 | Brand         |
| PALFORZIA<br>LEVEL 9                    | PEANUT POWDER-DNFP PACK 2 X 100 MG (200 MG DOSE)               | 2010004020H565 | Brand         |
| PALFORZIA<br>LEVEL 10                   | PEANUT POWDER-DNFP PACK 2 X 20 MG & 2 X 100 MG (240 MG DOSE)   | 2010004020H570 | Brand         |
| PALFORZIA<br>LEVEL 11                   | PEANUT ALLERGEN POWDER-DNFP TITRATION PACKET 300 MG            | 20100040203030 | Brand         |

| (TITRATION)                            |  |                |       |
|--|--|----------------|-------|
| PALFORZIA<br>LEVEL 11<br>(MAINTENANCE) | PEANUT ALLERGEN POWDER-DNFP<br>MAINTENANCE PACKET 300 MG | 20100040203050 | Brand |

- 1 Submission of medical records (e.g., chart notes) documenting one of the following:
  - Member has a persistent peanut allergy as documented in an allergy/immunology clinic visit within the past 12 months
  - Member has a documented positive skin prick test (wheal diameter greater than or equal to 3 mm) or peanut specific IgE (greater than or equal to 0.35 kUA/L) within the past 12 months

#### **AND**

2 - Used in conjunction with a peanut-avoidance diet

#### **AND**

3 - Prescribed by or in consultation with an allergist/immunologist

| *Member new to the plan (as evidenced by coverage effective date of I ess than or equal to 90 days) and were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers will go through rea |
|---|
| uthorization criteria   |

| Date     | Notes                   |
|----------|-------------------------|
| 8/4/2023 | 2024 New Implementation |

| Palynziq   |
|--|
| (3) The best design arms to adaptive. The tile was been been considered and being been for the constitution of the constitutio |
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|  |

| Guideline ID          | GL-138053 |
|-----------------------|-----------|
| <b>Guideline Name</b> | Palynziq  |
| Formulary             | Quartz    |

# **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

# Note:

Member new to the plan (as evidenced by coverage effective date of less than or equal to 90 days) who initiated therapy using a manufacturer-sponsored free drug program, provider samples, and/or vouchers will go through initial criteria, otherwise for continuation of therapy for new to plan, reauthorization criteria applies

| Product Na                   | Name: Palynziq (10 and 20 mg dose)                             |  |                |               |  |
|------------------------------|--|--|----------------|---------------|--|
| Approval Le                  | ength  | 4 month(s)   |                |               |  |
| Therapy Stage Guideline Type |  | Initial Authorization                                  |                |               |  |
|                              |  | Prior Authorization - All plans except IL and MN Plans |                |               |  |
| Product<br>Name              | Generic Name   |  | GPI            | Brand/Generic |  |
| PALYNZIQ                     | PEGVALIASE-PQPZ SUBCUTANEOUS SOLN PREF<br>SYRINGE 2.5 MG/0.5ML |  | 3090855040E510 | Brand         |  |

| PALYNZIQ | PEGVALIASE-PQPZ SUBCUTANEOUS SOLN PREF<br>SYRINGE 10 MG/0.5ML | 3090855040E520 | Brand |
|----------|---|----------------|-------|
| PALYNZIQ | PEGVALIASE-PQPZ SUBCUTANEOUS SOLN PREF<br>SYRINGE 20 MG/ML    | 3090855040E530 | Brand |

1 - Diagnosis of Phenylketonuria (PKU)

**AND** 

2 - Member is 18 years of age or older

**AND** 

- **3** Blood phenylalanine (Phe) concentration greater than 600 micromol/L (10 mg/dL) despite both of the following:
  - Six months of adherent use of a Phe restricted diet
  - Two-month trial and failure, contraindication, or intolerance of sapropterin

#### **AND**

4 - Sapropterin must be discontinued prior to start of Palynziq

| Product Name: Palynziq (10 and 20 mg dose) |                                       |  |
|--|---------------------------------------|--|
| Approval Length                            | 12 month(s)                           |  |
| Therapy Stage                              | Initial Authorization                 |  |
| Guideline Type                             | Prior Authorization - IL and MN Plans |  |

| Product<br>Name | Generic Name   | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| PALYNZIQ        | PEGVALIASE-PQPZ SUBCUTANEOUS SOLN PREF<br>SYRINGE 2.5 MG/0.5ML | 3090855040E510 | Brand         |
| PALYNZIQ        | PEGVALIASE-PQPZ SUBCUTANEOUS SOLN PREF<br>SYRINGE 10 MG/0.5ML  | 3090855040E520 | Brand         |
| PALYNZIQ        | PEGVALIASE-PQPZ SUBCUTANEOUS SOLN PREF                         | 3090855040E530 | Brand         |

|  | SYRINGE 20 MG/ML |  |  |
|--|------------------|--|--|

1 - Diagnosis of Phenylketonuria (PKU)

#### **AND**

2 - Member is 18 years of age or older

#### **AND**

- $\bf 3$  Blood phenylalanine (Phe) concentration greater than 600 micromol/L (10 mg/dL) despite both of the following:
  - Six months of adherent use of a Phe restricted diet
  - Two-month trial and failure, contraindication, or intolerance of sapropterin

#### **AND**

4 - Sapropterin must be discontinued prior to start of Palynziq

| Product Name: Palynziq (40 mg dose) |   |  |
|-------------------------------------|---|--|
| Approval Length 4 month(s)          |   |  |
| Therapy Stage                       | Initial Authorization                             |  |
| Guideline Type                      | Quantity Limit - All plans except IL and MN Plans |  |

| Product<br>Name | Generic Name   | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| PALYNZIQ        | PEGVALIASE-PQPZ SUBCUTANEOUS SOLN PREF<br>SYRINGE 2.5 MG/0.5ML | 3090855040E510 | Brand         |
| PALYNZIQ        | PEGVALIASE-PQPZ SUBCUTANEOUS SOLN PREF<br>SYRINGE 10 MG/0.5ML  | 3090855040E520 | Brand         |
| PALYNZIQ        | PEGVALIASE-PQPZ SUBCUTANEOUS SOLN PREF<br>SYRINGE 20 MG/ML     | 3090855040E530 | Brand         |

1 - Diagnosis of Phenylketonuria (PKU)

#### **AND**

2 - Member is 18 years of age or older

#### **AND**

- **3** Blood phenylalanine (Phe) concentration greater than 600 micromol/L (10 mg/dL) despite both of the following:
  - Six months of adherent use of a Phe restricted diet
  - Two-month trial and failure, contraindication, or intolerance of sapropterin

#### **AND**

4 - Sapropterin must be discontinued prior to start of Palynziq

#### **AND**

- **5** One of the following:
  - 24-week trial of 20 mg/day dosing and failure to achieve a 20% reduction from baseline in Phe levels
  - Phe levels remain greater than 600 micromol/L

| Product Name: Palynziq (40 mg dose) |            |                                 |     |               |
|-------------------------------------|------------|---------------------------------|-----|---------------|
| Approval Le                         | ength      | 12 month(s)                     |     |               |
| Therapy Stage                       |            | Initial Authorization           |     |               |
| Guideline Type                      |            | Quantity Limit- IL and MN Plans |     |               |
| Product<br>Name                     | Generic Na | me                              | GPI | Brand/Generic |

| PALYNZIQ | PEGVALIASE-PQPZ SUBCUTANEOUS SOLN PREF<br>SYRINGE 2.5 MG/0.5ML | 3090855040E510 | Brand |
|----------|--|----------------|-------|
| PALYNZIQ | PEGVALIASE-PQPZ SUBCUTANEOUS SOLN PREF<br>SYRINGE 10 MG/0.5ML  | 3090855040E520 | Brand |
| PALYNZIQ | PEGVALIASE-PQPZ SUBCUTANEOUS SOLN PREF<br>SYRINGE 20 MG/ML     | 3090855040E530 | Brand |

1 - Diagnosis of Phenylketonuria (PKU)

**AND** 

2 - Member is 18 years of age or older

**AND** 

- **3** Blood phenylalanine (Phe) concentration greater than 600 micromol/L (10 mg/dL) despite both of the following:
  - Six months of adherent use of a Phe restricted diet
  - Two-month trial and failure, contraindication, or intolerance of sapropterin

**AND** 

4 - Sapropterin must be discontinued prior to start of Palynziq

**AND** 

- **5** One of the following:
  - 24-week trial of 20 mg/day dosing and failure to achieve a 20% reduction from baseline in Phe levels
  - Phe levels remain greater than 600 micromol/L

Product Name: Palynziq

| Approval Length | 12 month(s)         |
|-----------------|---------------------|
| Therapy Stage   | Reauthorization     |
| Guideline Type  | Prior Authorization |

| Product<br>Name | Generic Name   | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| PALYNZIQ        | PEGVALIASE-PQPZ SUBCUTANEOUS SOLN PREF<br>SYRINGE 2.5 MG/0.5ML | 3090855040E510 | Brand         |
| PALYNZIQ        | PEGVALIASE-PQPZ SUBCUTANEOUS SOLN PREF<br>SYRINGE 10 MG/0.5ML  | 3090855040E520 | Brand         |
| PALYNZIQ        | PEGVALIASE-PQPZ SUBCUTANEOUS SOLN PREF<br>SYRINGE 20 MG/ML     | 3090855040E530 | Brand         |

1 - Used in conjunction with a Phe restricted diet

#### **AND**

- 2 Submission of medical records (e.g., chart notes) documenting ONE of the following:
  - 20% reduction in Phe levels from baseline
  - Phe levels remain greater than 600 micromol/L

#### **AND**

3 - Not on concurrent sapropterin

| Date       | Notes  |
|------------|--------|
| 12/20/2023 | Update |

| Parathyroid Hormone Analogues for Osteoporosi   |  |  |  |
|---|--|--|--|
| (2) handaga antinagan hala sa kalan antinan kama kama ka kahala panaha anasha anasha kalana |  |  |  |

| Guideline ID          | GL-137247                                      |
|-----------------------|--|
| <b>Guideline Name</b> | Parathyroid Hormone Analogues for Osteoporosis |
| Formulary             | Quartz   |

### **Guideline Note:**

| Effective Date:    | 1/1/2024 |
|--------------------|----------|
| P&T Approval Date: |          |
| P&T Revision Date: |          |

### Note:

Member new to the plan (as evidenced by coverage effective date of less than or equal to 90 days) who initiated therapy using a manufacturer-sponsored free drug program, provider samples, and/or vouchers will go through initial criteria, otherwise for continuation of therapy for new to plan, reauthorization criteria applies.

## 1. Criteria

| Product Name: Forteo, Teriparatide, Tymlos                            |             |  |
|---|-------------|--|
| Diagnosis Osteoporosis in Postmenopausal Women                        |             |  |
| Approval Length   | 24 month(s) |  |
| Therapy Stage Initial Authorization                                   |             |  |
| Guideline Type Prior Authorization - All Plans except IL and MN Plans |             |  |

| Product<br>Name | Generic Name   | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| TYMLOS          | ABALOPARATIDE SUBCUTANEOUS SOLN PEN-<br>INJECTOR 3120 MCG/1.56ML | 3004400500D230 | Brand         |
| FORTEO          | TERIPARATIDE (RECOMBINANT) SOLN PEN-INJ<br>600 MCG/2.4ML         | 3004407000D220 | Brand         |
| TERIPARATIDE    | TERIPARATIDE (RECOMBINANT) SOLN PEN-INJ<br>620 MCG/2.48ML        | 3004407000D221 | Brand         |

1 - Medication will be self-administered or administered by a family member or friend

#### AND

2 - Will not be used in combination with anti-resorptive therapy or after denosumab therapy

#### **AND**

**3** - Diagnosis of osteoporosis with a T-score of less than or equal to -2.5 at the femoral neck, total hip, lumbar spine, or 33% (one-third) radius

#### **AND**

- 4 Very high risk of fracture defined by AT LEAST ONE of the following:
  - Recent fracture (e.g. within past 12 months)
  - Fracture while on approved osteoporosis therapy
  - Multiple fractures
  - Fractures while on drugs causing skeletal harm (e.g. long-term glucocorticoid use)
  - Very low T-score (less than -3.0)
  - High risk for falls
  - History of injurious falls

#### AND

**5** - Applies to Forteo and Teriparatide only: Trial and failure, contraindication, or intolerance to abaloparatide

| Product Name: Forteo, Teriparatide, Tymlos |                                       |
|--|---------------------------------------|
| Diagnosis                                  | Osteoporosis in Postmenopausal Women  |
| Approval Length                            | 12 month(s)                           |
| Therapy Stage                              | Initial Authorization                 |
| Guideline Type                             | Prior Authorization - IL and MN Plans |

| Product<br>Name | Generic Name   | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| TYMLOS          | ABALOPARATIDE SUBCUTANEOUS SOLN PEN-<br>INJECTOR 3120 MCG/1.56ML | 3004400500D230 | Brand         |
| FORTEO          | TERIPARATIDE (RECOMBINANT) SOLN PEN-INJ<br>600 MCG/2.4ML         | 3004407000D220 | Brand         |
| TERIPARATIDE    | TERIPARATIDE (RECOMBINANT) SOLN PEN-INJ<br>620 MCG/2.48ML        | 3004407000D221 | Brand         |

1 - Medication will be self-administered or administered by a family member or friend

#### AND

2 - Will not be used in combination with anti-resorptive therapy or after denosumab therapy

#### AND

**3** - Diagnosis of osteoporosis with a T-score of less than or equal to -2.5 at the femoral neck, total hip, lumbar spine, or 33% (one-third) radius

#### AND

- **4** Very high risk of fracture defined by AT LEAST ONE of the following:
  - Recent fracture (e.g. within past 12 months)
  - Fracture while on approved osteoporosis therapy
  - Multiple fractures
  - Fractures while on drugs causing skeletal harm (e.g. long-term glucocorticoid use)
  - Very low T-score (less than -3.0)

- High risk for falls
- History of injurious falls

#### AND

**5** - Applies to Forteo and Teriparatide only: Trial and failure, contraindication, or intolerance to abaloparatide

| Product Name: Forteo, Teriparatide, Tymlos                            |                                     |  |
|---|-------------------------------------|--|
| Diagnosis Osteopenia in Postmenopausal Women                          |                                     |  |
| Approval Length   | 24 month(s)                         |  |
| Therapy Stage   | Therapy Stage Initial Authorization |  |
| Guideline Type Prior Authorization - All Plans except IL and MN Plans |                                     |  |

| Product<br>Name | Generic Name   | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| TYMLOS          | ABALOPARATIDE SUBCUTANEOUS SOLN PEN-<br>INJECTOR 3120 MCG/1.56ML | 3004400500D230 | Brand         |
| FORTEO          | TERIPARATIDE (RECOMBINANT) SOLN PEN-INJ<br>600 MCG/2.4ML         | 3004407000D220 | Brand         |
| TERIPARATIDE    | TERIPARATIDE (RECOMBINANT) SOLN PEN-INJ<br>620 MCG/2.48ML        | 3004407000D221 | Brand         |

### **Approval Criteria**

1 - Medication will be self-administered or administered by a family member or friend

#### **AND**

2 - Will not be used in combination with anti-resorptive therapy or after denosumab therapy

#### **AND**

 $\bf 3$  - Diagnosis of osteopenia with a T-score between -1.0 and -2.5 at the femoral neck, total hip, lumbar spine, or 33% (one-third) radius

#### AND

**4** - 10-year probability of a hip fracture of at least 3% or major osteoporosis-related fracture of at least 20%

#### **AND**

- **5** Very high risk of fracture defined by AT LEAST ONE of the following:
  - Recent fracture (e.g. within past 12 months)
  - Fracture while on approved osteoporosis therapy
  - Multiple fractures
  - Fractures while on drugs causing skeletal harm (e.g. long-term glucocorticoid use)
  - Very high FRAX (major osteoporotic fracture > 30%, hip fracture > 4.5%)
  - High risk for falls
  - History of injurious falls

#### **AND**

**6** - Applies to Forteo and Teriparatide only: Trial and failure, contraindication, or intolerance to abaloparatide

| Product Name: Forteo, Teriparatide, Tymlos |                                       |
|--|---------------------------------------|
| Diagnosis                                  | Osteopenia in Postmenopausal Women    |
| Approval Length                            | 12 month(s)                           |
| Therapy Stage                              | Initial Authorization                 |
| Guideline Type                             | Prior Authorization - IL and MN Plans |

| Product<br>Name | Generic Name   | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| TYMLOS          | ABALOPARATIDE SUBCUTANEOUS SOLN PEN-<br>INJECTOR 3120 MCG/1.56ML | 3004400500D230 | Brand         |
| FORTEO          | TERIPARATIDE (RECOMBINANT) SOLN PEN-INJ<br>600 MCG/2.4ML         | 3004407000D220 | Brand         |
| TERIPARATIDE    | TERIPARATIDE (RECOMBINANT) SOLN PEN-INJ<br>620 MCG/2.48ML        | 3004407000D221 | Brand         |

### **Approval Criteria**

1 - Medication will be self-administered or administered by a family member or friend

#### **AND**

2 - Will not be used in combination with anti-resorptive therapy or after denosumab therapy

#### AND

**3** - Diagnosis of osteopenia with a T-score between -1.0 and -2.5 at the femoral neck, total hip, lumbar spine, or 33% (one-third) radius

#### **AND**

**4** - 10-year probability of a hip fracture of at least 3% or major osteoporosis-related fracture of at least 20%

#### **AND**

- **5** Very high risk of fracture defined by AT LEAST ONE of the following:
  - Recent fracture (e.g. within past 12 months)
  - Fracture while on approved osteoporosis therapy
  - Multiple fractures
  - Fractures while on drugs causing skeletal harm (e.g. long-term glucocorticoid use)
  - Very high FRAX (major osteoporotic fracture > 30%, hip fracture > 4.5%)
  - High risk for falls
  - History of injurious falls

#### **AND**

**6** - Applies to Forteo and Teriparatide only: Trial and failure, contraindication, or intolerance to abaloparatide

| Product Name: Forteo, Teriparatide, Tymlos |   |
|--|---|
| Diagnosis                                  | Osteoporosis Due to Prolonged Steroid Use |

| Approval Length | 24 month(s)  |
|-----------------|--|
| Therapy Stage   | Initial Authorization                                  |
| Guideline Type  | Prior Authorization - All Plans except IL and MN Plans |

| Product<br>Name | Generic Name   | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| TYMLOS          | ABALOPARATIDE SUBCUTANEOUS SOLN PEN-<br>INJECTOR 3120 MCG/1.56ML | 3004400500D230 | Brand         |
| FORTEO          | TERIPARATIDE (RECOMBINANT) SOLN PEN-INJ<br>600 MCG/2.4ML         | 3004407000D220 | Brand         |
| TERIPARATIDE    | TERIPARATIDE (RECOMBINANT) SOLN PEN-INJ<br>620 MCG/2.48ML        | 3004407000D221 | Brand         |

1 - Medication will be self-administered or administered by a family member or friend

#### **AND**

2 - Will not be used in combination with anti-resorptive therapy or after denosumab therapy

#### **AND**

**3** - Trial and failure (e.g. low-trauma fractures or decrease in BMD while on alendronate 70 mg per week), contraindication, or intolerance to therapy with at least one bisphosphonate

#### **AND**

**4** - Applies to Forteo and Teriparatide only: Trial and failure, contraindication, or intolerance to abaloparatide

| Product Name: Forteo, | Product Name: Forteo, Teriparatide, Tymlos |  |
|-----------------------|--|--|
| Diagnosis             | Osteoporosis Due to Prolonged Steroid Use  |  |
| Approval Length       | 12 month(s)                                |  |
| Therapy Stage         | Initial Authorization                      |  |
| Guideline Type        | Prior Authorization - IL and MN Plans      |  |

| Product<br>Name | Generic Name   | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| TYMLOS          | ABALOPARATIDE SUBCUTANEOUS SOLN PEN-<br>INJECTOR 3120 MCG/1.56ML | 3004400500D230 | Brand         |
| FORTEO          | TERIPARATIDE (RECOMBINANT) SOLN PEN-INJ<br>600 MCG/2.4ML         | 3004407000D220 | Brand         |
| TERIPARATIDE    | TERIPARATIDE (RECOMBINANT) SOLN PEN-INJ<br>620 MCG/2.48ML        | 3004407000D221 | Brand         |

**TYMLOS** 

1 - Medication will be self-administered or administered by a family member or friend

#### **AND**

2 - Will not be used in combination with anti-resorptive therapy or after denosumab therapy

#### **AND**

**3** - Trial and failure (e.g. low-trauma fractures or decrease in BMD while on alendronate 70 mg per week), contraindication, or intolerance to therapy with at least one bisphosphonate

#### **AND**

**4** - Applies to Forteo and Teriparatide only: Trial and failure, contraindication, or intolerance to abaloparatide

| Product Name    | Product Name: Forteo, Teriparatide, Tymlos |  |                 |               |
|-----------------|--|--|-----------------|---------------|
| Diagnosis       |  | Primary or Hypogonadal Osteoporos      | is in Men       |               |
| Approval Length |  | 24 month(s)                            |                 |               |
| Therapy Stage   |  | Initial Authorization                  |                 |               |
| Guideline Type  |  | Prior Authorization - All Plans except | IL and MN Plans |               |
| Product<br>Name | Generic                                    | Name                                   | GPI             | Brand/Generic |

ABALOPARATIDE SUBCUTANEOUS SOLN PEN-

**Brand** 

3004400500D230

|              | INJECTOR 3120 MCG/1.56ML                                  |                |       |
|--------------|---|----------------|-------|
| FORTEO       | TERIPARATIDE (RECOMBINANT) SOLN PEN-INJ<br>600 MCG/2.4ML  | 3004407000D220 | Brand |
| TERIPARATIDE | TERIPARATIDE (RECOMBINANT) SOLN PEN-INJ<br>620 MCG/2.48ML | 3004407000D221 | Brand |

1 - Medication will be self-administered or administered by a family member or friend

#### **AND**

2 - Will not be used in combination with anti-resorptive therapy or after denosumab therapy

#### **AND**

- **3** One of the following:
- **3.1** Trial and failure (e.g. low-trauma fractures or decrease in BMD while on alendronate 70 mg per week), contraindication, or intolerance to therapy with at least one bisphosphonate

#### OR

3.2 T-score of less than -2.5 and at least one fragility fracture

#### **AND**

**4** - Applies to Forteo and Teriparatide only: Trial and failure, contraindication, or intolerance to abaloparatide

| Product Name: Forteo, Teriparatide, Tymlos |  |
|--|--|
| Diagnosis                                  | Primary or Hypogonadal Osteoporosis in Men |
| Approval Length                            | 12 month(s)                                |
| Therapy Stage                              | Initial Authorization                      |
| Guideline Type                             | Prior Authorization - IL and MN Plans      |

| Product<br>Name | Generic Name   | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| TYMLOS          | ABALOPARATIDE SUBCUTANEOUS SOLN PEN-<br>INJECTOR 3120 MCG/1.56ML | 3004400500D230 | Brand         |
| FORTEO          | TERIPARATIDE (RECOMBINANT) SOLN PEN-INJ<br>600 MCG/2.4ML         | 3004407000D220 | Brand         |
| TERIPARATIDE    | TERIPARATIDE (RECOMBINANT) SOLN PEN-INJ<br>620 MCG/2.48ML        | 3004407000D221 | Brand         |

1 - Medication will be self-administered or administered by a family member or friend

#### AND

2 - Will not be used in combination with anti-resorptive therapy or after denosumab therapy

### **AND**

- **3** One of the following:
- **3.1** Trial and failure (e.g. low-trauma fractures or decrease in BMD while on alendronate 70 mg per week), contraindication, or intolerance to therapy with at least one bisphosphonate

#### OR

3.2 T-score of less than -2.5 and at least one fragility fracture

#### **AND**

**4** - Applies to Forteo and Teriparatide only: Trial and failure, contraindication, or intolerance to abaloparatide

| Product Name: Forteo, Teriparatide, Tymlos |                 |
|--|-----------------|
| Diagnosis                                  | All Indications |
| Approval Length                            | 24 Month(s)*    |

| Therapy Stage  | Reauthorization  |
|----------------|--|
| Guideline Type | Prior Authorization - All Plans except IL and MN Plans |

| Product<br>Name | Generic Name   | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| TYMLOS          | ABALOPARATIDE SUBCUTANEOUS SOLN PEN-<br>INJECTOR 3120 MCG/1.56ML | 3004400500D230 | Brand         |
| FORTEO          | TERIPARATIDE (RECOMBINANT) SOLN PEN-INJ<br>600 MCG/2.4ML         | 3004407000D220 | Brand         |
| TERIPARATIDE    | TERIPARATIDE (RECOMBINANT) SOLN PEN-INJ<br>620 MCG/2.48ML        | 3004407000D221 | Brand         |

**1** - Member is new to the plan (as evidenced by coverage effective date of less than or equal to 90 days) or who are established on therapy, will have coverage under their drug benefit for the remainder of the current treatment course (up to 24 months total). Restrictions to specific network pharmacies and participation in medication management programs may apply.

| Notes | *Maximum coverage is limited to a 24 months per lifetime approval. For  |
|-------|---|
|       | teo, Teriparatide and Tymlos are hard-coded with a quantity limit of 24 |
|       | months of therapy per lifetime. Subsequent request will be reviewed us  |
|       | ing the off-label guideline.  |

| Product Name: Forteo, Teriparatide, Tymlos |                                       |
|--|---------------------------------------|
| Diagnosis                                  | All Indications                       |
| Approval Length                            | 12 Month(s)*                          |
| Therapy Stage                              | Reauthorization                       |
| Guideline Type                             | Prior Authorization - IL and MN Plans |

| Product<br>Name | Generic Name   | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| TYMLOS          | ABALOPARATIDE SUBCUTANEOUS SOLN PEN-<br>INJECTOR 3120 MCG/1.56ML | 3004400500D230 | Brand         |
| FORTEO          | TERIPARATIDE (RECOMBINANT) SOLN PEN-INJ<br>600 MCG/2.4ML         | 3004407000D220 | Brand         |
| TERIPARATIDE    | TERIPARATIDE (RECOMBINANT) SOLN PEN-INJ<br>620 MCG/2.48ML        | 3004407000D221 | Brand         |

### **Approval Criteria**

| 90 days) or who are estremainder of the current | te plan (as evidenced by coverage effective date of less than or equal to tablished on therapy, will have coverage under their drug benefit for the t treatment course (up to 24 months total). Restrictions to specific d participation in medication management programs may apply. |
|---|---|
| Notes   | *Maximum coverage is limited to 24 months per lifetime approval. Forte o, Teriparatide and Tymlos are hard-coded with a quantity limit of 24 m onths of therapy per lifetime. Subsequent request will be reviewed usin g the off-label guideline.                                     |

| Date      | Notes       |
|-----------|-------------|
| 12/6/2023 | New program |

| ŀ | Pegfilgras   | tım  |              |  |
|---|--|--|--------------|--|
| • | The bit at image current is eliquique. The fier may have been record, or | named, or didded. Worlly that the list points in the concernile. | and invalen. |  |
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|   |  |  |              |  |

| Guideline ID          | GL-129860     |
|-----------------------|---------------|
| <b>Guideline Name</b> | Pegfilgrastim |
| Formulary             | Quartz        |

# **Guideline Note:**

| Effective Date: |
|-----------------|
|-----------------|

## 1. Criteria

| Product Name: Fulphila, Fylnetra, Nyvepria, Stimufend, Udenyca, Ziextenzo |            |                     |     |               |
|---|------------|---------------------|-----|---------------|
| Approval Length 12 month(s)   |            |                     |     |               |
| Guideline Type  |            | Prior Authorization |     |               |
| Product (   | Generic Na | ame                 | GPI | Brand/Generic |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| FULPHILA        | PEGFILGRASTIM-JMDB SOLN PREFILLED SYRINGE 6 MG/0.6ML    | 8240157020E520 | Brand         |
| FYLNETRA        | PEGFILGRASTIM-PBBK SOLN PREFILLED SYRINGE 6 MG/0.6ML    | 8240157060E520 | Brand         |
| NYVEPRIA        | PEGFILGRASTIM-APGF SOLN PREFILLED SYRINGE 6<br>MG/0.6ML | 8240157002E520 | Brand         |
| STIMUFEND       | PEGFILGRASTIM-FPGK SOLN PREFILLED SYRINGE 6<br>MG/0.6ML | 8240157015E520 | Brand         |
| UDENYCA         | PEGFILGRASTIM-CBQV SOLN AUTO-INJECTOR 6<br>MG/0.6ML     | 8240157010D520 | Brand         |

| UDENYCA   | PEGFILGRASTIM-CBQV SOLN PREFILLED SYRINGE 6 MG/0.6ML | 8240157010E520 | Brand |
|-----------|--|----------------|-------|
| ZIEXTENZO | PEGFILGRASTIM-BMEZ SOLN PREFILLED SYRINGE 6 MG/0.6ML | 8240157005E520 | Brand |

- 1 One of the following:
- **1.1** Both of the following:
- **1.1.1** Trial and failure (e.g., febrile neutropenia, delay in chemotherapy), contraindication, or intolerance to a filgrastim drug product

#### AND

**1.1.2** Trial and failure, contraindication, or intolerance to use of Ziextenzo in the clinic as a clinic administered drug

OR

- 1.2 Both of the following (Applies to Minnesota Plans ONLY):
  - Member has stage four metastatic cancer
  - The requested drug is being used as supportive care for their cancer treatment

| Notes | *Pharmacy benefit coverage information (preferred/nonpreferred status |
|-------|---|
|       | , restriction, etc) only applies to plans with                        |
|       | Quartz pharmacy coverage  |

| Date       | Notes                   |
|------------|-------------------------|
| 10/12/2023 | 2024 New Implementation |

| Pegylated Interferons  |
|--|
| State of the state |
|  |

| Guideline ID   | GL-129861             |  |
|----------------|-----------------------|--|
| Guideline Name | Pegylated Interferons |  |
| Formulary      | Quartz                |  |

## **Guideline Note:**

| Effective Date: |
|-----------------|
|-----------------|

## 1. Criteria

| Product Name: Pegasy               | Product Name: Pegasys  |  |
|------------------------------------|--|--|
| Approval Length                    | ngth Approval Durations: Hepatitis = 48 weeks. Other indications = 12 months |  |
| Therapy Stage                      | Initial Authorization  |  |
| Guideline Type Prior Authorization |  |  |

| Product<br>Name | Generic Name   | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| PEGASYS         | PEGINTERFERON ALFA-2A SOLN PREFILLED SYR 180 MCG/0.5ML | 1235306005E540 | Brand         |
| PEGASYS         | PEGINTERFERON ALFA-2A INJ 180 MCG/ML                   | 12353060052020 | Brand         |

## **Approval Criteria**

| 1 - One of the following:                                      |  |
|--|--|
| <b>1.1</b> All of the following:                               |  |
| 1.1.1 Diagnosis of one of                                      | of the following:  |
| <ul><li>HBeAg positive ch</li><li>HBeAg negative cl</li></ul>  | ·  |
|  | AND  |
| 1.1.2 Member has comp  | pensated liver disease   |
|  | AND  |
| 1.1.3 Evidence of both of                                      | of the following:  |
| <ul><li>Viral replication</li><li>Liver inflammation</li></ul> |  |
|  | OR   |
|  | is being used alone or in a combination regimen that has a class 1 or e from the National Comprehensive Cancer Network (NCCN) in the tember*   |
|  | AND  |
| 2 - One of the following;                                      |  |
|  | self-administered by member<br>administered by a family member   |
| s<br>ni  | Continuation of therapy/coverage criteria will not be applied to person who were not previously approved for coverage whose therapy was i itiated using a manufacturer-sponsored free drug program, provider simples, and/or vouchers. |

Product Name: Pegasys

| 1              | Approval Durations: Hepatitis = 48 weeks. Other indications = 12 months |
|----------------|---|
| Therapy Stage  | Reauthorization   |
| Guideline Type | Prior Authorization   |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| PEGASYS         | PEGINTERFERON ALFA-2A SOLN PREFILLED SYR 180<br>MCG/0.5ML | 1235306005E540 | Brand         |
| PEGASYS         | PEGINTERFERON ALFA-2A INJ 180 MCG/ML                      | 12353060052020 | Brand         |

- **1** One of the following:
- **1.1** All of the following:
- **1.1.1** Diagnosis of one of the following:
  - HBeAg positive chronic hepatitis B
  - HBeAg negative chronic hepatitis B

**AND** 

1.1.2 Member has compensated liver disease

AND

- **1.1.3** Evidence of both of the following:
  - Viral replication
  - Liver inflammation

OR

**1.2** The requested drug is being used alone or in a combination regimen that has a class 1 or 2 recommendation for use from the National Comprehensive Cancer Network (NCCN) in the specific condition of the member\*

#### **AND**

- 2 One of the following;
  - Medication will be self-administered by member
  - · Medication will be administered by a family member

#### **AND**

**3** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months, response to therapy is stable or improvement seen on therapy with evidence-based clinical rationale to support continuing therapy

#### **AND**

**4** - Restrictions to specific network pharmacies and participation in medication management programs may apply

| Notes | *Continuation of therapy/coverage criteria will not be applied to person |  |
|-------|--|--|
|       | s who were not previously approved for coverage whose therapy was i      |  |
|       | nitiated using a manufacturer-sponsored free drug program, provider s    |  |
|       | amples, and/or vouchers.   |  |

| Date      | Notes                   |
|-----------|-------------------------|
| 8/14/2023 | 2024 New Implementation |

| Prad                          | Pradaxa Oral Pellets  |  |  |  |   |
|-------------------------------|---|--|--|--|---|
| The blast image cannot be the | played. The fire may have been moved, vacuumed, or allohed. Welly | y fluid de leis points in the conscribulació instales. |  |  | _ |
|                               |   |  |  |  |   |

| Guideline ID          | GL-129132            |  |
|-----------------------|----------------------|--|
| <b>Guideline Name</b> | Pradaxa Oral Pellets |  |
| Formulary             | Quartz               |  |

# **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

## 1. Criteria

| Product Name: Pradaxa Oral Pellets |                                |
|------------------------------------|--------------------------------|
| Approval Length                    | 12 month(s)                    |
| Therapy Stage                      | Initial Authorization          |
| Guideline Type                     | Step Therapy - IL and MN Plans |

| Product<br>Name   | Generic Name   | GPI            | Brand/Generic |
|---|--|----------------|---------------|
| PRADAXA   | DABIGATRAN ETEXILATE MESYLATE PELLET PACK 83337030203020 Brand 20 MG |                | Brand         |
| PRADAXA   | PRADAXA DABIGATRAN ETEXILATE MESYLATE PELLET PACK 30 MG              |                | Brand         |
| PRADAXA   | DABIGATRAN ETEXILATE MESYLATE PELLET PACK<br>40 MG                   | 83337030203030 | Brand         |
| PRADAXA DABIGATRAN ETEXILATE MESYLATE PELLET PACK 50 MG |  | 83337030203035 | Brand         |

| PRADAXA | DABIGATRAN ETEXILATE MESYLATE PELLET PACK<br>110 MG | 83337030203040 | Brand |
|---------|---|----------------|-------|
| PRADAXA | DABIGATRAN ETEXILATE MESYLATE PELLET PACK<br>150 MG | 83337030203045 | Brand |

1 - Trial and failure, contraindication, or intolerance to rivaroxaban suspension

| Product Name: Pradaxa Oral Pellets |                               |  |
|------------------------------------|-------------------------------|--|
| Approval Length 12 month(s)        |                               |  |
| Therapy Stage                      | Reauthorization               |  |
| Guideline Type                     | Step Therapy - IL or MN Plans |  |

| Product<br>Name  | Generic Name  | GPI            | Brand/Generic |
|--|---|----------------|---------------|
| PRADAXA  | DABIGATRAN ETEXILATE MESYLATE PELLET PACK<br>20 MG  | 83337030203020 | Brand         |
| PRADAXA  | DABIGATRAN ETEXILATE MESYLATE PELLET PACK<br>30 MG  | 83337030203025 | Brand         |
| PRADAXA  | DABIGATRAN ETEXILATE MESYLATE PELLET PACK<br>40 MG  | 83337030203030 | Brand         |
| PRADAXA  | DABIGATRAN ETEXILATE MESYLATE PELLET PACK<br>50 MG  | 83337030203035 | Brand         |
| PRADAXA  | DABIGATRAN ETEXILATE MESYLATE PELLET PACK<br>110 MG | 83337030203040 | Brand         |
| PRADAXA DABIGATRAN ETEXILATE MESYLATE PELLET PACK 150 MG |   | 83337030203045 | Brand         |

## **Approval Criteria**

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug

| Product Name: Pradaxa Oral Pellets                       |                      |  |     |               |
|--|----------------------|--|-----|---------------|
| Approval Length 12/31/2039                               |                      |  |     |               |
| Guideline Type Step Therapy - All Plans except IL and MN |                      |  |     |               |
| Product  | Product Generic Name |  | GPI | Brand/Generic |

| Name   |   |                |       |
|--|---|----------------|-------|
| PRADAXA  | DABIGATRAN ETEXILATE MESYLATE PELLET PACK<br>20 MG  | 83337030203020 | Brand |
| PRADAXA  | DABIGATRAN ETEXILATE MESYLATE PELLET PACK<br>30 MG  | 83337030203025 | Brand |
| PRADAXA DABIGATRAN ETEXILATE MESYLATE PELLET PACK 40 MG  PRADAXA DABIGATRAN ETEXILATE MESYLATE PELLET PACK 50 MG |   | 83337030203030 | Brand |
|  |   | 83337030203035 | Brand |
| PRADAXA  | DABIGATRAN ETEXILATE MESYLATE PELLET PACK<br>110 MG | 83337030203040 | Brand |
| PRADAXA  | DABIGATRAN ETEXILATE MESYLATE PELLET PACK<br>150 MG | 83337030203045 | Brand |

**1** - Trial and failure, contraindication, or intolerance to rivaroxaban suspension

| Date      | Notes       |
|-----------|-------------|
| 8/25/2023 | New Program |

| (3) Nationary warm shape. Nath as two or most, a reason and from the primarile or warms | Preferred and Unrestricted Insulin Quantity Limit Excep |   |  |  |  |  |  |
|---|---|---|--|--|--|--|--|
|   |   | Shakerara and hidagen hida as basical mad count of bill bill to purch any order of bill bill to purch and an analysis of bill bill bill bill bill bill bill bil |  |  |  |  |  |

| Guideline ID          | GL-139113   |  |
|-----------------------|---|--|
| <b>Guideline Name</b> | Preferred and Unrestricted Insulin Quantity Limit Exception |  |
| Formulary             | Quartz  |  |

## **Guideline Note:**

| Effective Date: | 1/17/2024 |
|-----------------|-----------|
|-----------------|-----------|

## 1. Criteria

| Product Name: Novolin N, Novolin R, Novolin 70/30, Novolog, Novolog 70/30, Humulin R U50<br>Semglee-yfgn |                |   | Humulin R U500, |       |
|--|----------------|---|-----------------|-------|
| Approval Length Guideline Type   |                | 12/31/2039  Quantity Limit - All plans except IL and MN Plans |                 |       |
|  |                |   |                 |       |
| NOVOLIN N  | INSUI<br>UNIT/ | LIN NPH (HUMAN) (ISOPHANE) INJ 100<br>ML                      | 27104020001805  | Brand |
| NOVOLIN R  | INSUI          | LIN REGULAR (HUMAN) INJ 100 UNIT/ML                           | 27104010002005  | Brand |
| NOVOLIN N<br>FLEXPEN RELION  |                | LIN NPH (HUMAN) (ISOPHANE) SUSP<br>NJECTOR 100 UNIT/ML        | 2710402000D320  | Brand |
| NOVOLIN N<br>FLEXPEN   |                | LIN NPH (HUMAN) (ISOPHANE) SUSP<br>NJECTOR 100 UNIT/ML        | 2710402000D320  | Brand |
| NOVOLIN N INSUL<br>RELION UNIT/  |                | LIN NPH (HUMAN) (ISOPHANE) INJ 100<br>ML                      | 27104020001805  | Brand |

| NOVOLIN 70/30<br>FLEXPEN RELION                  | INSULIN NPH & REGULAR SUSP PEN-INJ 100<br>UNIT/ML (70-30)       | 2710409000D320 | Brand |
|--|---|----------------|-------|
| NOVOLIN 70/30<br>FLEXPEN                         | INSULIN NPH & REGULAR SUSP PEN-INJ 100<br>UNIT/ML (70-30)       | 2710409000D320 | Brand |
| NOVOLIN 70/30<br>RELION                          | INSULIN NPH ISOPHANE & REGULAR HUMAN INJ 100 UNIT/ML (70-30)    | 27104090001810 | Brand |
| NOVOLIN 70/30                                    | INSULIN NPH ISOPHANE & REGULAR HUMAN INJ 100 UNIT/ML (70-30)    | 27104090001810 | Brand |
| NOVOLOG<br>FLEXPEN                               | INSULIN ASPART SOLN PEN-INJECTOR 100<br>UNIT/ML                 | 2710400200D220 | Brand |
| NOVOLOG<br>FLEXPEN RELION                        | INSULIN ASPART SOLN PEN-INJECTOR 100<br>UNIT/ML                 | 2710400200D220 | Brand |
| NOVOLOG<br>PENFILL                               | INSULIN ASPART SOLN CARTRIDGE 100<br>UNIT/ML                    | 2710400200E220 | Brand |
| NOVOLOG<br>RELION                                | INSULIN ASPART INJ SOLN 100 UNIT/ML                             | 27104002002022 | Brand |
| NOVOLOG  | INSULIN ASPART INJ SOLN 100 UNIT/ML                             | 27104002002022 | Brand |
| NOVOLOG MIX<br>70/30 PREFILLED<br>FLEXPEN        | INSULIN ASPART PROT & ASPART SUS PENINJ 100 UNIT/ML (70-30)     | 2710407000D320 | Brand |
| NOVOLOG MIX<br>70/30 PREFILLED<br>FLEXPEN RELION | INSULIN ASPART PROT & ASPART SUS PENINJ 100 UNIT/ML (70-30)     | 2710407000D320 | Brand |
| NOVOLOG MIX<br>70/30 RELION                      | INSULIN ASPART PROT & ASPART (HUMAN)<br>INJ 100 UNIT/ML (70-30) | 27104070001820 | Brand |
| NOVOLOG MIX<br>70/30                             | INSULIN ASPART PROT & ASPART (HUMAN)<br>INJ 100 UNIT/ML (70-30) | 27104070001820 | Brand |
| HUMULIN R U-500<br>KWIKPEN                       | INSULIN REGULAR (HUMAN) SOLN PEN-<br>INJECTOR 500 UNIT/ML       | 2710401000D250 | Brand |
| NOVOLIN R<br>RELION                              | INSULIN REGULAR (HUMAN) INJ 100 UNIT/ML                         | 27104010002005 | Brand |
| HUMULIN R U-500<br>(CONCENTRATED)                | INSULIN REGULAR (HUMAN) INJ 500 UNIT/ML                         | 27104010002015 | Brand |
| SEMGLEE  | INSULIN GLARGINE-YFGN SOLN PEN-<br>INJECTOR 100 UNIT/ML         | 2710400390D220 | Brand |
| SEMGLEE  | INSULIN GLARGINE-YFGN INJ 100 UNIT/ML                           | 27104003902020 | Brand |
|  |   |                |       |

1 - Submission of medical records (e.g., chart notes) documenting insulin dosing and directions

### AND

2 - Member requires more than 150 units per 30 days or, for U500 pens, more than 100 units per 30 days, or U500 vial, more than 333 units per 30 days based on daily prescribed dosing

Notes

The approval edits for quantity limit exceptions should be rounded up t o allow the full trade package size, when necessary (e.g., the requeste d quantity is 45ml per 30 days and the product is available in 30ml and 100ml, approve to a quantity of 60ml per 30 days, if the guideline criteria has been met).

| Product Name: Novolin N, Novolin R, Novolin 70/30, Novolog, Novolog 70/30, Humulin R U500, Semglee-yfgn |      |                                  |     |               |
|---|------|----------------------------------|-----|---------------|
| Approval Length   |      | 12 month(s)                      |     |               |
| Therapy Stage   |      | Initial Authorization            |     |               |
| Guideline Type  |      | Quantity Limit - IL and MN Plans |     |               |
| Product Name  | Gene | eric Name                        | GPI | Brand/Generic |

| Product Name                    | Generic Name  | GPI            | Brand/Generic |
|---------------------------------|---|----------------|---------------|
| NOVOLIN N                       | INSULIN NPH (HUMAN) (ISOPHANE) INJ 100<br>UNIT/ML               | 27104020001805 | Brand         |
| NOVOLIN R                       | INSULIN REGULAR (HUMAN) INJ 100 UNIT/ML                         | 27104010002005 | Brand         |
| NOVOLIN R<br>FLEXPEN RELION     | INSULIN REGULAR (HUMAN) SOLN PEN-<br>INJECTOR 100 UNIT/ML       | 2710401000D220 | Brand         |
| NOVOLIN R<br>FLEXPEN            | INSULIN REGULAR (HUMAN) SOLN PEN-<br>INJECTOR 100 UNIT/ML       | 2710401000D220 | Brand         |
| NOVOLIN R<br>RELION             | INSULIN REGULAR (HUMAN) INJ 100 UNIT/ML                         | 27104010002005 | Brand         |
| NOVOLIN N<br>FLEXPEN RELION     | INSULIN NPH (HUMAN) (ISOPHANE) SUSP<br>PEN-INJECTOR 100 UNIT/ML | 2710402000D320 | Brand         |
| NOVOLIN N<br>FLEXPEN            | INSULIN NPH (HUMAN) (ISOPHANE) SUSP<br>PEN-INJECTOR 100 UNIT/ML | 2710402000D320 | Brand         |
| NOVOLIN N<br>RELION             | INSULIN NPH (HUMAN) (ISOPHANE) INJ 100<br>UNIT/ML               | 27104020001805 | Brand         |
| NOVOLIN 70/30<br>FLEXPEN RELION | INSULIN NPH & REGULAR SUSP PEN-INJ 100<br>UNIT/ML (70-30)       | 2710409000D320 | Brand         |
| NOVOLIN 70/30<br>FLEXPEN        | INSULIN NPH & REGULAR SUSP PEN-INJ 100<br>UNIT/ML (70-30)       | 2710409000D320 | Brand         |
| NOVOLIN 70/30<br>RELION         | INSULIN NPH ISOPHANE & REGULAR HUMAN<br>INJ 100 UNIT/ML (70-30) | 27104090001810 | Brand         |
| NOVOLIN 70/30                   | INSULIN NPH ISOPHANE & REGULAR HUMAN INJ 100 UNIT/ML (70-30)    | 27104090001810 | Brand         |
| NOVOLOG<br>FLEXPEN              | INSULIN ASPART SOLN PEN-INJECTOR 100<br>UNIT/ML                 | 2710400200D220 | Brand         |
| NOVOLOG<br>FLEXPEN RELION       | INSULIN ASPART SOLN PEN-INJECTOR 100<br>UNIT/ML                 | 2710400200D220 | Brand         |

| NOVOLOG<br>PENFILL                               | INSULIN ASPART SOLN CARTRIDGE 100<br>UNIT/ML                    | 2710400200E220 | Brand |
|--|---|----------------|-------|
| NOVOLOG<br>RELION                                | INSULIN ASPART INJ SOLN 100 UNIT/ML                             | 27104002002022 | Brand |
| NOVOLOG  | INSULIN ASPART INJ SOLN 100 UNIT/ML                             | 27104002002022 | Brand |
| NOVOLOG MIX<br>70/30 PREFILLED<br>FLEXPEN        | INSULIN ASPART PROT & ASPART SUS PENINJ 100 UNIT/ML (70-30)     | 2710407000D320 | Brand |
| NOVOLOG MIX<br>70/30 PREFILLED<br>FLEXPEN RELION | INSULIN ASPART PROT & ASPART SUS PENINJ 100 UNIT/ML (70-30)     | 2710407000D320 | Brand |
| NOVOLOG MIX<br>70/30 RELION                      | INSULIN ASPART PROT & ASPART (HUMAN)<br>INJ 100 UNIT/ML (70-30) | 27104070001820 | Brand |
| NOVOLOG MIX<br>70/30                             | INSULIN ASPART PROT & ASPART (HUMAN)<br>INJ 100 UNIT/ML (70-30) | 27104070001820 | Brand |
| HUMULIN R U-500<br>KWIKPEN                       | INSULIN REGULAR (HUMAN) SOLN PEN-<br>INJECTOR 500 UNIT/ML       | 2710401000D250 | Brand |
| HUMULIN R U-500<br>(CONCENTRATED)                | INSULIN REGULAR (HUMAN) INJ 500 UNIT/ML                         | 27104010002015 | Brand |
| SEMGLEE  | INSULIN GLARGINE-YFGN SOLN PEN-<br>INJECTOR 100 UNIT/ML         | 2710400390D220 | Brand |
| SEMGLEE  | INSULIN GLARGINE-YFGN INJ 100 UNIT/ML                           | 27104003902020 | Brand |

1 - Submission of medical records (e.g., chart notes) documenting insulin dosing and directions

#### **AND**

**2** - Member requires more than 150 units per 30 days or, for U500 pens, more than 100 units per 30 days or, for U500 vial, more than 333 units per 30 days based on daily prescribed dosing

| The approval edits for quantity limit exceptions should be rounded up t o allow the full trade package size, when necessary (e.g., the requeste |
|---|
| d quantity is 45ml per 30 days and the product is available in 30ml and   |
| 100ml, approve to a quantity of 60ml per 30 days, if the guideline criteri  |
| a has been met).  |

| Product Name: Novolin<br>Semglee-yfgn | N, Novolin R, Novolin 70/30, Novolog, Novolog 70/30, Humulin R U500, |
|---------------------------------------|--|
| Approval Length                       | 12 month(s)  |

| Therapy Stage  | Reauthorization                  |
|----------------|----------------------------------|
| Guideline Type | Quantity Limit - IL and MN Plans |

| Product Name                                     | Generic Name   | GPI            | Brand/Generic |
|--|--|----------------|---------------|
| NOVOLIN N  | INSULIN NPH (HUMAN) (ISOPHANE) INJ 100<br>UNIT/ML                | 27104020001805 | Brand         |
| NOVOLIN R  | INSULIN REGULAR (HUMAN) INJ 100 UNIT/ML                          | 27104010002005 | Brand         |
| NOVOLIN R<br>FLEXPEN RELION                      | INSULIN REGULAR (HUMAN) SOLN PEN-<br>INJECTOR 100 UNIT/ML        | 2710401000D220 | Brand         |
| NOVOLIN R<br>FLEXPEN                             | INSULIN REGULAR (HUMAN) SOLN PEN-<br>INJECTOR 100 UNIT/ML        | 2710401000D220 | Brand         |
| NOVOLIN R<br>RELION                              | INSULIN REGULAR (HUMAN) INJ 100 UNIT/ML                          | 27104010002005 | Brand         |
| NOVOLIN N<br>FLEXPEN RELION                      | INSULIN NPH (HUMAN) (ISOPHANE) SUSP<br>PEN-INJECTOR 100 UNIT/ML  | 2710402000D320 | Brand         |
| NOVOLIN N<br>FLEXPEN                             | INSULIN NPH (HUMAN) (ISOPHANE) SUSP<br>PEN-INJECTOR 100 UNIT/ML  | 2710402000D320 | Brand         |
| NOVOLIN N<br>RELION                              | INSULIN NPH (HUMAN) (ISOPHANE) INJ 100<br>UNIT/ML                | 27104020001805 | Brand         |
| HUMULIN 70/30<br>KWIKPEN                         | INSULIN NPH & REGULAR SUSP PEN-INJ 100<br>UNIT/ML (70-30)        | 2710409000D320 | Brand         |
| NOVOLIN 70/30<br>FLEXPEN RELION                  | INSULIN NPH & REGULAR SUSP PEN-INJ 100<br>UNIT/ML (70-30)        | 2710409000D320 | Brand         |
| NOVOLIN 70/30<br>FLEXPEN                         | INSULIN NPH & REGULAR SUSP PEN-INJ 100<br>UNIT/ML (70-30)        | 2710409000D320 | Brand         |
| NOVOLIN 70/30<br>RELION                          | INSULIN NPH ISOPHANE & REGULAR HUMAN INJ 100 UNIT/ML (70-30)     | 27104090001810 | Brand         |
| NOVOLIN 70/30                                    | INSULIN NPH ISOPHANE & REGULAR HUMAN INJ 100 UNIT/ML (70-30)     | 27104090001810 | Brand         |
| NOVOLOG<br>FLEXPEN                               | INSULIN ASPART SOLN PEN-INJECTOR 100<br>UNIT/ML                  | 2710400200D220 | Brand         |
| NOVOLOG<br>FLEXPEN RELION                        | INSULIN ASPART SOLN PEN-INJECTOR 100<br>UNIT/ML                  | 2710400200D220 | Brand         |
| NOVOLOG<br>PENFILL                               | INSULIN ASPART SOLN CARTRIDGE 100<br>UNIT/ML                     | 2710400200E220 | Brand         |
| NOVOLOG<br>RELION                                | INSULIN ASPART INJ SOLN 100 UNIT/ML                              | 27104002002022 | Brand         |
| NOVOLOG  | INSULIN ASPART INJ SOLN 100 UNIT/ML                              | 27104002002022 | Brand         |
| NOVOLOG MIX<br>70/30 PREFILLED<br>FLEXPEN        | INSULIN ASPART PROT & ASPART SUS PEN-<br>INJ 100 UNIT/ML (70-30) | 2710407000D320 | Brand         |
| NOVOLOG MIX<br>70/30 PREFILLED<br>FLEXPEN RELION | INSULIN ASPART PROT & ASPART SUS PEN-<br>INJ 100 UNIT/ML (70-30) | 2710407000D320 | Brand         |
| NOVOLOG MIX                                      | INSULIN ASPART PROT & ASPART (HUMAN)                             | 27104070001820 | Brand         |

| 70/30 RELION                      | INJ 100 UNIT/ML (70-30)   |                |       |
|-----------------------------------|---|----------------|-------|
| NOVOLOG MIX<br>70/30              | INSULIN ASPART PROT & ASPART (HUMAN)<br>INJ 100 UNIT/ML (70-30) | 27104070001820 | Brand |
| HUMULIN R U-500<br>KWIKPEN        | INSULIN REGULAR (HUMAN) SOLN PEN-<br>INJECTOR 500 UNIT/ML       | 2710401000D250 | Brand |
| HUMULIN R U-500<br>(CONCENTRATED) | INSULIN REGULAR (HUMAN) INJ 500 UNIT/ML                         | 27104010002015 | Brand |
| SEMGLEE                           | INSULIN GLARGINE-YFGN SOLN PEN-<br>INJECTOR 100 UNIT/ML         | 2710400390D220 | Brand |
| SEMGLEE                           | INSULIN GLARGINE-YFGN INJ 100 UNIT/ML                           | 27104003902020 | Brand |

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug

| Notes | The approval edits for quantity limit exceptions should be rounded up t o allow the full trade package size, when necessary (e.g., the requeste d quantity is 45ml per 30 days and the product is available in 30ml and |
|-------|---|
|       | 100ml, approve to a quantity of 60ml per 30 days, if the guideline criteri a has been met).   |

| Date      | Notes          |
|-----------|----------------|
| 1/17/2024 | Update program |

| (3) This companies designed. The last term designed and t |  |
|--|--|

| Guideline ID          | GL-131588  |  |
|-----------------------|--|--|
| <b>Guideline Name</b> | Preferred Blood Glucose Test Strips Quantity Limit Exception |  |
| Formulary             | Quartz   |  |

## **Guideline Note:**

| Effective Date: |
|-----------------|
|-----------------|

## 1. Criteria

| Product Name: Onetouch Verio, Onetouch Ultra                     |  |  |
|--|--|--|
| Approval Length 12/31/2039                                       |  |  |
| Guideline Type Quantity Limit - All plans except IL and MN Plans |  |  |

| Product<br>Name                     | Generic Name             | GPI            | Brand/Generic |
|-------------------------------------|--------------------------|----------------|---------------|
| ONETOUCH<br>VERIO<br>TEST<br>STRIPS | GLUCOSE BLOOD TEST STRIP | 94100030006100 | Brand         |
| ONETOUCH<br>ULTRA                   | GLUCOSE BLOOD TEST STRIP | 94100030006100 | Brand         |

## **Approval Criteria**

**1** - Submission of medical records (e.g., chart notes) documenting directions and frequency of blood sugar checks indicating member requires more than 200 strips per 30 days

| Product Name: Onetouch Verio, Onetouch Ultra    |  |
|---|--|
| Approval Length 12 month(s)                     |  |
| Guideline Type Quantity Limit - IL and MN Plans |  |

| Product<br>Name                     | Generic Name             | GPI            | Brand/Generic |
|-------------------------------------|--------------------------|----------------|---------------|
| ONETOUCH<br>VERIO<br>TEST<br>STRIPS | GLUCOSE BLOOD TEST STRIP | 94100030006100 | Brand         |
| ONETOUCH<br>ULTRA                   | GLUCOSE BLOOD TEST STRIP | 94100030006100 | Brand         |

## **Approval Criteria**

**1** - Submission of medical records (e.g., chart notes) documenting directions and frequency of blood sugar checks indicating member requires more than 200 strips per 30 days

| Date       | Notes                   |
|------------|-------------------------|
| 10/24/2023 | 2024 New Implementation |

| Prevymis (letermovir)  |  |  |  |
|--|--|--|--|
| (2) The interference and the desired to the tensor of the set of t |  |  |  |
|  |  |  |  |

| Guideline ID                         | GL-135735 |
|--------------------------------------|-----------|
| Guideline Name Prevymis (letermovir) |           |
| Formulary                            | Quartz    |

## **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

## 1. Criteria

| Product Name: Prevymis |                                |  |                |               |
|------------------------|--------------------------------|--|----------------|---------------|
| Approval Length        |                                | 1 Course up to 200 Days                                |                |               |
| Guideline Type         |                                | Prior Authorization - ALL Plans Except IL and MN Plans |                |               |
| Product<br>Name        | Generic Name                   |  | GPI            | Brand/Generic |
| PREVYMIS               | PREVYMIS LETERMOVIR TAB 240 MG |  | 12200045000320 | Brand         |

## **Approval Criteria**

PREVYMIS LETERMOVIR TAB 480 MG

**1** - Requested drug is being used for cytomegalovirus (CMV) prophylaxis with one of the following:

Brand

12200045000340

- Post allogenic hematopoietic stem cell transplant
- Post kidney transplant

#### **AND**

**2** - Submission of medical records (e.g., chart notes) documenting cytomegalovirus (CMV)-seropositive recipient (R+) or a CMV positive donor (D+)

#### **AND**

- 3 One of the following:
  - Drug is initiated within the first allogenic hematopoietic stem cell transplant: 28 days post-transplant
  - Drug is initiated within the first kidney transplant: 7 days post-transplant

#### **AND**

**4** - Submission of medical records (e.g., chart notes) documenting that member does not have active CMV infection (CMV PCR level over 250 IU/mL) and is not receiving preemptive treatment (e.g., foscarnet)

#### **AND**

- **5** Prescribed by or in consultation with one of the following:
  - hematologist
  - oncologist
  - infectious disease specialist
  - transplant specialist

|  | *Member new to the plan (as evidenced by coverage effective date of I ess than or equal to 90 days) who are established on therapy, will have coverage under their drug benefit for the remainder of the current treat ment course (to a maximum of day 200 post-transplant)  ***Member new to the plan (as evidenced by coverage effective date of less than or equal to 90 days) who initiated therapy using a manufactu rer-sponsored free drug program, provider samples, and/or vouchers w ill go through initial criteria, otherwise for continuation of therapy for ne |
|--|---|
|--|---|

| w to plan, reauthorization criteria applies |  |
|---|--|
|---|--|

| Product Name: Prevymis |                                       |
|------------------------|---------------------------------------|
| Approval Length        | 12 months with 7 fills                |
| Therapy Stage          | Initial Authorization                 |
| Guideline Type         | Prior Authorization - IL and MN Plans |

| Product<br>Name | Generic Name          | GPI            | Brand/Generic |
|-----------------|-----------------------|----------------|---------------|
| PREVYMIS        | LETERMOVIR TAB 240 MG | 12200045000320 | Brand         |
| PREVYMIS        | LETERMOVIR TAB 480 MG | 12200045000340 | Brand         |

- **1** Requested drug is being used for cytomegalovirus (CMV) prophylaxis with one of the following:
  - Post allogenic hematopoietic stem cell transplant
  - Post kidney transplant

### AND

**2** - Submission of medical records (e.g., chart notes) documenting cytomegalovirus (CMV)-seropositive recipient (R+) or a CMV positive donor (D+)

#### AND

- **3** One of the following:
  - Drug is initiated within the first allogenic hematopoietic stem cell transplant: 28 days post-transplant
  - Drug is initiated within the first kidney transplant: 7 days post-transplant

#### AND

**4** - Submission of medical records (e.g., chart notes) documenting that member does not have active CMV infection (CMV PCR level over 250 IU/mL) and is not receiving preemptive

treatment (e.g., foscarnet)

#### **AND**

- **5** Prescribed by or in consultation with one of the following:
  - hematologist
  - oncologist
  - infectious disease specialist
  - transplant specialist

| Notes | *Member new to the plan (as evidenced by coverage effective date of I ess than or equal to 90 days) who are established on therapy, will have coverage under their drug benefit for the remainder of the current treat ment course (to a maximum of day 200 post-transplant)  ***Member new to the plan (as evidenced by coverage effective date of less than or equal to 90 days) who initiated therapy using a manufactu rer-sponsored free drug program, provider samples, and/or vouchers w ill go through initial criteria, otherwise for continuation of therapy for ne w to plan, reauthorization criteria applies |
|-------|---|
|       |   |

| Product Name: Prevymis |                                       |
|------------------------|---------------------------------------|
| Approval Length        | 12 month(s)                           |
| Therapy Stage          | Reauthorization                       |
| Guideline Type         | Prior Authorization - IL and MN Plans |

| Product<br>Name | Generic Name          | GPI            | Brand/Generic |
|-----------------|-----------------------|----------------|---------------|
| PREVYMIS        | LETERMOVIR TAB 240 MG | 12200045000320 | Brand         |
| PREVYMIS        | LETERMOVIR TAB 480 MG | 12200045000340 | Brand         |

### **Approval Criteria**

**1** - Submission of medical records (e.g., chart notes) documenting evidence-based clinical rationale for using a duration beyond 200 days post-transplant

| Notes | *Member new to the plan (as evidenced by coverage effective date of I ess than or equal to 90 days) who are established on therapy, will have coverage under their drug benefit for the remainder of the current treat ment course (to a maximum of day 200 post-transplant)  ***Member new to the plan (as evidenced by coverage effective date of |
|-------|---|
|-------|---|

| less than or equal to 90 days) who initiated therapy using a manufactu        |
|---|
| rer-sponsored free drug program, provider samples, and/or vouchers w          |
| ill go through initial criteria, otherwise for continuation of therapy for ne |
| w to plan, reauthorization criteria applies                                   |

| Date       | Notes                   |
|------------|-------------------------|
| 11/13/2023 | 2024 new implementation |

| Pulmonary Arterial Hypertension (PAH)  | ) Agents |
|--|----------|
| The best of the second state of the second sta |          |

| Guideline ID   | GL-129862                                    |
|----------------|--|
| Guideline Name | Pulmonary Arterial Hypertension (PAH) Agents |
| Formulary      | Quartz                                       |

# **Guideline Note:**

| Effective Date: |
|-----------------|
|-----------------|

## 1. Criteria

| Product Name: Preferred Drugs: Adempas, generic ambrisentan, generic bosentan, Opsumit, generic sildenafil, generic tadalafil, Uptravi |                       |  |  |
|--|-----------------------|--|--|
| Approval Length  | 12 month(s)           |  |  |
| Therapy Stage  | Initial Authorization |  |  |
| Guideline Type Prior Authorization - IL and MN Plans   |                       |  |  |
|  |                       |  |  |

| Product<br>Name | Generic Name          | GPI            | Brand/Generic |
|-----------------|-----------------------|----------------|---------------|
| AMBRISENTAN     | AMBRISENTAN TAB 5 MG  | 40160007000310 | Generic       |
| AMBRISENTAN     | AMBRISENTAN TAB 10 MG | 40160007000320 | Generic       |
| BOSENTAN        | BOSENTAN TAB 62.5 MG  | 40160015000320 | Generic       |
| BOSENTAN        | BOSENTAN TAB 125 MG   | 40160015000330 | Generic       |
| OPSUMIT         | MACITENTAN TAB 10 MG  | 40160050000320 | Brand         |

| ADEMPAS                      | RIOCIGUAT TAB 0.5 MG                                    | 40134050000310 | Brand   |
|------------------------------|---|----------------|---------|
| ADEMPAS                      | RIOCIGUAT TAB 1 MG                                      | 40134050000320 | Brand   |
| ADEMPAS                      | RIOCIGUAT TAB 1.5 MG                                    | 40134050000330 | Brand   |
| ADEMPAS                      | RIOCIGUAT TAB 2 MG                                      | 40134050000340 | Brand   |
| ADEMPAS                      | RIOCIGUAT TAB 2.5 MG                                    | 40134050000350 | Brand   |
| UPTRAVI<br>TITRATION<br>PACK | SELEXIPAG TAB THERAPY PACK 200 MCG (140) & 800 MCG (60) | 4012007000B720 | Brand   |
| UPTRAVI                      | SELEXIPAG TAB 200 MCG                                   | 40120070000310 | Brand   |
| UPTRAVI                      | SELEXIPAG TAB 400 MCG                                   | 40120070000315 | Brand   |
| UPTRAVI                      | SELEXIPAG TAB 600 MCG                                   | 40120070000320 | Brand   |
| UPTRAVI                      | SELEXIPAG TAB 800 MCG                                   | 40120070000325 | Brand   |
| UPTRAVI                      | SELEXIPAG TAB 1000 MCG                                  | 40120070000330 | Brand   |
| UPTRAVI                      | SELEXIPAG TAB 1200 MCG                                  | 40120070000335 | Brand   |
| UPTRAVI                      | SELEXIPAG TAB 1400 MCG                                  | 40120070000340 | Brand   |
| UPTRAVI                      | SELEXIPAG TAB 1600 MCG                                  | 40120070000345 | Brand   |
| UPTRAVI                      | SELEXIPAG FOR IV SOLN 1800 MCG                          | 40120070002120 | Brand   |
| SILDENAFIL<br>CITRATE        | SILDENAFIL CITRATE TAB 20 MG                            | 40143060100320 | Generic |
| SILDENAFIL<br>CITRATE        | SILDENAFIL CITRATE FOR SUSPENSION 10 MG/ML              | 40143060101920 | Generic |
| SILDENAFIL                   | SILDENAFIL CITRATE FOR SUSPENSION 10 MG/ML              | 40143060101920 | Generic |
| TADALAFIL                    | TADALAFIL TAB 20 MG (PAH)                               | 40143080000320 | Generic |
| ı <del></del>                |   |                |         |

**1** - Diagnosis of pulmonary arterial hypertension

### AND

- **2** Prescribed by or in consultation with one of the following:

  - Cardiologist Pulmonologist

| Notes  Member new to the plan (as evidenced by coverage effective date of ss than or equal to 90 days) who initiated therapy using a manufactur -sponsored free drug program, provider samples, and/or vouchers will go through initial criteria, otherwise for continuation of therapy for new o plan, reauthorization criteria applies |
|--|
|--|

| Product Name: Non-Preferred Drugs: Orenitram, Ventavis |                       |  |
|--|-----------------------|--|
| Approval Length 12 month(s)                            |                       |  |
| Therapy Stage  | Initial Authorization |  |
| Guideline Type Prior Authorization - IL and MN Plans   |                       |  |

| Product<br>Name                          | Generic Name  | GPI            | Brand/Generic |
|--|---|----------------|---------------|
| VENTAVIS                                 | ILOPROST INHALATION SOLUTION 10 MCG/ML                          | 40170060002020 | Brand         |
| VENTAVIS                                 | ILOPROST INHALATION SOLUTION 20 MCG/ML                          | 40170060002040 | Brand         |
| ORENITRAM<br>TITRATION<br>KIT MONTH<br>1 | TREPROSTINIL TAB ER TITR PK (MO1) 126 X0.125MG & 42 X0.25MG     | 4017008005C110 | Brand         |
| ORENITRAM<br>TITRATION<br>KIT MONTH<br>2 | TREPROSTINIL TAB ER TITR PK (MO2) 126 X0.125MG & 210 X0.25MG    | 4017008005C120 | Brand         |
| ORENITRAM<br>TITRATION<br>KIT MONTH<br>3 | TREPROSTINIL TAB ER TITR<br>PK(MO3)126X0.125MG&42X0.25MG&84X1MG | 4017008005C130 | Brand         |
| ORENITRAM                                | TREPROSTINIL DIOLAMINE TAB ER 0.125 MG (BASE EQUIV)             | 40170080050410 | Brand         |
| ORENITRAM                                | TREPROSTINIL DIOLAMINE TAB ER 0.25 MG (BASE EQUIV)              | 40170080050415 | Brand         |
| ORENITRAM                                | TREPROSTINIL DIOLAMINE TAB ER 1 MG (BASE EQUIV)                 | 40170080050420 | Brand         |
| ORENITRAM                                | TREPROSTINIL DIOLAMINE TAB ER 2.5 MG (BASE EQUIV)               | 40170080050425 | Brand         |
| ORENITRAM                                | TREPROSTINIL DIOLAMINE TAB ER 5 MG (BASE EQUIV)                 | 40170080050435 | Brand         |

**1** - Diagnosis of pulmonary arterial hypertension

### AND

- 2 Prescribed by or in consultation with one of the following:
  - Cardiologist
  - Pulmonologist

#### **AND**

3 - Trial and failure, contraindication, or intolerance to inhaled treprostinil (Tyvaso)

| Member new to the plan (as evidenced by coverage effective date of le ss than or equal to 90 days) who initiated therapy using a manufacturer -sponsored free drug program, provider samples, and/or vouchers will go through initial criteria, otherwise for continuation of therapy for new t |
|---|
| o plan, reauthorization criteria applies  |

Product Name: Preferred Drugs: Adempas, generic ambrisentan, generic bosentan, Opsumit, generic sildenafil, generic tadalafil, Uptravi; and Non-Preferred Drugs: Orenitram, Ventavis

Approval Length 12 month(s)

Therapy Stage Reauthorization

Guideline Type Prior Authorization - IL and MN Plans

| Product<br>Name              | Generic Name  | GPI            | Brand/Generic |
|------------------------------|---|----------------|---------------|
| AMBRISENTAN                  | AMBRISENTAN TAB 5 MG                                    | 40160007000310 | Generic       |
| AMBRISENTAN                  | AMBRISENTAN TAB 10 MG                                   | 40160007000320 | Generic       |
| BOSENTAN                     | BOSENTAN TAB 62.5 MG                                    | 40160015000320 | Generic       |
| BOSENTAN                     | BOSENTAN TAB 125 MG                                     | 40160015000330 | Generic       |
| OPSUMIT                      | MACITENTAN TAB 10 MG                                    | 40160050000320 | Brand         |
| ADEMPAS                      | RIOCIGUAT TAB 0.5 MG                                    | 40134050000310 | Brand         |
| ADEMPAS                      | RIOCIGUAT TAB 1 MG                                      | 40134050000320 | Brand         |
| ADEMPAS                      | RIOCIGUAT TAB 1.5 MG                                    | 40134050000330 | Brand         |
| ADEMPAS                      | RIOCIGUAT TAB 2 MG                                      | 40134050000340 | Brand         |
| ADEMPAS                      | RIOCIGUAT TAB 2.5 MG                                    | 40134050000350 | Brand         |
| UPTRAVI<br>TITRATION<br>PACK | SELEXIPAG TAB THERAPY PACK 200 MCG (140) & 800 MCG (60) | 4012007000B720 | Brand         |

| UPTRAVI                               | SELEXIPAG TAB 200 MCG   | 40120070000310 | Brand   |
|---------------------------------------|---|----------------|---------|
| UPTRAVI                               | SELEXIPAG TAB 400 MCG   | 40120070000315 | Brand   |
| UPTRAVI                               | SELEXIPAG TAB 600 MCG   | 40120070000320 | Brand   |
| UPTRAVI                               | SELEXIPAG TAB 800 MCG   | 40120070000325 | Brand   |
| UPTRAVI                               | SELEXIPAG TAB 1000 MCG  | 40120070000330 | Brand   |
| UPTRAVI                               | SELEXIPAG TAB 1200 MCG  | 40120070000335 | Brand   |
| UPTRAVI                               | SELEXIPAG TAB 1400 MCG  | 40120070000340 | Brand   |
| UPTRAVI                               | SELEXIPAG TAB 1600 MCG  | 40120070000345 | Brand   |
| UPTRAVI                               | SELEXIPAG FOR IV SOLN 1800 MCG                                  | 40120070002120 | Brand   |
| SILDENAFIL<br>CITRATE                 | SILDENAFIL CITRATE TAB 20 MG                                    | 40143060100320 | Generic |
| SILDENAFIL<br>CITRATE                 | SILDENAFIL CITRATE FOR SUSPENSION 10<br>MG/ML                   | 40143060101920 | Generic |
| SILDENAFIL                            | SILDENAFIL CITRATE FOR SUSPENSION 10<br>MG/ML                   | 40143060101920 | Generic |
| TADALAFIL                             | TADALAFIL TAB 20 MG (PAH)                                       | 40143080000320 | Generic |
| VENTAVIS                              | ILOPROST INHALATION SOLUTION 10 MCG/ML                          | 40170060002020 | Brand   |
| VENTAVIS                              | ILOPROST INHALATION SOLUTION 20 MCG/ML                          | 40170060002040 | Brand   |
| ORENITRAM<br>TITRATION KIT<br>MONTH 1 | TREPROSTINIL TAB ER TITR PK (MO1) 126<br>X0.125MG & 42 X0.25MG  | 4017008005C110 | Brand   |
| ORENITRAM<br>TITRATION KIT<br>MONTH 2 | TREPROSTINIL TAB ER TITR PK (MO2) 126<br>X0.125MG & 210 X0.25MG | 4017008005C120 | Brand   |
| ORENITRAM<br>TITRATION KIT<br>MONTH 3 | TREPROSTINIL TAB ER TITR<br>PK(MO3)126X0.125MG&42X0.25MG&84X1MG | 4017008005C130 | Brand   |
| ORENITRAM                             | TREPROSTINIL DIOLAMINE TAB ER 0.125 MG (BASE EQUIV)             | 40170080050410 | Brand   |
| ORENITRAM                             | TREPROSTINIL DIOLAMINE TAB ER 0.25 MG (BASE EQUIV)              | 40170080050415 | Brand   |
| ORENITRAM                             | TREPROSTINIL DIOLAMINE TAB ER 1 MG (BASE EQUIV)                 | 40170080050420 | Brand   |
| ORENITRAM                             | TREPROSTINIL DIOLAMINE TAB ER 2.5 MG (BASE EQUIV)               | 40170080050425 | Brand   |
| ORENITRAM                             | TREPROSTINIL DIOLAMINE TAB ER 5 MG (BASE EQUIV)                 | 40170080050435 | Brand   |

| 1 - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug |   |  |  |
|---|---|--|--|
| Notes   | Member new to the plan (as evidenced by coverage effective date of le ss than or equal to 90 days) who initiated therapy using a manufacturer -sponsored free drug program, provider samples, and/or vouchers will go through initial criteria, otherwise for continuation of therapy for new to plan, reauthorization criteria applies |  |  |

| Product Name: Preferred Drugs: Adempas, generic ambrisentan, generic bosentan, Opsumit, generic sildenafil, generic tadalafil, Uptravi |            |  |
|--|------------|--|
| Approval Length  | 12/31/2039 |  |
| Guideline Type Prior Authorization - All Plans Except IL and MN Plans  |            |  |

| Product<br>Name              | Generic Name  | GPI            | Brand/Generic |
|------------------------------|---|----------------|---------------|
| AMBRISENTAN                  | AMBRISENTAN TAB 5 MG                                    | 40160007000310 | Generic       |
| AMBRISENTAN                  | AMBRISENTAN TAB 10 MG                                   | 40160007000320 | Generic       |
| BOSENTAN                     | BOSENTAN TAB 62.5 MG                                    | 40160015000320 | Generic       |
| BOSENTAN                     | BOSENTAN TAB 125 MG                                     | 40160015000330 | Generic       |
| OPSUMIT                      | MACITENTAN TAB 10 MG                                    | 40160050000320 | Brand         |
| ADEMPAS                      | RIOCIGUAT TAB 0.5 MG                                    | 40134050000310 | Brand         |
| ADEMPAS                      | RIOCIGUAT TAB 1 MG                                      | 40134050000320 | Brand         |
| ADEMPAS                      | RIOCIGUAT TAB 1.5 MG                                    | 40134050000330 | Brand         |
| ADEMPAS                      | RIOCIGUAT TAB 2 MG                                      | 40134050000340 | Brand         |
| ADEMPAS                      | RIOCIGUAT TAB 2.5 MG                                    | 40134050000350 | Brand         |
| UPTRAVI<br>TITRATION<br>PACK | SELEXIPAG TAB THERAPY PACK 200 MCG (140) & 800 MCG (60) | 4012007000B720 | Brand         |
| UPTRAVI                      | SELEXIPAG TAB 200 MCG                                   | 40120070000310 | Brand         |
| UPTRAVI                      | SELEXIPAG TAB 400 MCG                                   | 40120070000315 | Brand         |
| UPTRAVI                      | SELEXIPAG TAB 600 MCG                                   | 40120070000320 | Brand         |
| UPTRAVI                      | SELEXIPAG TAB 800 MCG                                   | 40120070000325 | Brand         |
| UPTRAVI                      | SELEXIPAG TAB 1000 MCG                                  | 40120070000330 | Brand         |
| UPTRAVI                      | SELEXIPAG TAB 1200 MCG                                  | 40120070000335 | Brand         |
| UPTRAVI                      | SELEXIPAG TAB 1400 MCG                                  | 40120070000340 | Brand         |
| UPTRAVI                      | SELEXIPAG TAB 1600 MCG                                  | 40120070000345 | Brand         |

| UPTRAVI               | SELEXIPAG FOR IV SOLN 1800 MCG                | 40120070002120 | Brand   |
|-----------------------|---|----------------|---------|
| SILDENAFIL<br>CITRATE | SILDENAFIL CITRATE TAB 20 MG                  | 40143060100320 | Generic |
| SILDENAFIL<br>CITRATE | SILDENAFIL CITRATE FOR SUSPENSION 10<br>MG/ML | 40143060101920 | Generic |
| SILDENAFIL            | SILDENAFIL CITRATE FOR SUSPENSION 10<br>MG/ML | 40143060101920 | Generic |
| TADALAFIL             | TADALAFIL TAB 20 MG (PAH)                     | 40143080000320 | Generic |

**1** - Diagnosis of pulmonary arterial hypertension

### AND

- **2** Prescribed by or in consultation with one of the following:

  - Cardiologist Pulmonologist

| Notes | Member new to the plan (as evidenced by coverage effective date of le ss than or equal to 90 days) who initiated therapy using a manufacturer -sponsored free drug program, provider samples, and/or vouchers will go through initial criteria, otherwise for continuation of therapy for new to plan, reauthorization criteria applies |
|-------|---|
|-------|---|

| Product Name: Non-Preferred Drugs: Orenitram, Ventavis                |            |  |
|---|------------|--|
| Approval Length   | 12/31/2039 |  |
| Guideline Type Prior Authorization - All Plans Except IL and MN Plans |            |  |

| Product<br>Name                          | Generic Name   | GPI            | Brand/Generic |
|--|--|----------------|---------------|
| VENTAVIS                                 | ILOPROST INHALATION SOLUTION 10 MCG/ML                       | 40170060002020 | Brand         |
| VENTAVIS                                 | ILOPROST INHALATION SOLUTION 20 MCG/ML                       | 40170060002040 | Brand         |
| ORENITRAM<br>TITRATION<br>KIT MONTH<br>1 | TREPROSTINIL TAB ER TITR PK (MO1) 126 X0.125MG & 42 X0.25MG  | 4017008005C110 | Brand         |
| ORENITRAM<br>TITRATION                   | TREPROSTINIL TAB ER TITR PK (MO2) 126 X0.125MG & 210 X0.25MG | 4017008005C120 | Brand         |

| KIT MONTH<br>2                           |   |                |       |
|--|---|----------------|-------|
| ORENITRAM<br>TITRATION<br>KIT MONTH<br>3 | TREPROSTINIL TAB ER TITR<br>PK(MO3)126X0.125MG&42X0.25MG&84X1MG | 4017008005C130 | Brand |
| ORENITRAM                                | TREPROSTINIL DIOLAMINE TAB ER 0.125 MG (BASE EQUIV)             | 40170080050410 | Brand |
| ORENITRAM                                | TREPROSTINIL DIOLAMINE TAB ER 0.25 MG (BASE EQUIV)              | 40170080050415 | Brand |
| ORENITRAM                                | TREPROSTINIL DIOLAMINE TAB ER 1 MG (BASE EQUIV)                 | 40170080050420 | Brand |
| ORENITRAM                                | TREPROSTINIL DIOLAMINE TAB ER 2.5 MG (BASE EQUIV)               | 40170080050425 | Brand |
| ORENITRAM                                | TREPROSTINIL DIOLAMINE TAB ER 5 MG (BASE EQUIV)                 | 40170080050435 | Brand |

1 - Diagnosis of pulmonary arterial hypertension

### AND

- 2 Prescribed by or in consultation with one of the following:

  - Cardiologist Pulmonologist

#### **AND**

3 - Trial and failure, contraindication, or intolerance to inhaled treprostinil (Tyvaso)

| Notes | Member new to the plan (as evidenced by coverage effective date of le        |
|-------|--|
|       | ss than or equal to 90 days) who initiated therapy using a manufacturer      |
|       | -sponsored free drug program, provider samples, and/or vouchers will         |
|       | go through initial criteria, otherwise for continuation of therapy for new t |
|       | o plan, reauthorization criteria applies                                     |

| Date       | Notes                   |
|------------|-------------------------|
| 10/12/2023 | 2024 New Implementation |

| Pyrukynd  |
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| Guideline ID          | GL-130133 |
|-----------------------|-----------|
| <b>Guideline Name</b> | Pyrukynd  |
| Formulary             | Quartz    |

# **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

## 1. Criteria

| Product Name: Pyrukynd  |                       |  |
|---|-----------------------|--|
| Approval Length   | 6 month(s)            |  |
| Therapy Stage   | Initial Authorization |  |
| Guideline Type Prior Authorization - All plans except IL and MN Plans |                       |  |

| Product<br>Name           | Generic Name   | GPI            | Brand/Generic |
|---------------------------|--|----------------|---------------|
| PYRUKYND<br>TAPER<br>PACK | MITAPIVAT SULFATE TAB THERAPY PACK 5 MG                  | 8587005070B710 | Brand         |
| PYRUKYND<br>TAPER<br>PACK |  |                | Brand         |
| PYRUKYND<br>TAPER<br>PACK | MITAPIVAT SULFATE TAB THERAPY PACK 7 X 50 MG & 7 X 20 MG | 8587005070B735 | Brand         |

| PYRUKYND | MITAPIVAT SULFATE TAB 5 MG  | 85870050700310 | Brand |
|----------|-----------------------------|----------------|-------|
| PYRUKYND | MITAPIVAT SULFATE TAB 20 MG | 85870050700325 | Brand |
| PYRUKYND | MITAPIVAT SULFATE TAB 50 MG | 85870050700340 | Brand |

1 - Diagnosis of pyruvate kinase deficiency

#### **AND**

**2** - Prescribed by, or in consultation with, a Hematologist or other expert in treating hemolytic anemia

#### **AND**

3 - Hemoglobin less than or equal to 10 mg/dL

### **AND**

4 - Greater than or equal to 1 red blood cell (RBC) transfusion in the past 12 months

#### **AND**

**5** - Member is 18 years of age or older

| Member new to the plan (as evidenced by coverage effective date of le ss than or equal to 90 days) who initiated therapy using a manufacturer -sponsored free drug program, provider samples, and/or vouchers will go through initial criteria, otherwise for continuation of therapy for new t |
|---|
| o plan, reauthorization criteria applies  |
|   |

| Product Name: Pyrukynd                               |                       |
|--|-----------------------|
| Approval Length 12 month(s)                          |                       |
| Therapy Stage  | Initial Authorization |
| Guideline Type Prior Authorization - IL and MN Plans |                       |

| Product<br>Name           | Generic Name  | GPI            | Brand/Generic |
|---------------------------|---|----------------|---------------|
| PYRUKYND<br>TAPER<br>PACK | MITAPIVAT SULFATE TAB THERAPY PACK 5 MG                     | 8587005070B710 | Brand         |
| PYRUKYND<br>TAPER<br>PACK | MITAPIVAT SULFATE TAB THERAPY PACK 7 X 20 MG<br>& 7 X 5 MG  | 8587005070B720 | Brand         |
| PYRUKYND<br>TAPER<br>PACK | MITAPIVAT SULFATE TAB THERAPY PACK 7 X 50 MG<br>& 7 X 20 MG | 8587005070B735 | Brand         |
| PYRUKYND                  | MITAPIVAT SULFATE TAB 5 MG                                  | 85870050700310 | Brand         |
| PYRUKYND                  | MITAPIVAT SULFATE TAB 20 MG                                 | 85870050700325 | Brand         |
| PYRUKYND                  | MITAPIVAT SULFATE TAB 50 MG                                 | 85870050700340 | Brand         |

1 - Diagnosis of pyruvate kinase deficiency

#### **AND**

**2** - Prescribed by, or in consultation with, a Hematologist or other expert in treating hemolytic anemia

#### **AND**

3 - Hemoglobin less than or equal to 10 mg/dL

#### **AND**

4 - Greater than or equal to 1 red blood cell (RBC) transfusion in the past 12 months

#### AND

5 - Member is 18 years of age or older

| Notes | Member new to the plan (as evidenced by coverage effective date of le      |
|-------|--|
|       | mismissi nen te ane pism (se e masmes al le consegue emesante distre en le |

| ss than or equal to 90 days) who initiated therapy using a manufacturer -sponsored free drug program, provider samples, and/or vouchers will go through initial criteria, otherwise for continuation of therapy for new to plan, reauthorization criteria applies |
|---|
|---|

| Product Name: Pyrukynd |                     |
|------------------------|---------------------|
| Approval Length        | 12 month(s)         |
| Therapy Stage          | Reauthorization     |
| Guideline Type         | Prior Authorization |

| Product<br>Name           | Generic Name  | GPI            | Brand/Generic |
|---------------------------|---|----------------|---------------|
| PYRUKYND<br>TAPER<br>PACK | MITAPIVAT SULFATE TAB THERAPY PACK 5 MG                     | 8587005070B710 | Brand         |
| PYRUKYND<br>TAPER<br>PACK | MITAPIVAT SULFATE TAB THERAPY PACK 7 X 20 MG & 7 X 5 MG     | 8587005070B720 | Brand         |
| PYRUKYND<br>TAPER<br>PACK | MITAPIVAT SULFATE TAB THERAPY PACK 7 X 50 MG<br>& 7 X 20 MG | 8587005070B735 | Brand         |
| PYRUKYND                  | MITAPIVAT SULFATE TAB 5 MG                                  | 85870050700310 | Brand         |
| PYRUKYND                  | MITAPIVAT SULFATE TAB 20 MG                                 | 85870050700325 | Brand         |
| PYRUKYND                  | MITAPIVAT SULFATE TAB 50 MG                                 | 85870050700340 | Brand         |

1 - Diagnosis of pyruvate kinase deficiency

#### **AND**

**2** - Submission of medical records (e.g., chart notes) documenting that within the past 6 months (for initial starts) or past 12 months the member demonstrates positive clinical response to therapy

| Member new to the plan (as evidenced by coverage effective date of le ss than or equal to 90 days) who initiated therapy using a manufacturer -sponsored free drug program, provider samples, and/or vouchers will go through initial criteria, otherwise for continuation of therapy for new t |
|---|
| o plan, reauthorization criteria applies  |

| Date      | Notes                   |
|-----------|-------------------------|
| 10/6/2023 | 2024 New Implementation |

| Qbrexza (Glycopyrronium topical)   |  |  |  |
|--|--|--|--|
| Statement and the statement of the state |  |  |  |
|  |  |  |  |

| Guideline ID                                    | GL-129624 |
|---|-----------|
| Guideline Name Qbrexza (Glycopyrronium topical) |           |
| Formulary                                       | Quartz    |

## **Guideline Note:**

| Effective Date: |
|-----------------|
|-----------------|

### 1. Criteria

| Product Name: Qbrexza                                |                       |
|--|-----------------------|
| Approval Length 12 month(s)                          |                       |
| Therapy Stage  | Initial Authorization |
| Guideline Type Prior Authorization - IL and MN Plans |                       |

| Product<br>Name | Generic Name                                       | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| QBREXZA         | GLYCOPYRRONIUM TOSYLATE PAD 2.4% (BASE EQUIVALENT) | 90970030204320 | Brand         |

## **Approval Criteria**

**1** - Diagnosis of axillary hyperhidrosis with clinical documentation of a persistent or chronic cutaneous condition due to excessive sweating (e.g. skin maceration, dermatitis, fungal

infections)

#### **AND**

**2** - Failure of an adequate trial or intolerance to BOTH prescription strength topical aluminum antiperspirants and an oral anticholinergic drug such as glycopyrrolate or oxybutynin

| Product Name: Qbrexza                                      |              |                                       |       |               |
|--|--------------|---------------------------------------|-------|---------------|
| Approval Length  |              | 12 month(s)                           |       |               |
| Therapy Stage  |              | Reauthorization                       |       |               |
| Guideline Type   |              | Prior Authorization - IL and MN Plans |       |               |
| Product<br>Name  | Generic Name |                                       | GPI   | Brand/Generic |
| QBREXZA GLYCOPYRRONIUM TOSYLATE PAD 2.4% (BASE EQUIVALENT) |              | 90970030204320                        | Brand |               |

### **Approval Criteria**

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug.

| Product Name: Qbrexza   |  |
|---|--|
| Approval Length 12/31/2039                                      |  |
| Guideline Type Prior Authorization - All plans except IL and MN |  |

| Product<br>Name | Generic Name                                       | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| QBREXZA         | GLYCOPYRRONIUM TOSYLATE PAD 2.4% (BASE EQUIVALENT) | 90970030204320 | Brand         |

### **Approval Criteria**

**1** - Diagnosis of axillary hyperhidrosis with clinical documentation of a persistent or chronic cutaneous condition due to excessive sweating (e.g. skin maceration, dermatitis, fungal infections)

### AND

**2** - Failure of an adequate trial or intolerance to BOTH prescription strength topical aluminum antiperspirants and an oral anticholinergic drug such as glycopyrrolate or oxybutynin

| Date      | Notes       |
|-----------|-------------|
| 10/6/2023 | New Program |

| Quantity Limit Exceptions   |  |  |
|---|--|--|
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| Guideline ID GL-134957 |                           |  |
|------------------------|---------------------------|--|
| <b>Guideline Name</b>  | Quantity Limit Exceptions |  |
| Formulary              | Quartz                    |  |

# **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

## 1. Criteria

| Diagnosis                     | CRITERIA FOR COVERAGE OF QUANTITY EXCEPTIONS (DOSE ≤ MAXIMUM DOSE IN PRESCRIBING INFORMATION) - Titration or loading dose |     |               |
|-------------------------------|---|-----|---------------|
| Approval Length One Time Fill |   |     |               |
| Guideline Type Administrative |   |     |               |
| Product Name Gene             | ric Name  | GPI | Brand/Generic |

### **Approval Criteria**

1 - Request is for a titration or loading dose

| Diagnosis | CRITERIA FOR COVERAGE OF QUANTITY EXCEPTIONS (DOSE ≤ |
|-----------|--|

|                                       | MAXIMUM DOSE IN PRESCRIBING INFORMATION) |
|---------------------------------------|--|
| Approval Length                       | 12 month(s)                              |
| Guideline Type                        | Administrative                           |
| · · · · · · · · · · · · · · · · · · · |  |

| Product Name | Generic Name | GPI | Brand/Generic |
|--------------|--------------|-----|---------------|
|--------------|--------------|-----|---------------|

1 - Person is on a dose alternating schedule

OR

2 - For topical applications: person requires a larger quantity to cover a larger surface area

OR

3 - Requested strength/dose is commercially unavailable

OR

**4** - If the request is for reauthorization, prescriber submits medical records (e.g., chart notes) of documentation from the previous 12 months that the member is continuing therapy with the requested drug and dosing regimen

| Diagnosis       |      | CRITERIA FOR COVERAGE OF QUANTITY EXCEPTIONS (DOSE > MAXIMUM DOSE IN PRESCRIBING INFORMATION) |     |               |
|-----------------|------|---|-----|---------------|
| Approval Length |      | 12 month(s)   |     |               |
| Guideline Type  |      | Administrative  |     |               |
| Product Name    | Gene | ric Name  | GPI | Brand/Generic |

### **Approval Criteria**

1 - Both of the following:

- **1.1** One of the following:
- **1.1.1** Higher dose or quantity is supported by clinical research in two articles from major peer reviewed medical journals that present data supporting the proposed higher than maximum doses for the diagnosis provided as generally safe and effective

OR

**1.1.2** Higher dose or quantity is supported by American Hospital Formulary Service Drug Information or Micromedex DRUGDEX System

#### **AND**

- 1.2 One of the following
- **1.2.1** Maximum doses specified under the quantity restriction have been tried for an adequate period of time and been deemed ineffective in the treatment of the member's disease or medical condition

OR

**1.2.2** If lower doses have not been tried, there is clinical support (i.e., clinical literature, patient attributes, or characteristics of the drug) that the number of doses available under the quantity restriction will be ineffective in the treatment of the member's disease or medical condition

OR

**2** - If the request is for reauthorization, prescriber submits medical records (e.g., chart notes) of documentation from the previous 12 months that the member is continuing therapy with the requested drug and dosing regimen

| Diagnosis       | All Indications |
|-----------------|-----------------|
| Approval Length | 12 month(s)     |
| Therapy Stage   | Reauthorization |
| Guideline Type  | Administrative  |

| Product Name | Generic Name | GPI | Brand/Generic |
|--------------|--------------|-----|---------------|
|--------------|--------------|-----|---------------|

1 - Prescriber submits medical records (e.g., chart notes) of documentation from the previous12 months that the member is continuing therapy with the requested drug and dosing regimen

| Date      | Notes       |
|-----------|-------------|
| 12/5/2023 | New program |

| Radicava (Edaravone)   |
|--|
| The history was to dispect to below to close and a seed a seed and they have been consulted to some the person to consulted to cons |
|  |

| Guideline ID          | GL-129159            |  |
|-----------------------|----------------------|--|
| <b>Guideline Name</b> | Radicava (Edaravone) |  |
| Formulary             | Quartz               |  |

# **Guideline Note:**

| Effective Date: |
|-----------------|
|-----------------|

## 1. Criteria

| Product Name: Radicava ORS |                       |
|----------------------------|-----------------------|
| Approval Length            | 12 month(s)           |
| Therapy Stage              | Initial Authorization |
| Guideline Type             | Prior Authorization   |

| Product<br>Name                   | Generic Name                   | GPI            | Brand/Generic |
|-----------------------------------|--------------------------------|----------------|---------------|
| RADICAVA<br>ORS<br>STARTER<br>KIT | EDARAVONE ORAL SUSP 105 MG/5ML | 74509030001820 | Brand         |
| RADICAVA<br>ORS                   | EDARAVONE ORAL SUSP 105 MG/5ML | 74509030001820 | Brand         |

## **Approval Criteria**

| 1 - Diagnosis of definite or probable ALS based on El Escorial revised Airlie House diagnostic criteria                           |
|---|
| AND   |
| 2 - Prescribed by, or in consultation with, a Neurologist or other specialist in treating amyotrophic lateral sclerosis (ALS)     |
| AND   |
| <b>3</b> - Age 20-75  |
| AND   |
| 4 - Independent living status (i.e., Japan ALS Severity Classification Grade 1 or 2)  |
| AND   |
| 5 - Score of ≥ 2 on all 12 items of the ALS Functional Rating Scale (ALSFRS-R) (assessed and documented within the last 3 months) |
| AND   |
| 6 - FVC % predicted ≥ 80% (assessed and documented within the last 3 months)  |
| AND   |
| 7 - Duration of disease from the first symptom of 2 years or less   |
| AND   |
| 8 - Current use of riluzole or documented contraindication/intolerance/ lack of therapeutic effect of therapy                     |

| Product Name: Radicava ORS  |                     |  |
|-----------------------------|---------------------|--|
| Approval Length 12 month(s) |                     |  |
| Therapy Stage               | Reauthorization     |  |
| Guideline Type              | Prior Authorization |  |

| Product<br>Name                   | Generic Name                   | GPI            | Brand/Generic |
|-----------------------------------|--------------------------------|----------------|---------------|
| RADICAVA<br>ORS<br>STARTER<br>KIT | EDARAVONE ORAL SUSP 105 MG/5ML | 74509030001820 | Brand         |
| RADICAVA<br>ORS                   | EDARAVONE ORAL SUSP 105 MG/5ML | 74509030001820 | Brand         |

**1** - Documentation that use of the drug has slowed the progression of ALS and function is improved relative to the expected natural course of the disease

| Date      | Notes       |
|-----------|-------------|
| 9/11/2023 | New program |

| Rayos (pre  | Rayos (prednisone DR)  |  |  |  |
|---|--|--|--|--|
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| Guideline ID          | GL-136613             |
|-----------------------|-----------------------|
| <b>Guideline Name</b> | Rayos (prednisone DR) |
| Formulary             | Quartz                |

# **Guideline Note:**

| Effective Date:    | 1/1/2024 |
|--------------------|----------|
| P&T Approval Date: |          |
| P&T Revision Date: |          |

# 1. Criteria

| Product Name: Rayos                                     |  |
|---|--|
| Approval Length 12 month(s)                             |  |
| Therapy Stage Initial Authorization                     |  |
| Guideline Type Prior Authorization-IL and MN Plans Only |  |

| Product<br>Name | Generic Name                        | GPI            | Brand/Generic |
|-----------------|-------------------------------------|----------------|---------------|
| RAYOS           | PREDNISONE TAB DELAYED RELEASE 1 MG | 22100045000610 | Brand         |
| RAYOS           | PREDNISONE TAB DELAYED RELEASE 2 MG | 22100045000620 | Brand         |
| RAYOS           | PREDNISONE TAB DELAYED RELEASE 5 MG | 22100045000630 | Brand         |

- 1 One of the following:
- **1.1** Both of the following:
- **1.1.1** Therapy-limiting intolerance of immediate-release prednisone despite dose adjustment and/or timing modification

OR

**1.1.2** The prescriber provides an evidence-based clinical rationale for why the side effects are not likely to occur with the extended-release formulation

OR

**1.2** Minnesota plans only: Member with stage four metastatic cancer and the requested drug is being used as supportive care to treat fatigue related to their cancer diagnosis or chemotherapy regimen

| Product Name: Rayos |  |  |
|---------------------|--|--|
| Approval Length     | 12 month(s)                              |  |
| Therapy Stage       | Reauthorization                          |  |
| Guideline Type      | Prior Authorization-IL and MN Plans Only |  |

| Product<br>Name | Generic Name                        | GPI            | Brand/Generic |
|-----------------|-------------------------------------|----------------|---------------|
| RAYOS           | PREDNISONE TAB DELAYED RELEASE 1 MG | 22100045000610 | Brand         |
| RAYOS           | PREDNISONE TAB DELAYED RELEASE 2 MG | 22100045000620 | Brand         |
| RAYOS           | PREDNISONE TAB DELAYED RELEASE 5 MG | 22100045000630 | Brand         |

### **Approval Criteria**

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug.

| Product Name: Rayos         |  |  |
|-----------------------------|--|--|
| Approval Length 12 month(s) |  |  |
| Guideline Type              | Prior Authorization-All plans except IL and MN |  |

| Product<br>Name | Generic Name                        | GPI            | Brand/Generic |
|-----------------|-------------------------------------|----------------|---------------|
| RAYOS           | PREDNISONE TAB DELAYED RELEASE 1 MG | 22100045000610 | Brand         |
| RAYOS           | PREDNISONE TAB DELAYED RELEASE 2 MG | 22100045000620 | Brand         |
| RAYOS           | PREDNISONE TAB DELAYED RELEASE 5 MG | 22100045000630 | Brand         |

**1** - Therapy-limiting intolerance of immediate-release prednisone despite dose adjustment and/or timing modification

#### **AND**

 ${f 2}$  - The prescriber provides an evidence-based clinical rationale for why the side effects are not likely to occur with the extended-release formulation

| Date       | Notes          |
|------------|----------------|
| 11/21/2023 | Update program |

| Relyvrio (sodium phenylbutyrate and taurursodio |  |  |
|---|--|--|
|   | The third processing the state and come and come and the state process to construct the state. |  |

| Guideline ID          | GL-131273   |  |
|-----------------------|---|--|
| <b>Guideline Name</b> | Relyvrio (sodium phenylbutyrate and taurursodiol) |  |
| Formulary             | Quartz  |  |

## **Guideline Note:**

| Effective Date: |
|-----------------|
|-----------------|

## 1. Criteria

| Product Name: Relyvrio |                                 |
|------------------------|---------------------------------|
| Approval Length        | 12 month(s)                     |
| Therapy Stage          | Initial Authorization           |
| Guideline Type         | Prior Authorization - ALL Plans |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| RELYVRIO        | SODIUM PHENYLBUTYRATE-TAURURSODIOL POWD PACK 3-1 GM | 74509902703020 | Brand         |

### **Approval Criteria**

1 - Diagnosis of definite or probable amyotrophic lateral sclerosis (ALS)

|  | AND   |
|--|---|
| <b>2</b> - Member is 18 years  | of age or older   |
|  | AND   |
| <b>3</b> - Submission of medi<br>greater than 60%, withi   | cal records (e.g., chart notes) documenting Slow vital capacity (SVC) n the past 3 months   |
|  | AND   |
| 4 - Member has not cui   | rently had a tracheostomy or on permanent assisted ventilation  |
|  | AND   |
| 5 - Duration of disease  | from the first symptom, is of 18 months or less   |
|  | AND   |
| 6 - Member is currently using riluzole or has a documented contraindication/intolerance/or lack of therapeutic effect of therapy |   |
|  | AND   |
| 7 - Prescribed by or in  | consultation with one of the following:   |
| <ul><li>neurologist</li><li>other specialist</li></ul>   | in the treatment of ALS   |
| Notes  | *Member new to the plan (as evidenced by coverage effective date of I ess than or equal to 90 days) who initiated therapy using a manufactur er-sponsored free drug program, provider samples, and/or vouchers wil I go through initial criteria, otherwise for continuation of therapy for new to plan, reauthorization criteria applies |

| Product Name: Relyvrio |                                 |
|------------------------|---------------------------------|
| Approval Length        | 12 month(s)                     |
| Therapy Stage          | Reauthorization                 |
| Guideline Type         | Prior Authorization - ALL Plans |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| RELYVRIO        | SODIUM PHENYLBUTYRATE-TAURURSODIOL POWD PACK 3-1 GM | 74509902703020 | Brand         |

**1** - Submission of medical records (e.g., chart notes) documenting that the use of the drug has slowed the progression of ALS and function is improved relative to the expected natural course of the disease

| *Member new to the plan (as evidenced by coverage effective date of I ess than or equal to 90 days) who initiated therapy using a manufactur er-sponsored free drug program, provider samples, and/or vouchers wil I go through initial criteria, otherwise for continuation of therapy for new to plan, reauthorization criteria applies |
|---|
| to plan, reauthorization criteria applies   |

| Date      | Notes                   |
|-----------|-------------------------|
| 10/6/2023 | 2024 New Implementation |

| Repatha (evolocumab)   |  |  |  |
|--|--|--|--|
| Statemagness and aligners. While they located used a seed a seed of the filtre position according and an experimental position and a |  |  |  |

| Guideline ID   | GL-131591            |
|----------------|----------------------|
| Guideline Name | Repatha (evolocumab) |
| Formulary      | Quartz               |

### **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

### Note:

\*Member new to the plan (as evidenced by coverage effective date of less than or equal to 90 days) who initiated therapy using a manufacturer-sponsored free drug program, provider samples, and/or vouchers will go through initial criteria, otherwise for continuation of therapy for new to plan, reauthorization criteria applies

### 1. Criteria

| Product Name: Repatha |  |                       |                |               |
|-----------------------|--|-----------------------|----------------|---------------|
| Approval Leng         | gth  | 12 month(s)           |                |               |
| Therapy Stage         | Э  | Initial Authorization |                |               |
| Guideline Type        |  | Prior Authorization   |                |               |
| Product<br>Name       | Generic  | Name                  | GPI            | Brand/Generic |
| REPATHA<br>SURECLICK  | EVOLOCUMAB SUBCUTANEOUS SOLN AUTO-<br>INJECTOR 140 MG/ML |                       | 3935002000D520 | Brand         |

| REPATHA<br>PUSHTRONEX<br>SYSTEM | EVOLOCUMAB SUBCUTANEOUS SOLN<br>CARTRIDGE/INFUSOR 420 MG/3.5ML | 3935002000E230 | Brand |
|---------------------------------|--|----------------|-------|
| REPATHA                         | EVOLOCUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 140 MG/ML       | 3935002000E520 | Brand |

- **1** Diagnosis of one of the following:
  - Heterozygous Familial Hypercholesteremia
  - Homozygous Familial Hypercholesterolemia
  - Established arteriosclerotic cardiovascular disease (ASCVD)

#### **AND**

**2** - Submission of medical records (e.g., chart notes) documenting that medication is prescribed by or in consultation with a cardiologist, endocrinologist, or lipidologist

#### **AND**

**3** - Member has LDL-C greater than or equal to 70 mg/dL while on maximally tolerated statin doses

#### **AND**

- 4 One of the following:
- **4.1** All of the following:
- **4.1.1** Member is statin tolerant and will continue statin treatment in combination with PCSK9

#### **AND**

- **4.1.2** One of the following:
  - Adherent treatment with a high potency statin (ex. atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily) for a minimum of 8 weeks duration
  - Member cannot tolerate high potency statin and adherent treatment with a maximally

tolerated dose of any statin for a minimum of 8 weeks duration

#### OR

- **4.2** Member is statin intolerant as defined by all of the following:
  - Member was unable to tolerate at least two statins with one started at the lowest starting dose
  - Statin dose reduction was attempted to resolve symptoms or lab abnormalities (not discontinuation)
  - Symptoms or lab abnormalities reversed with statin discontinuation but returned with rechallenge of statins
  - Symptoms or lab abnormalities are not due to established predispositions such as drug interactions, significant changes in physical activity, or underlying muscle disease

#### OR

**4.3** Member has a contraindication to statin use such as active liver disease or persistently elevated serum transaminases

| Product Name: Repatha |                                       |  |
|-----------------------|---------------------------------------|--|
| Approval Length       | 12 month(s)                           |  |
| Therapy Stage         | Reauthorization                       |  |
| Guideline Type        | Prior Authorization - IL and MN Plans |  |

| Product<br>Name                 | Generic Name   | GPI            | Brand/Generic |
|---------------------------------|--|----------------|---------------|
| REPATHA<br>SURECLICK            | EVOLOCUMAB SUBCUTANEOUS SOLN AUTO-<br>INJECTOR 140 MG/ML       | 3935002000D520 | Brand         |
| REPATHA<br>PUSHTRONEX<br>SYSTEM | EVOLOCUMAB SUBCUTANEOUS SOLN<br>CARTRIDGE/INFUSOR 420 MG/3.5ML | 3935002000E230 | Brand         |
| REPATHA                         | EVOLOCUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 140 MG/ML       | 3935002000E520 | Brand         |

### **Approval Criteria**

**1** - Submission of medical records (e.g., chart notes) within the past 12 month demonstrating a reduction in LDL-C from baseline

### **AND**

2 - Member continues treatment with baseline lipid-lowering therapies

| Product Name: Repatha      |  |
|----------------------------|--|
| Approval Length 12/31/2039 |  |
| Therapy Stage              | Reauthorization  |
| Guideline Type             | Prior Authorization - All plans except IL and MN Plans |

| Product<br>Name                 | Generic Name   | GPI            | Brand/Generic |
|---------------------------------|--|----------------|---------------|
| REPATHA<br>SURECLICK            | EVOLOCUMAB SUBCUTANEOUS SOLN AUTO-<br>INJECTOR 140 MG/ML       | 3935002000D520 | Brand         |
| REPATHA<br>PUSHTRONEX<br>SYSTEM | EVOLOCUMAB SUBCUTANEOUS SOLN<br>CARTRIDGE/INFUSOR 420 MG/3.5ML | 3935002000E230 | Brand         |
| REPATHA                         | EVOLOCUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 140 MG/ML       | 3935002000E520 | Brand         |

### **Approval Criteria**

 ${f 1}$  - Submission of medical records (e.g., chart notes) within the past 12 month demonstrating a reduction in LDL-C from baseline

### **AND**

2 - Member continues treatment with baseline lipid-lowering therapies

| Date      | Notes                   |
|-----------|-------------------------|
| 10/8/2023 | 2024 New Implementation |

| Restricted Diclofenac                                    |   |  |  |
|--|---|--|--|
| (a) The lebest longs control for displayer. The file re- | ng han han nami, serang se diland lang hali hali palah da panta da mentebuari hadin |  |  |

| Guideline ID          | GL-131458             |
|-----------------------|-----------------------|
| <b>Guideline Name</b> | Restricted Diclofenac |
| Formulary             | Quartz                |

## **Guideline Note:**

| Effective Date: |
|-----------------|
|-----------------|

## 1. Criteria

| Product Name: Generic Zipsor, Generic Cambia                          |  |
|---|--|
| Approval Length 12/31/2039  |  |
| Guideline Type Prior Authorization - All plans except IL and MN Plans |  |

| Product<br>Name         | Generic Name                                    | GPI            | Brand/Generic |
|-------------------------|---|----------------|---------------|
|                         | DICLOFENAC POTASSIUM (MIGRAINE) PACKET 50<br>MG | 67600040103020 | Generic       |
| DICLOFENAC<br>POTASSIUM | DICLOFENAC POTASSIUM CAP 25 MG                  | 66100007100120 | Generic       |

## **Approval Criteria**

1 - Trial and failure (with maximized doses) or intolerance of a preferred oral diclofenac

#### **AND**

**2** - Trial and failure (with maximized doses) or intolerance of another preferred oral nonsteroidal anti-inflammatory drug (NSAID)

Product Name: Diclofenac 2% solution (generic Pennsaid), Diclofenac 1.5% solution,
Diclofenac 3% gel

Approval Length 12/31/2039

Guideline Type Prior Authorization - All plans except IL and MN Plans

| Product<br>Name      | Generic Name                                 | GPI            | Brand/Generic |
|----------------------|--|----------------|---------------|
| DICLOFENAC<br>SODIUM | DICLOFENAC SODIUM SOLN 2%                    | 90210030302030 | Generic       |
| DICLOFENAC<br>SODIUM | DICLOFENAC SODIUM SOLN 1.5%                  | 90210030302025 | Generic       |
| DICLOFENAC<br>SODIUM | DICLOFENAC SODIUM (ACTINIC KERATOSES) GEL 3% | 90374035304020 | Generic       |

### **Approval Criteria**

- **1** Both of the following:
- **1.1** Trial and failure (with maximized doses), contraindication or intolerance to two preferred oral NSAIDs

#### AND

**1.2** Trial and failure of maximized dosing of generic diclofenac 1% gel

OR

2 - (Diclofenac 3% gel only) Used for short-term treatment of actinic keratosis

Product Name: Generic Zipsor, Generic Cambia

| Approval Length | 12 month(s)                           |
|-----------------|---------------------------------------|
| Therapy Stage   | Initial Authorization                 |
| Guideline Type  | Prior Authorization - IL and MN Plans |

| Product<br>Name         | Generic Name                                    | GPI            | Brand/Generic |
|-------------------------|---|----------------|---------------|
|                         | DICLOFENAC POTASSIUM (MIGRAINE) PACKET 50<br>MG | 67600040103020 | Generic       |
| DICLOFENAC<br>POTASSIUM | DICLOFENAC POTASSIUM CAP 25 MG                  | 66100007100120 | Generic       |

- 1 Both of the following:
- 1.1 Trial and failure (with maximized doses) or intolerance of a preferred oral diclofenac

### **AND**

**1.2** Trial and failure (with maximized doses) or intolerance of another preferred oral nonsteroidal anti-inflammatory drug (NSAID)

### OR

 ${f 2}$  - (Minnesota plans only) – Member has stage four metastatic cancer and the requested drug is being used to treat cancer-related pain

| Product Name: Diclofenac 2% solution (generic Pennsaid), Diclofenac 1.5% solution, Diclofenac 3% gel |  |  |
|--|--|--|
| Approval Length 12 month(s)  |  |  |
| Therapy Stage Initial Authorization  |  |  |
| Guideline Type Prior Authorization - IL and MN Plans   |  |  |

| Product<br>Name      | Generic Name                | GPI            | Brand/Generic |
|----------------------|-----------------------------|----------------|---------------|
| DICLOFENAC<br>SODIUM | DICLOFENAC SODIUM SOLN 2%   | 90210030302030 | Generic       |
| DICLOFENAC<br>SODIUM | DICLOFENAC SODIUM SOLN 1.5% | 90210030302025 | Generic       |

| DICLOFENAC DICLOFENAC SODIUM (ACTINIC KERATOSES) GEL SODIUM | 90374035304020 | Generic |
|---|----------------|---------|
|---|----------------|---------|

- **1** Both of the following:
- **1.1** Trial and failure (with maximized doses), contraindication or intolerance to two preferred oral NSAIDs

#### **AND**

1.2 Trial and failure of maximized dosing of generic diclofenac 1% gel

### OR

2 - (Diclofenac 3% gel only) Used for short-term treatment of actinic keratosis

### OR

 $\bf 3$  - (Minnesota plans only) – Member has stage four metastatic cancer and the requested drug is being used to treat cancer-related pain

| Product Name: Generic Zipsor, Generic Cambia, Diclofenac 2% solution (generic Pennsaid), Diclofenac 1.5% solution, Diclofenac 3% gel |                 |  |
|--|-----------------|--|
| Approval Length 12 month(s)  |                 |  |
| Therapy Stage  | Reauthorization |  |
| Guideline Type Prior Authorization - IL and MN Plans   |                 |  |

| Product<br>Name      | Generic Name                                 | GPI            | Brand/Generic |
|----------------------|--|----------------|---------------|
|                      | DICLOFENAC POTASSIUM (MIGRAINE) PACKET 50 MG | 67600040103020 | Generic       |
| DICLOFENAC<br>SODIUM | DICLOFENAC SODIUM SOLN 2%                    | 90210030302030 | Generic       |
| DICLOFENAC<br>SODIUM | DICLOFENAC SODIUM SOLN 1.5%                  | 90210030302025 | Generic       |

| DICLOFENAC<br>SODIUM    | DICLOFENAC SODIUM (ACTINIC KERATOSES) GEL 3% | 90374035304020 | Generic |
|-------------------------|--|----------------|---------|
| DICLOFENAC<br>POTASSIUM | DICLOFENAC POTASSIUM CAP 25 MG               | 66100007100120 | Generic |

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug

| Date       | Notes                   |
|------------|-------------------------|
| 10/24/2023 | 2024 New Implementation |

| Restricted Inhaled Corticosteroid  |  |
|--|--|
| Substrates are related for the to National state of some of the State of people to contribute countries. |  |

| Guideline ID          | GL-143612                         |
|-----------------------|-----------------------------------|
| <b>Guideline Name</b> | Restricted Inhaled Corticosteroid |
| Formulary             | Quartz                            |

# **Guideline Note:**

| Effective Date: |
|-----------------|
|-----------------|

# 1. Criteria

| Product Name: Pulmicort Flexhaler, Alvesco |                                       |  |
|--|---------------------------------------|--|
| Approval Length                            | 12 month(s)                           |  |
| Therapy Stage                              | Initial Authorization                 |  |
| Guideline Type                             | Prior Authorization - IL and MN Plans |  |

| Product<br>Name        | Generic Name  | GPI            | Brand/Generic |
|------------------------|---|----------------|---------------|
| PULMICORT<br>FLEXHALER | BUDESONIDE INHAL AERO POWD 90 MCG/ACT (BREATH ACTIVATED)  | 44400015008009 | Brand         |
| PULMICORT<br>FLEXHALER | BUDESONIDE INHAL AERO POWD 180 MCG/ACT (BREATH ACTIVATED) | 44400015008018 | Brand         |
| ALVESCO                | CICLESONIDE INHAL AEROSOL 80 MCG/ACT                      | 44400017003420 | Brand         |
| ALVESCO                | CICLESONIDE INHAL AEROSOL 160 MCG/ACT                     | 44400017003440 | Brand         |

1 - Submission of medical records (e.g., chart notes) documenting trial and failure (e.g., objective change in symptom control such as Asthma Control Test score, nocturnal awakenings, increased rescue inhaler use, etc.) with an equipotent dose as outlined in the Global Initiative for Asthma (GINA) guidelines, intolerance, or contraindication to a preferred fluticasone product (e.g., Arnuity Ellipta or Flovent)

OR

**2** - The requested drug is being used as an add-on inhaler to a preferred fluticasone or mometasone maintenance inhaler for patients who need to "step-up" their asthma treatment plan (i.e. go from Green Zone to Yellow Zone, etc.) due to an increase in symptoms

OR

**3** - (For Pulmicort only): Submission of medical records (e.g., chart notes) documenting a current pregnancy

| Product Name: Pulmicort Flexhaler, Alvesco |                                       |  |
|--|---------------------------------------|--|
| Approval Length                            | 12 month(s)                           |  |
| Therapy Stage                              | Reauthorization                       |  |
| Guideline Type                             | Prior Authorization - IL and MN Plans |  |

| Product<br>Name        | Generic Name   | GPI            | Brand/Generic |
|------------------------|--|----------------|---------------|
| PULMICORT<br>FLEXHALER | BUDESONIDE INHAL AERO POWD 90 MCG/ACT (BREATH ACTIVATED) | 44400015008009 | Brand         |
| PULMICORT<br>FLEXHALER |  | 44400015008018 | Brand         |
| ALVESCO                | CICLESONIDE INHAL AEROSOL 80 MCG/ACT                     | 44400017003420 | Brand         |
| ALVESCO                | CICLESONIDE INHAL AEROSOL 160 MCG/ACT                    | 44400017003440 | Brand         |

### **Approval Criteria**

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug

| Product Name: Pulmicort Flexhaler, Alvesco                            |  |  |
|---|--|--|
| Approval Length 12/31/2039  |  |  |
| Guideline Type Prior Authorization - All plans except IL and MN Plans |  |  |

| Product<br>Name        | Generic Name                          | GPI            | Brand/Generic |
|------------------------|---------------------------------------|----------------|---------------|
| PULMICORT<br>FLEXHALER |                                       | 44400015008009 | Brand         |
| PULMICORT<br>FLEXHALER |                                       | 44400015008018 | Brand         |
| ALVESCO                | CICLESONIDE INHAL AEROSOL 80 MCG/ACT  | 44400017003420 | Brand         |
| ALVESCO                | CICLESONIDE INHAL AEROSOL 160 MCG/ACT | 44400017003440 | Brand         |

1 - Submission of medical records (e.g., chart notes) documenting trial and failure (e.g., objective change in symptom control such as Asthma Control Test score, nocturnal awakenings, increased rescue inhaler use, etc.) with an equipotent dose as outlined in the Global Initiative for Asthma (GINA) guidelines, intolerance, or contraindication to a preferred fluticasone product (e.g., Arnuity Ellipta or Flovent)

OR

2 - The requested drug is being used as an add-on inhaler to a preferred fluticasone or mometasone maintenance inhaler for patients who need to "step-up" their asthma treatment plan (i.e. go from Green Zone to Yellow Zone, etc.) due to an increase in symptoms

OR

**3** - (For Pulmicort only): Submission of medical records (e.g., chart notes) documenting a current pregnancy

| Date      | Notes           |
|-----------|-----------------|
| 2/28/2024 | Removed Asmanex |

| Restricted Long-acting Morphine Su   |  |  |  |  |  |
|--|--|--|--|--|--|
| The transfer and state of the s |  |  |  |  |  |

| Guideline ID          | GL-131573                               |
|-----------------------|---|
| <b>Guideline Name</b> | Restricted Long-acting Morphine Sulfate |
| Formulary             | Quartz                                  |

# **Guideline Note:**

| Effective Date: |
|-----------------|
|-----------------|

## 1. Criteria

| Product Name: Morphine ER capsules (Kadian and Evinza equivalent) |                            |  |                 |  |
|---|----------------------------|--|-----------------|--|
| Approval Le   | Approval Length 12/31/2039 |  |                 |  |
| Guideline Type  |                            | Prior Authorization - All plans except | IL and MN Plans |  |
| Product Generic Name  |                            | GPI                                    | Brand/Generic   |  |

| Product<br>Name           | Generic Name                       | GPI            | Brand/Generic |
|---------------------------|------------------------------------|----------------|---------------|
| MORPHINE<br>SULFATE<br>ER | MORPHINE SULFATE CAP ER 24HR 10 MG | 65100055107010 | Generic       |
| MORPHINE<br>SULFATE<br>ER | MORPHINE SULFATE CAP ER 24HR 20 MG | 65100055107020 | Generic       |
| MORPHINE<br>SULFATE<br>ER | MORPHINE SULFATE CAP ER 24HR 30 MG | 65100055107030 | Generic       |
| MORPHINE<br>SULFATE       | MORPHINE SULFATE CAP ER 24HR 50 MG | 65100055107040 | Generic       |

| ER                        |   |                |         |
|---------------------------|---|----------------|---------|
| MORPHINE<br>SULFATE<br>ER | MORPHINE SULFATE CAP ER 24HR 60 MG        | 65100055107045 | Generic |
| MORPHINE<br>SULFATE<br>ER | MORPHINE SULFATE CAP ER 24HR 80 MG        | 65100055107050 | Generic |
| MORPHINE<br>SULFATE<br>ER | MORPHINE SULFATE CAP ER 24HR 100 MG       | 65100055107060 | Generic |
| MORPHINE<br>SULFATE<br>ER | MORPHINE SULFATE BEADS CAP ER 24HR 30 MG  | 65100055207020 | Generic |
| MORPHINE<br>SULFATE<br>ER | MORPHINE SULFATE BEADS CAP ER 24HR 45 MG  | 65100055207025 | Generic |
| MORPHINE<br>SULFATE<br>ER | MORPHINE SULFATE BEADS CAP ER 24HR 60 MG  | 65100055207030 | Generic |
| MORPHINE<br>SULFATE<br>ER | MORPHINE SULFATE BEADS CAP ER 24HR 75 MG  | 65100055207035 | Generic |
| MORPHINE<br>SULFATE<br>ER | MORPHINE SULFATE BEADS CAP ER 24HR 90 MG  | 65100055207040 | Generic |
| MORPHINE<br>SULFATE<br>ER | MORPHINE SULFATE BEADS CAP ER 24HR 120 MG | 65100055207050 | Generic |

**1** - Trial and failure, contraindication or intolerance to an equivalent dose of generic extended release morphine tablets (MS Contin equivalent)

| Product Name: Morphine ER capsules (Kadian and Evinza equivalent) |              |                                       |                |               |
|---|--------------|---------------------------------------|----------------|---------------|
| Approval Length 12 month(s)                                       |              |                                       |                |               |
| Therapy Sta   | age          | Initial Authorization                 |                |               |
| Guideline Type  |              | Prior Authorization - IL and MN Plans |                |               |
| Product<br>Name   | Generic Name |                                       | GPI            | Brand/Generic |
| MORPHINE<br>SULFATE<br>ER   | LFATE        |                                       | 65100055107010 | Generic       |

| MORPHINE SULFATE CAP ER 24HR 20 MG        | 65100055107020  | Generic  |
|---|---|--|
| MORPHINE SULFATE CAP ER 24HR 30 MG        | 65100055107030  | Generic  |
| MORPHINE SULFATE CAP ER 24HR 50 MG        | 65100055107040  | Generic  |
| MORPHINE SULFATE CAP ER 24HR 60 MG        | 65100055107045  | Generic  |
| MORPHINE SULFATE CAP ER 24HR 80 MG        | 65100055107050  | Generic  |
| MORPHINE SULFATE CAP ER 24HR 100 MG       | 65100055107060  | Generic  |
| MORPHINE SULFATE BEADS CAP ER 24HR 30 MG  | 65100055207020  | Generic  |
| MORPHINE SULFATE BEADS CAP ER 24HR 45 MG  | 65100055207025  | Generic  |
| MORPHINE SULFATE BEADS CAP ER 24HR 60 MG  | 65100055207030  | Generic  |
| MORPHINE SULFATE BEADS CAP ER 24HR 75 MG  | 65100055207035  | Generic  |
| MORPHINE SULFATE BEADS CAP ER 24HR 90 MG  | 65100055207040  | Generic  |
| MORPHINE SULFATE BEADS CAP ER 24HR 120 MG | 65100055207050  | Generic  |
|   | MORPHINE SULFATE CAP ER 24HR 30 MG  MORPHINE SULFATE CAP ER 24HR 50 MG  MORPHINE SULFATE CAP ER 24HR 60 MG  MORPHINE SULFATE CAP ER 24HR 80 MG  MORPHINE SULFATE CAP ER 24HR 100 MG  MORPHINE SULFATE BEADS CAP ER 24HR 30 MG  MORPHINE SULFATE BEADS CAP ER 24HR 45 MG  MORPHINE SULFATE BEADS CAP ER 24HR 60 MG  MORPHINE SULFATE BEADS CAP ER 24HR 75 MG  MORPHINE SULFATE BEADS CAP ER 24HR 90 MG | MORPHINE SULFATE CAP ER 24HR 30 MG  MORPHINE SULFATE CAP ER 24HR 50 MG  MORPHINE SULFATE CAP ER 24HR 60 MG  MORPHINE SULFATE CAP ER 24HR 80 MG  MORPHINE SULFATE CAP ER 24HR 80 MG  MORPHINE SULFATE CAP ER 24HR 100 MG  MORPHINE SULFATE CAP ER 24HR 100 MG  MORPHINE SULFATE BEADS CAP ER 24HR 30 MG  MORPHINE SULFATE BEADS CAP ER 24HR 45 MG  MORPHINE SULFATE BEADS CAP ER 24HR 45 MG  MORPHINE SULFATE BEADS CAP ER 24HR 60 MG  MORPHINE SULFATE BEADS CAP ER 24HR 60 MG  MORPHINE SULFATE BEADS CAP ER 24HR 60 MG  MORPHINE SULFATE BEADS CAP ER 24HR 75 MG  MORPHINE SULFATE BEADS CAP ER 24HR 75 MG  MORPHINE SULFATE BEADS CAP ER 24HR 90 MG  MORPHINE SULFATE BEADS CAP ER 24HR 90 MG  MORPHINE SULFATE BEADS CAP ER 24HR 90 MG  65100055207040 |

**1** - Trial and failure, contraindication or intolerance to an equivalent dose of generic extended release morphine tablets (MS Contin equivalent)

### OR

 ${\bf 2}$  - (Minnesota plans only) – Member has stage four metastatic cancer and the requested drug is being used to treat cancer-related pain

| Product Name: Morphine ER capsules (Kadian and Evinza equivalent) |                             |  |  |
|---|-----------------------------|--|--|
| Approval Length 12 month(s)                                       |                             |  |  |
| Therapy Stage   | erapy Stage Reauthorization |  |  |
| Guideline Type Prior Authorization - IL and MN Plans              |                             |  |  |

| Product<br>Name           | Generic Name                              | GPI            | Brand/Generic |
|---------------------------|---|----------------|---------------|
| MORPHINE<br>SULFATE<br>ER | MORPHINE SULFATE CAP ER 24HR 10 MG        | 65100055107010 | Generic       |
| MORPHINE<br>SULFATE<br>ER | MORPHINE SULFATE CAP ER 24HR 20 MG        | 65100055107020 | Generic       |
| MORPHINE<br>SULFATE<br>ER | MORPHINE SULFATE CAP ER 24HR 30 MG        | 65100055107030 | Generic       |
| MORPHINE<br>SULFATE<br>ER | MORPHINE SULFATE CAP ER 24HR 50 MG        | 65100055107040 | Generic       |
| MORPHINE<br>SULFATE<br>ER | MORPHINE SULFATE CAP ER 24HR 60 MG        | 65100055107045 | Generic       |
| MORPHINE<br>SULFATE<br>ER | MORPHINE SULFATE CAP ER 24HR 80 MG        | 65100055107050 | Generic       |
| MORPHINE<br>SULFATE<br>ER | MORPHINE SULFATE CAP ER 24HR 100 MG       | 65100055107060 | Generic       |
| MORPHINE<br>SULFATE<br>ER | MORPHINE SULFATE BEADS CAP ER 24HR 30 MG  | 65100055207020 | Generic       |
| MORPHINE<br>SULFATE<br>ER | MORPHINE SULFATE BEADS CAP ER 24HR 45 MG  | 65100055207025 | Generic       |
| MORPHINE<br>SULFATE<br>ER | MORPHINE SULFATE BEADS CAP ER 24HR 60 MG  | 65100055207030 | Generic       |
| MORPHINE<br>SULFATE<br>ER | MORPHINE SULFATE BEADS CAP ER 24HR 75 MG  | 65100055207035 | Generic       |
| MORPHINE<br>SULFATE<br>ER | MORPHINE SULFATE BEADS CAP ER 24HR 90 MG  | 65100055207040 | Generic       |
| MORPHINE<br>SULFATE<br>ER | MORPHINE SULFATE BEADS CAP ER 24HR 120 MG | 65100055207050 | Generic       |

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug

| Date       | Notes                   |
|------------|-------------------------|
| 10/13/2023 | 2024 New Implementation |

| Restricted Methotrexate Injection  |
|--|
| 3 Shake integrated with the State and a seaso and a seaso and before the period for contribute season. |
|  |

| Guideline ID GL-131419 |  |  |
|------------------------|--|--|
| <b>Guideline Name</b>  | Name Restricted Methotrexate Injection |  |
| Formulary              | Quartz                                 |  |

# **Guideline Note:**

| Effective Date: |
|-----------------|
|-----------------|

# 1. Criteria

| Product Name: Rasuvo, Otrexup, Reditrex                 |  |  |
|---|--|--|
| Approval Length 12 month(s)                             |  |  |
| Therapy Stage Initial Authorization                     |  |  |
| Guideline Type Prior Authorization-IL and MN Plans Only |  |  |

| Product<br>Name | Generic Name   | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| RASUVO          | METHOTREXATE SOLN PF AUTO-INJECTOR 7.5<br>MG/0.15ML  | 6625005000D510 | Brand         |
| RASUVO          | METHOTREXATE SOLN PF AUTO-INJECTOR 10<br>MG/0.2ML    | 6625005000D512 | Brand         |
| RASUVO          | METHOTREXATE SOLN PF AUTO-INJECTOR 12.5<br>MG/0.25ML | 6625005000D517 | Brand         |
| RASUVO          | METHOTREXATE SOLN PF AUTO-INJECTOR 15<br>MG/0.3ML    | 6625005000D519 | Brand         |

| RASUVO   | METHOTREXATE SOLN PF AUTO-INJECTOR 17.5<br>MG/0.35ML | 6625005000D522 | Brand |
|----------|--|----------------|-------|
| OTREXUP  | METHOTREXATE SOLN PF AUTO-INJECTOR 20<br>MG/0.4ML    | 6625005000D525 | Brand |
| RASUVO   | METHOTREXATE SOLN PF AUTO-INJECTOR 20<br>MG/0.4ML    | 6625005000D525 | Brand |
| RASUVO   | METHOTREXATE SOLN PF AUTO-INJECTOR 22.5<br>MG/0.45ML | 6625005000D527 | Brand |
| RASUVO   | METHOTREXATE SOLN PF AUTO-INJECTOR 25<br>MG/0.5ML    | 6625005000D535 | Brand |
| RASUVO   | METHOTREXATE SOLN PF AUTO-INJECTOR 30 MG/0.6ML       | 6625005000D545 | Brand |
| OTREXUP  | METHOTREXATE SOLN PF AUTO-INJECTOR 10<br>MG/0.4ML    | 6625005000D515 | Brand |
| OTREXUP  | METHOTREXATE SOLN PF AUTO-INJECTOR 12.5<br>MG/0.4ML  | 6625005000D518 | Brand |
| OTREXUP  | METHOTREXATE SOLN PF AUTO-INJECTOR 15<br>MG/0.4ML    | 6625005000D520 | Brand |
| OTREXUP  | METHOTREXATE SOLN PF AUTO-INJECTOR 17.5<br>MG/0.4ML  | 6625005000D523 | Brand |
| OTREXUP  | METHOTREXATE SOLN PF AUTO-INJECTOR 22.5<br>MG/0.4ML  | 6625005000D528 | Brand |
| OTREXUP  | METHOTREXATE SOLN PF AUTO-INJECTOR 25<br>MG/0.4ML    | 6625005000D530 | Brand |
| REDITREX | METHOTREXATE SOLN PREFILLED SYRINGE 7.5<br>MG/0.3ML  | 6625005000E508 | Brand |
| REDITREX | METHOTREXATE SOLN PREFILLED SYRINGE 10 MG/0.4ML      | 6625005000E510 | Brand |
| REDITREX | METHOTREXATE SOLN PREFILLED SYRINGE 12.5<br>MG/0.5ML | 6625005000E512 | Brand |
| REDITREX | METHOTREXATE SOLN PREFILLED SYRINGE 15<br>MG/0.6ML   | 6625005000E515 | Brand |
| REDITREX | METHOTREXATE SOLN PREFILLED SYRINGE 17.5<br>MG/0.7ML | 6625005000E522 | Brand |
| REDITREX | METHOTREXATE SOLN PREFILLED SYRINGE 20<br>MG/0.8ML   | 6625005000E526 | Brand |
| REDITREX | METHOTREXATE SOLN PREFILLED SYRINGE 22.5<br>MG/0.9ML | 6625005000E532 | Brand |
| REDITREX | METHOTREXATE SOLN PREFILLED SYRINGE 25               | 6625005000E536 | Brand |

1 - Documented disability that does not allow administration of methotrexate from conventional

vials utilizing conventional syringes

### AND

# 2 - The person or a family member/caregiver are self-administering the medication

| Product Name: Rasuvo, Otrexup, Reditrex                 |                 |  |
|---|-----------------|--|
| Approval Length 12 month(s)                             |                 |  |
| Therapy Stage   | Reauthorization |  |
| Guideline Type Prior Authorization-IL and MN Plans Only |                 |  |

| Product<br>Name | Generic Name   | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| RASUVO          | METHOTREXATE SOLN PF AUTO-INJECTOR 7.5 MG/0.15ML     | 6625005000D510 | Brand         |
| RASUVO          | METHOTREXATE SOLN PF AUTO-INJECTOR 10 MG/0.2ML       | 6625005000D512 | Brand         |
| RASUVO          | METHOTREXATE SOLN PF AUTO-INJECTOR 12.5 MG/0.25ML    | 6625005000D517 | Brand         |
| RASUVO          | METHOTREXATE SOLN PF AUTO-INJECTOR 15 MG/0.3ML       | 6625005000D519 | Brand         |
| RASUVO          | METHOTREXATE SOLN PF AUTO-INJECTOR 17.5<br>MG/0.35ML | 6625005000D522 | Brand         |
| OTREXUP         | METHOTREXATE SOLN PF AUTO-INJECTOR 20<br>MG/0.4ML    | 6625005000D525 | Brand         |
| RASUVO          | METHOTREXATE SOLN PF AUTO-INJECTOR 20<br>MG/0.4ML    | 6625005000D525 | Brand         |
| RASUVO          | METHOTREXATE SOLN PF AUTO-INJECTOR 22.5<br>MG/0.45ML | 6625005000D527 | Brand         |
| RASUVO          | METHOTREXATE SOLN PF AUTO-INJECTOR 25 MG/0.5ML       | 6625005000D535 | Brand         |
| RASUVO          | METHOTREXATE SOLN PF AUTO-INJECTOR 30 MG/0.6ML       | 6625005000D545 | Brand         |
| OTREXUP         | METHOTREXATE SOLN PF AUTO-INJECTOR 10 MG/0.4ML       | 6625005000D515 | Brand         |
| OTREXUP         | METHOTREXATE SOLN PF AUTO-INJECTOR 12.5<br>MG/0.4ML  | 6625005000D518 | Brand         |
| OTREXUP         | METHOTREXATE SOLN PF AUTO-INJECTOR 15<br>MG/0.4ML    | 6625005000D520 | Brand         |
| OTREXUP         | METHOTREXATE SOLN PF AUTO-INJECTOR 17.5<br>MG/0.4ML  | 6625005000D523 | Brand         |

|          |  | I              |       |
|----------|--|----------------|-------|
| OTREXUP  | METHOTREXATE SOLN PF AUTO-INJECTOR 22.5<br>MG/0.4ML  | 6625005000D528 | Brand |
| OTREXUP  | METHOTREXATE SOLN PF AUTO-INJECTOR 25<br>MG/0.4ML    | 6625005000D530 | Brand |
| REDITREX | METHOTREXATE SOLN PREFILLED SYRINGE 7.5 MG/0.3ML     | 6625005000E508 | Brand |
| REDITREX | METHOTREXATE SOLN PREFILLED SYRINGE 10 MG/0.4ML      | 6625005000E510 | Brand |
| REDITREX | METHOTREXATE SOLN PREFILLED SYRINGE 12.5<br>MG/0.5ML | 6625005000E512 | Brand |
| REDITREX | METHOTREXATE SOLN PREFILLED SYRINGE 15 MG/0.6ML      | 6625005000E515 | Brand |
| REDITREX | METHOTREXATE SOLN PREFILLED SYRINGE 17.5 MG/0.7ML    | 6625005000E522 | Brand |
| REDITREX | METHOTREXATE SOLN PREFILLED SYRINGE 20 MG/0.8ML      | 6625005000E526 | Brand |
| REDITREX | METHOTREXATE SOLN PREFILLED SYRINGE 22.5<br>MG/0.9ML | 6625005000E532 | Brand |
| REDITREX | METHOTREXATE SOLN PREFILLED SYRINGE 25 MG/ML         | 6625005000E536 | Brand |

**1** - Documentation from the past 12 months that the person is continuing therapy with the requested drug

| Product Name: Rasuvo, Otrexup, Reditrex                       |  |  |
|---|--|--|
| Approval Length 12/31/2039                                    |  |  |
| Guideline Type Prior Authorization-All plans except IL and MN |  |  |

| Product<br>Name | Generic Name                                      | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| RASUVO          | METHOTREXATE SOLN PF AUTO-INJECTOR 7.5 MG/0.15ML  | 6625005000D510 | Brand         |
| RASUVO          | METHOTREXATE SOLN PF AUTO-INJECTOR 10 MG/0.2ML    | 6625005000D512 | Brand         |
| RASUVO          | METHOTREXATE SOLN PF AUTO-INJECTOR 12.5 MG/0.25ML | 6625005000D517 | Brand         |
| RASUVO          | METHOTREXATE SOLN PF AUTO-INJECTOR 15 MG/0.3ML    | 6625005000D519 | Brand         |
| RASUVO          | METHOTREXATE SOLN PF AUTO-INJECTOR 17.5 MG/0.35ML | 6625005000D522 | Brand         |

| METHOTOEYATE COLLINGE ALITO INJECTOR CO              |  |  |
|--|--|--|
| METHOTREXATE SOLN PF AUTO-INJECTOR 20<br>MG/0.4ML    | 6625005000D525   | Brand  |
| METHOTREXATE SOLN PF AUTO-INJECTOR 20<br>MG/0.4ML    | 6625005000D525   | Brand  |
| METHOTREXATE SOLN PF AUTO-INJECTOR 22.5<br>MG/0.45ML | 6625005000D527   | Brand  |
| METHOTREXATE SOLN PF AUTO-INJECTOR 25<br>MG/0.5ML    | 6625005000D535   | Brand  |
| METHOTREXATE SOLN PF AUTO-INJECTOR 30<br>MG/0.6ML    | 6625005000D545   | Brand  |
| METHOTREXATE SOLN PF AUTO-INJECTOR 10<br>MG/0.4ML    | 6625005000D515   | Brand  |
| METHOTREXATE SOLN PF AUTO-INJECTOR 12.5<br>MG/0.4ML  | 6625005000D518   | Brand  |
| METHOTREXATE SOLN PF AUTO-INJECTOR 15<br>MG/0.4ML    | 6625005000D520   | Brand  |
| METHOTREXATE SOLN PF AUTO-INJECTOR 17.5<br>MG/0.4ML  | 6625005000D523   | Brand  |
| METHOTREXATE SOLN PF AUTO-INJECTOR 22.5<br>MG/0.4ML  | 6625005000D528   | Brand  |
| METHOTREXATE SOLN PF AUTO-INJECTOR 25<br>MG/0.4ML    | 6625005000D530   | Brand  |
| METHOTREXATE SOLN PREFILLED SYRINGE 7.5<br>MG/0.3ML  | 6625005000E508   | Brand  |
| METHOTREXATE SOLN PREFILLED SYRINGE 10<br>MG/0.4ML   | 6625005000E510   | Brand  |
| METHOTREXATE SOLN PREFILLED SYRINGE 12.5<br>MG/0.5ML | 6625005000E512   | Brand  |
| METHOTREXATE SOLN PREFILLED SYRINGE 15<br>MG/0.6ML   | 6625005000E515   | Brand  |
| METHOTREXATE SOLN PREFILLED SYRINGE 17.5<br>MG/0.7ML | 6625005000E522   | Brand  |
| METHOTREXATE SOLN PREFILLED SYRINGE 20<br>MG/0.8ML   | 6625005000E526   | Brand  |
| METHOTREXATE SOLN PREFILLED SYRINGE 22.5<br>MG/0.9ML | 6625005000E532   | Brand  |
| METHOTREXATE SOLN PREFILLED SYRINGE 25<br>MG/ML      | 6625005000E536   | Brand  |
|  | METHOTREXATE SOLN PF AUTO-INJECTOR 20 MG/0.4ML METHOTREXATE SOLN PF AUTO-INJECTOR 22.5 MG/0.45ML METHOTREXATE SOLN PF AUTO-INJECTOR 25 MG/0.5ML METHOTREXATE SOLN PF AUTO-INJECTOR 30 MG/0.6ML METHOTREXATE SOLN PF AUTO-INJECTOR 10 MG/0.4ML METHOTREXATE SOLN PF AUTO-INJECTOR 12.5 MG/0.4ML METHOTREXATE SOLN PF AUTO-INJECTOR 15 MG/0.4ML METHOTREXATE SOLN PF AUTO-INJECTOR 17.5 MG/0.4ML METHOTREXATE SOLN PF AUTO-INJECTOR 22.5 MG/0.4ML METHOTREXATE SOLN PF AUTO-INJECTOR 25 MG/0.4ML METHOTREXATE SOLN PF AUTO-INJECTOR 25 MG/0.4ML METHOTREXATE SOLN PREFILLED SYRINGE 7.5 MG/0.3ML METHOTREXATE SOLN PREFILLED SYRINGE 10 MG/0.4ML METHOTREXATE SOLN PREFILLED SYRINGE 15 MG/0.5ML METHOTREXATE SOLN PREFILLED SYRINGE 15 MG/0.5ML METHOTREXATE SOLN PREFILLED SYRINGE 17.5 MG/0.7ML METHOTREXATE SOLN PREFILLED SYRINGE 17.5 MG/0.7ML METHOTREXATE SOLN PREFILLED SYRINGE 20 MG/0.8ML METHOTREXATE SOLN PREFILLED SYRINGE 22.5 MG/0.8ML METHOTREXATE SOLN PREFILLED SYRINGE 22.5 MG/0.9ML | METHOTREXATE SOLN PF AUTO-INJECTOR 20 MG/0.4ML  METHOTREXATE SOLN PF AUTO-INJECTOR 22.5 MG/0.45ML  METHOTREXATE SOLN PF AUTO-INJECTOR 25 MG/0.5ML  METHOTREXATE SOLN PF AUTO-INJECTOR 25 MG/0.5ML  METHOTREXATE SOLN PF AUTO-INJECTOR 30 MG/0.6ML  METHOTREXATE SOLN PF AUTO-INJECTOR 10 MG/0.4ML  METHOTREXATE SOLN PF AUTO-INJECTOR 12.5 MG/0.4ML  METHOTREXATE SOLN PF AUTO-INJECTOR 15 MG/0.4ML  METHOTREXATE SOLN PF AUTO-INJECTOR 15 MG/0.4ML  METHOTREXATE SOLN PF AUTO-INJECTOR 17.5 MG/0.4ML  METHOTREXATE SOLN PF AUTO-INJECTOR 22.5 MG/0.4ML  METHOTREXATE SOLN PF AUTO-INJECTOR 25 MG/0.4ML  METHOTREXATE SOLN PF AUTO-INJECTOR 25 MG/0.4ML  METHOTREXATE SOLN PF AUTO-INJECTOR 25 MG/0.4ML  METHOTREXATE SOLN PREFILLED SYRINGE 7.5 MG/0.4ML  METHOTREXATE SOLN PREFILLED SYRINGE 10 MG/0.4ML  METHOTREXATE SOLN PREFILLED SYRINGE 12.5 MG/0.5ML  METHOTREXATE SOLN PREFILLED SYRINGE 15 MG/0.5ML  METHOTREXATE SOLN PREFILLED SYRINGE 17.5 MG/0.5ML  METHOTREXATE SOLN PREFILLED SYRINGE 17.5 MG/0.5ML  METHOTREXATE SOLN PREFILLED SYRINGE 17.5 MG/0.5ML  METHOTREXATE SOLN PREFILLED SYRINGE 15 MG/0.5ML  METHOTREXATE SOLN PREFILLED SYRINGE 20 MG/0.7ML  METHOTREXATE SOLN PREFILLED SYRINGE 20 MG/0.7ML  METHOTREXATE SOLN PREFILLED SYRINGE 20 MG/0.7ML  METHOTREXATE SOLN PREFILLED SYRINGE 22.5 MG/0.9ML  METHOTREXATE SOLN PREFILLED SYRINGE 25 MG/0.9ML  METHOTREXATE SOLN PREFILLED SYRINGE 25 MG/0.9ML |

**1** - Documented disability that does not allow administration of methotrexate from conventional vials utilizing conventional syringes

### AND

2 - The person or a family member/caregiver are self-administering the medication

| Date       | Notes       |
|------------|-------------|
| 10/24/2023 | New Program |

| Restricted Minocycline ER  |  |  |  |
|--|--|--|--|
| The behavior and included to the tenth and close of a side of a si |  |  |  |

| Guideline ID          | GL-137244                 |
|-----------------------|---------------------------|
| <b>Guideline Name</b> | Restricted Minocycline ER |
| Formulary             | Quartz                    |

# **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

# 1. Criteria

| Product Name: Brand Coremino, Generic Solodyn, generic minocycline extended release |                                     |  |  |
|---|-------------------------------------|--|--|
| Approval Length 12 month(s)   |                                     |  |  |
| Therapy Stage   | Therapy Stage Initial Authorization |  |  |
| Guideline Type Prior Authorization-IL and MN Plans Only                             |                                     |  |  |

| Product Name                       | Generic Name                       | GPI            | Brand/Generic |
|------------------------------------|------------------------------------|----------------|---------------|
| MINOCYCLINE<br>HYDROCHLORIDE<br>ER | MINOCYCLINE HCL TAB ER 24HR 55 MG  | 04000040107522 | Generic       |
| MINOCYCLINE<br>HYDROCHLORIDE<br>ER | MINOCYCLINE HCL TAB ER 24HR 65 MG  | 04000040107525 | Generic       |
| MINOCYCLINE<br>HYDROCHLORIDE<br>ER | MINOCYCLINE HCL TAB ER 24HR 80 MG  | 04000040107528 | Generic       |
| MINOCYCLINE                        | MINOCYCLINE HCL TAB ER 24HR 105 MG | 04000040107533 | Generic       |

| HYDROCHLORIDE<br>ER                |                                    |                |         |
|------------------------------------|------------------------------------|----------------|---------|
| MINOCYCLINE<br>HYDROCHLORIDE<br>ER | MINOCYCLINE HCL TAB ER 24HR 115 MG | 04000040107535 | Generic |
| COREMINO                           | MINOCYCLINE HCL TAB ER 24HR 45 MG  | 04000040107520 | Generic |
| MINOCYCLINE<br>HYDROCHLORIDE<br>ER | MINOCYCLINE HCL TAB ER 24HR 45 MG  | 04000040107520 | Generic |
| COREMINO                           | MINOCYCLINE HCL TAB ER 24HR 90 MG  | 04000040107530 | Generic |
| MINOCYCLINE<br>HYDROCHLORIDE<br>ER | MINOCYCLINE HCL TAB ER 24HR 90 MG  | 04000040107530 | Generic |
| COREMINO                           | MINOCYCLINE HCL TAB ER 24HR 135 MG | 04000040107540 | Generic |
| MINOCYCLINE<br>HYDROCHLORIDE<br>ER | MINOCYCLINE HCL TAB ER 24HR 135 MG | 04000040107540 | Generic |

**1** - Trial and intolerance (clinically significant side effects that limit use) from a preferred minocycline product at equivalent doses

#### **AND**

f 2 - The prescriber provides an evidence-based clinical rationale why a different result would be expected with use of minocycline ER

| Product Name: Brand Coremino, Generic Solodyn, generic minocycline extended release |                               |  |  |  |
|---|-------------------------------|--|--|--|
| Approval Length 12 month(s)   |                               |  |  |  |
| Therapy Stage   | Therapy Stage Reauthorization |  |  |  |
| Guideline Type Prior Authorization-IL and MN Plans Only                             |                               |  |  |  |
|   |                               |  |  |  |

| Product Name                       | Generic Name                      | GPI            | Brand/Generic |
|------------------------------------|-----------------------------------|----------------|---------------|
| MINOCYCLINE<br>HYDROCHLORIDE<br>ER | MINOCYCLINE HCL TAB ER 24HR 55 MG | 04000040107522 | Generic       |
| MINOCYCLINE<br>HYDROCHLORIDE<br>ER | MINOCYCLINE HCL TAB ER 24HR 65 MG | 04000040107525 | Generic       |

| MINOCYCLINE<br>HYDROCHLORIDE<br>ER | MINOCYCLINE HCL TAB ER 24HR 80 MG  | 04000040107528 | Generic |
|------------------------------------|------------------------------------|----------------|---------|
| MINOCYCLINE<br>HYDROCHLORIDE<br>ER | MINOCYCLINE HCL TAB ER 24HR 105 MG | 04000040107533 | Generic |
| MINOCYCLINE<br>HYDROCHLORIDE<br>ER | MINOCYCLINE HCL TAB ER 24HR 115 MG | 04000040107535 | Generic |
| COREMINO                           | MINOCYCLINE HCL TAB ER 24HR 45 MG  | 04000040107520 | Generic |
| MINOCYCLINE<br>HYDROCHLORIDE<br>ER | MINOCYCLINE HCL TAB ER 24HR 45 MG  | 04000040107520 | Generic |
| COREMINO                           | MINOCYCLINE HCL TAB ER 24HR 90 MG  | 04000040107530 | Generic |
| MINOCYCLINE<br>HYDROCHLORIDE<br>ER | MINOCYCLINE HCL TAB ER 24HR 90 MG  | 04000040107530 | Generic |
| COREMINO                           | MINOCYCLINE HCL TAB ER 24HR 135 MG | 04000040107540 | Generic |
| MINOCYCLINE<br>HYDROCHLORIDE<br>ER | MINOCYCLINE HCL TAB ER 24HR 135 MG | 04000040107540 | Generic |

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug

| Product Name: Brand Coremino, Generic Solodyn, generic minocycline extended release |  |  |
|---|--|--|
| Approval Length One fill  |  |  |
| Guideline Type  | Prior Authorization-All plans except IL and MN |  |

| Product Name                       | Generic Name                       | GPI            | Brand/Generic |
|------------------------------------|------------------------------------|----------------|---------------|
| MINOCYCLINE<br>HYDROCHLORIDE<br>ER | MINOCYCLINE HCL TAB ER 24HR 55 MG  | 04000040107522 | Generic       |
| MINOCYCLINE<br>HYDROCHLORIDE<br>ER | MINOCYCLINE HCL TAB ER 24HR 65 MG  | 04000040107525 | Generic       |
| MINOCYCLINE<br>HYDROCHLORIDE<br>ER | MINOCYCLINE HCL TAB ER 24HR 80 MG  | 04000040107528 | Generic       |
| MINOCYCLINE<br>HYDROCHLORIDE<br>ER | MINOCYCLINE HCL TAB ER 24HR 105 MG | 04000040107533 | Generic       |

| MINOCYCLINE<br>HYDROCHLORIDE<br>ER | MINOCYCLINE HCL TAB ER 24HR 115 MG | 04000040107535 | Generic |
|------------------------------------|------------------------------------|----------------|---------|
| COREMINO                           | MINOCYCLINE HCL TAB ER 24HR 45 MG  | 04000040107520 | Generic |
| MINOCYCLINE<br>HYDROCHLORIDE<br>ER | MINOCYCLINE HCL TAB ER 24HR 45 MG  | 04000040107520 | Generic |
| COREMINO                           | MINOCYCLINE HCL TAB ER 24HR 90 MG  | 04000040107530 | Generic |
| MINOCYCLINE<br>HYDROCHLORIDE<br>ER | MINOCYCLINE HCL TAB ER 24HR 90 MG  | 04000040107530 | Generic |
| COREMINO                           | MINOCYCLINE HCL TAB ER 24HR 135 MG | 04000040107540 | Generic |
| MINOCYCLINE<br>HYDROCHLORIDE<br>ER | MINOCYCLINE HCL TAB ER 24HR 135 MG | 04000040107540 | Generic |

**1** - Trial and intolerance (clinically significant side effects that limit use) from a preferred minocycline product at equivalent doses

### AND

**2** - The prescriber provides an evidence-based clinical rationale why a different result would be expected with use of minocycline ER

| Date      | Notes       |
|-----------|-------------|
| 12/6/2023 | New program |

| Restricted Non-preferred Medication                    |   |  |  |
|--|---|--|--|
| The biddings cannot be displayed. The fier may have be | n mand, verand, er delek half ford to his probles der anventile and hauben. |  |  |
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|  |   |  |  |

| Guideline ID          | GL-134517                            |
|-----------------------|--------------------------------------|
| <b>Guideline Name</b> | Restricted Non-preferred Medications |
| Formulary             | Quartz                               |

# **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

## 1. Criteria

| Product Name: Restricted Non-preferred Drugs Greater than or equal to 5 therapeutic alternatives |  |  |  |
|--|--|--|--|
| Diagnosis Illinois Plan ONLY   |  |  |  |
| Approval Length 12   |  |  |  |
| Guideline Type Administrative  |  |  |  |
| Product Name   Generic Name   GPI   Brand/Generic  |  |  |  |

### **Approval Criteria**

- **1** Both of the following:
- **1.1** The requested medication has a diagnosis that is one of the following:

- Food Drug Administration (FDA)-approved indication
- A medically accepted indication that is supported by nationally recognized compendia (see table of Compendia Requirements within the Background Section)

#### **AND**

- **1.2** For drugs with greater than or equal to 5 therapeutic alternatives (in the same drug class or different drug class that treats the same disease as the requested drug) one of the following:
- **1.2.1** Trial and failure or intolerance, or contraindication to at least 2 preferred alternatives in the same drug class

#### OR

**1.2.2** Trial and failure to at least 2 preferred alternatives from other drug classes that treat the same disease if there are not 2 formulary alternatives in the same drug class and provider attests that it is clinically appropriate treatment of the diagnosis

#### OR

**1.2.3** Member is new to the plan (as evidenced by coverage effective date of less than or equal to 90 days) who are established on nonpreferred therapy, will have coverage under their drug benefit with submission of medical records (e.g., chart notes) documenting symptom improvement or disease stability

#### OR

2 - The requested drug is FDA approved for the treatment of tick-borne disease

| Product Name: Restricted Non-preferred Drugs less than 5 therapeutic alternatives |                    |     |               |
|---|--------------------|-----|---------------|
| Diagnosis   | Illinois Plan ONLY |     |               |
| Approval Length   | 12                 |     |               |
| Guideline Type  | Administrative     |     |               |
| Product Name Gene   | ric Name           | GPI | Brand/Generic |
|   |                    |     |               |

- **1** Both of the following:
- **1.1** The requested medication has a diagnosis that is one of the following:
  - Food Drug Administration (FDA)-approved indication
  - A medically accepted indication that is supported by nationally recognized compendia (see table of Compendia Requirements within the Background Section)

#### **AND**

- **1.2** For drugs with less than 5 therapeutic alternatives (in the same drug class or different drug class that treats the same disease as the requested drug) one of the following:
- **1.2.1** Trial and failure or intolerance, or contraindication to at least 1 preferred alternative in the same drug class

OR

**1.2.2** Trial and failure to at least 1 preferred alternative from other drug classes that treat the same disease if there are not 1 formulary alternatives in the same drug class and provider attests that it is clinically appropriate treatment of the diagnosis

OR

**1.2.3** Member is new to the plan (as evidenced by coverage effective date of less than or equal to 90 days) who are established on nonpreferred therapy, will have coverage under their drug benefit with submission of medical records (e.g., chart notes) documenting symptom improvement or disease stability

OR

2 - The requested drug is for the treatment of tick-borne disease

Product Name: Restricted Non-preferred Drugs Greater than or equal to 5 therapeutic alternatives

| Diagnosis       | Minnesota Plans ONLY  |
|-----------------|-----------------------|
| Approval Length | 12 month(s)           |
| Therapy Stage   | Initial Authorization |
| Guideline Type  | Administrative        |

- **1** Both of the following:
- **1.1** The requested medication has a diagnosis that is one of the following:
  - Food Drug Administration (FDA)-approved indication
  - A medically accepted indication that is supported by nationally recognized compendia (see table of Compendia Requirements within the Background Section)

#### AND

- **1.2** For drugs with greater than or equal to 5 therapeutic alternatives (in the same drug class or different drug class that treats the same disease as the requested drug) one of the following:
- **1.2.1** Trial and failure or intolerance, or contraindication to at least 2 preferred alternatives in the same drug class

OR

**1.2.2** Trial and failure to at least 2 preferred alternatives from other drug classes that treat the same disease if there are not 2 formulary alternatives in the same drug class and provider attests that it is clinically appropriate treatment of the diagnosis

OR

**1.2.3** Member is new to the plan (as evidenced by coverage effective date of less than or equal to 90 days) who are established on nonpreferred therapy, will have coverage under their drug benefit with submission of medical records (e.g., chart notes) documenting symptom improvement or disease stability

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|--------|---|
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- 2 Both of the following:
- 2.1 Provider attests the patient has emotional disturbance or mental illness

#### **AND**

**2.2** Prescriber submits medical records (e.g., chart notes) that all equivalent drugs in the formulary were considered and it has been determined that the drug prescribed will best treat the person's condition

#### OR

**3** - For continuation of care: the person has been treated for 90 days prior to the change, the medication is working, and the prescriber attests the drug prescribed will best treat the person's condition

#### OR

**4** - The requested drug is for stage four metastatic cancer and prescribed drug is used for cancer related treatment including but not limited to: pain, constipation, nausea, or prevention/treatment of infection

| Product Name: Restricted Non-preferred Drugs less than 5 therapeutic alternatives |                       |  |
|---|-----------------------|--|
| Diagnosis   | Minnesota Plans ONLY  |  |
| Approval Length   | 12 month(s)           |  |
| Therapy Stage   | Initial Authorization |  |
| Guideline Type  | Administrative        |  |

| Product Name | Generic Name | GPI | Brand/Generic |
|--------------|--------------|-----|---------------|
|--------------|--------------|-----|---------------|

### **Approval Criteria**

- **1** Both of the following:
- **1.1** The requested medication has a diagnosis that is one of the following:

- Food Drug Administration (FDA)-approved indication
- A medically accepted indication that is supported by nationally recognized compendia (see table of Compendia Requirements within the Background Section)

#### **AND**

- **1.2** For drugs with less than 5 therapeutic alternatives (in the same drug class or different drug class that treats the same disease as the requested drug) one of the following:
- **1.2.1** Trial and failure or intolerance, or contraindication to at least 1 preferred alternative in the same drug class

#### OR

**1.2.2** Trial and failure to at least 1 preferred alternative from other drug classes that treat the same disease if there are not 1 formulary alternatives in the same drug class and provider attests that it is clinically appropriate treatment of the diagnosis

#### OR

- 2 Both of the following:
- 2.1 Provider attests the patient has emotional disturbance or mental illness

#### **AND**

**2.2** Submission of medical records (e.g., chart notes) that all equivalent drugs in the formulary were considered and it has been determined that the drug prescribed will best treat the person's condition

#### OR

**3** - For continuation of care: the person has been treated for 90 days prior to the change, the medication is working, and the prescriber attests the drug prescribed will best treat the person's condition

OR

**4** - The requested drug is for stage four metastatic cancer and prescribed drug is used for cancer related treatment including but not limited to: pain, constipation, nausea, or prevention/treatment of infection

| Product Name: Restricted Non-preferred Drugs greater than or equal to 5 therapeutic alternatives |  |  |               |
|--|--|--|---------------|
| Approval Length 12 month(s)  |  |  |               |
| Therapy Stage Initial Authorization  |  |  |               |
| Guideline Type Administrative - All plans except IL and MN                                       |  |  |               |
| Product Name Generic Name GPI Brand/Gene   |  |  | Brand/Generic |

### **Approval Criteria**

- 1 The requested medication has a diagnosis that is one of the following:
  - Food Drug Administration (FDA)-approved indication
  - A medically accepted indication that is supported by nationally recognized compendia (see table of Compendia Requirements within the Background Section)

#### AND

- **2** For drugs with greater than or equal to 5 therapeutic alternatives (in the same drug class or different drug class that treats the same disease as the requested drug) one of the following:
- **2.1** Trial and failure or intolerance, or contraindication to at least 2 preferred alternatives in the same drug class

OR

**2.2** Trial and failure to at least 2 preferred alternatives from other drug classes that treat the same disease if there are not 2 formulary alternatives in the same drug class and provider attests that it is clinically appropriate treatment of the diagnosis

OR

**2.3** Member is new to the plan (as evidenced by coverage effective date of less than or equal to 90 days) who are established on nonpreferred therapy, will have coverage under their drug benefit with submission of medical records (e.g., chart notes) documenting symptom improvement or disease stability

| Product Name: Restricted Non-preferred Drugs less than 5 therapeutic alternatives |  |             |               |  |
|---|--|-------------|---------------|--|
| Approval Length   |  | 12 month(s) |               |  |
| Therapy Stage Initial Authorization   |  |             |               |  |
| Guideline Type Administrative - All other plans except IL and MN                  |  |             |               |  |
| Product Name   Generic Name   GPI   Brand/Gener                                   |  |             | Brand/Generic |  |

#### **Approval Criteria**

- 1 The requested medication has a diagnosis that is one of the following:
  - Food Drug Administration (FDA)-approved indication
  - A medically accepted indication that is supported by nationally recognized compendia (see table of Compendia Requirements within the Background Section)

#### **AND**

- **2** For drugs with less than 5 therapeutic alternatives (in the same drug class or different drug class that treats the same disease as the requested drug) one of the following:
- **2.1** Trial and failure or intolerance, or contraindication to at least 1 preferred alternative in the same drug class

OR

**2.2** Trial and failure to at least 1 preferred alternative from other drug classes that treat the same disease if there are not 1 formulary alternatives in the same drug class and provider attests that it is clinically appropriate treatment of the diagnosis

OR

2.3 Member is new to the plan (as evidenced by coverage effective date of less than or equal

to 90 days) who are established on nonpreferred therapy, will have coverage under their drug benefit with submission of medical records (e.g., chart notes) documenting symptom improvement or disease stability

| Product Name: All Indications above      |                 |  |               |
|--|-----------------|--|---------------|
| Diagnosis                                | All Plans       |  |               |
| Approval Length                          | 12 month(s)     |  |               |
| Therapy Stage                            | Reauthorization |  |               |
| Guideline Type Administrative            |                 |  |               |
| Product Name Generic Name GPI Brand/Gene |                 |  | Brand/Generic |

### **Approval Criteria**

**1** - Paid claims or submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug

| Date      | Notes       |
|-----------|-------------|
| 12/7/2023 | New Program |

| Restricted Nonpreferred Proton Pump  | Inhibitor (PPI) |
|--|-----------------|
| The Section process of the Section and section and section and Section Section and section |                 |

| Guideline ID          | GL-131574   |  |
|-----------------------|---|--|
| <b>Guideline Name</b> | Restricted Nonpreferred Proton Pump Inhibitor (PPI) |  |
| Formulary             | Quartz  |  |

## **Guideline Note:**

| Effective Date: |
|-----------------|
|-----------------|

## 1. Criteria

| Product Name: Gen   | eric dexlansoprazole |  |
|---|----------------------|--|
| Approval Length   | 12/31/2039           |  |
| Guideline Type Prior Authorization - All Plans except IL and MN Plans |                      |  |
|   |                      |  |

| Product Name    | Generic Name                                 | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| DEXLANSOPRAZOLE | DEXLANSOPRAZOLE CAP DELAYED<br>RELEASE 30 MG | 49270020006520 | Generic       |
| DEXLANSOPRAZOLE | DEXLANSOPRAZOLE CAP DELAYED<br>RELEASE 60 MG | 49270020006530 | Generic       |

## **Approval Criteria**

**1** - Trial and failure, contraindication, or intolerance to at least THREE of the following preferred PPI alternatives:

- omeprazole pantoprazole
- lansoprazole
- rabeprazole tablets
- esomeprazole capsules

| Product Name: Generic dexlansoprazole |                               |  |
|---------------------------------------|-------------------------------|--|
| Approval Length                       | 12 month(s)                   |  |
| Therapy Stage                         | Initial Authorization         |  |
| Guideline Type                        | Prior Authorization - IL Plan |  |

| Product Name    | Generic Name                                 | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| DEXLANSOPRAZOLE | DEXLANSOPRAZOLE CAP DELAYED<br>RELEASE 30 MG | 49270020006520 | Generic       |
| DEXLANSOPRAZOLE | DEXLANSOPRAZOLE CAP DELAYED<br>RELEASE 60 MG | 49270020006530 | Generic       |

- 1 Trial and failure, contraindication, or intolerance to at least THREE of the following preferred PPI alternatives:
  - omeprazole
  - pantoprazole
  - lansoprazole
  - rabeprazole tablets
  - esomeprazole capsules

| Product Name: Generic dexlansoprazole |                               |  |  |  |
|---------------------------------------|-------------------------------|--|--|--|
| Approval Length                       | 12 month(s)                   |  |  |  |
| Therapy Stage                         | Initial Authorization         |  |  |  |
| Guideline Type                        | Prior Authorization - MN Plan |  |  |  |
|                                       |                               |  |  |  |

| Product Name    | Generic Name                                 | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| DEXLANSOPRAZOLE | DEXLANSOPRAZOLE CAP DELAYED<br>RELEASE 30 MG | 49270020006520 | Generic       |
| DEXLANSOPRAZOLE | DEXLANSOPRAZOLE CAP DELAYED<br>RELEASE 60 MG | 49270020006530 | Generic       |

- **1** Trial and failure, contraindication, or intolerance to at least THREE of the following preferred PPI alternatives:
  - omeprazole
  - pantoprazole
  - lansoprazole
  - rabeprazole tablets
  - esomeprazole capsules

OR

**2** - Diagnosis of stage four metastatic cancer and the requested drug is being used as supportive care to treat symptoms directly related to their cancer or chemotherapy regimen

| Product Name: Generic dexlansoprazole |  |
|---------------------------------------|--|
| Diagnosis Quantity Exception          |  |
| Approval Length                       | 12/31/2039   |
| Guideline Type                        | Prior Authorization - All Plans except IL and MN Plans |

| Product Name    | Generic Name                                 | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| DEXLANSOPRAZOLE | DEXLANSOPRAZOLE CAP DELAYED<br>RELEASE 30 MG | 49270020006520 | Generic       |
| DEXLANSOPRAZOLE | DEXLANSOPRAZOLE CAP DELAYED<br>RELEASE 60 MG | 49270020006530 | Generic       |

## **Approval Criteria**

1 - Member has extraesophageal symptoms

OR

**2** - The requested dosing schedule cannot be met using commercially available dose forms within the quantity limit and the prescriber provides an evidence-based rationale for using a dose outside of the quantity limit

OR

**3** - For use in compounded prescriptions where the quantity limit would prevent the pharmacy from being able to make the compounded formulation

| Product Name: Generic dexlansoprazole                |                       |
|--|-----------------------|
| Diagnosis  | Quantity Exception    |
| Approval Length                                      | 12 month(s)           |
| Therapy Stage  | Initial Authorization |
| Guideline Type Prior Authorization - IL and MN Plans |                       |

| Product Name    | Generic Name                                 | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| DEXLANSOPRAZOLE | DEXLANSOPRAZOLE CAP DELAYED<br>RELEASE 30 MG | 49270020006520 | Generic       |
| DEXLANSOPRAZOLE | DEXLANSOPRAZOLE CAP DELAYED<br>RELEASE 60 MG | 49270020006530 | Generic       |

## **Approval Criteria**

1 - Member has extraesophageal symptoms

OR

**2** - The requested dosing schedule cannot be met using commercially available dose forms within the quantity limit and the prescriber provides an evidence-based rationale for using a dose outside of the quantity limit

OR

 $oldsymbol{3}$  - For use in compounded prescriptions where the quantity limit would prevent the pharmacy from being able to make the compounded formulation

| Product Name: Generic dexlansoprazole |             |
|---------------------------------------|-------------|
| Approval Length                       | 12 month(s) |

| Therapy Stage  | Reauthorization                       |          |  |  |
|----------------|---------------------------------------|----------|--|--|
| Guideline Type | Prior Authorization - IL and MN Plans | <b>i</b> |  |  |
|                |                                       |          |  |  |

| Product Name    | Generic Name                                 | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| DEXLANSOPRAZOLE | DEXLANSOPRAZOLE CAP DELAYED<br>RELEASE 30 MG | 49270020006520 | Generic       |
| DEXLANSOPRAZOLE | DEXLANSOPRAZOLE CAP DELAYED<br>RELEASE 60 MG | 49270020006530 | Generic       |

**1** - Prescriber provides clinical documentation from the past 12 months that the person is continuing therapy with the requested drug

# 2. Revision History

| Date      | Notes                   |
|-----------|-------------------------|
| 10/6/2023 | 2024 New Implementation |

| Restricted Oral Antipsychotics Step  |  |
|--|--|
| (2) Indicates were violated. In this to the control control of the bit particle control of the c |  |

# **Prior Authorization Guideline**

| Guideline ID          | GL-127882                           |
|-----------------------|-------------------------------------|
| <b>Guideline Name</b> | Restricted Oral Antipsychotics Step |
| Formulary             | Quartz                              |

# **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

# 1. Criteria

| Product Name: Generic Asenapine, Vraylar, Fanapt, Caplyta, Generic Lurasidone, Rexulti |                       |  |
|--|-----------------------|--|
| Approval Length  | 12 month(s)           |  |
| Therapy Stage  | Initial Authorization |  |
| Guideline Type Step Therapy - IL and MN Plans  |                       |  |

| Product Name            | Generic Name   | GPI            | Brand/Generic |
|-------------------------|--|----------------|---------------|
| ASENAPINE<br>MALEATE SL | ASENAPINE MALEATE SL TAB 2.5 MG (BASE EQUIV)           | 59155015100710 | Generic       |
| ASENAPINE<br>MALEATE SL | ASENAPINE MALEATE SL TAB 5 MG (BASE EQUIV)             | 59155015100720 | Generic       |
| ASENAPINE<br>MALEATE SL | ASENAPINE MALEATE SL TAB 10 MG (BASE EQUIV)            | 59155015100730 | Generic       |
| VRAYLAR                 | CARIPRAZINE HCL CAP THERAPY PACK 1.5 MG (1) & 3 MG (6) | 5940001810B220 | Brand         |
| VRAYLAR                 | CARIPRAZINE HCL CAP 1.5 MG (BASE EQUIVALENT)           | 59400018100120 | Brand         |

| VRAYLAR                     | CARIPRAZINE HCL CAP 3 MG (BASE<br>EQUIVALENT)              | 59400018100130 | Brand   |
|-----------------------------|--|----------------|---------|
| VRAYLAR                     | CARIPRAZINE HCL CAP 4.5 MG (BASE EQUIVALENT)               | 59400018100140 | Brand   |
| VRAYLAR                     | CARIPRAZINE HCL CAP 6 MG (BASE<br>EQUIVALENT)              | 59400018100150 | Brand   |
| FANAPT                      | ILOPERIDONE TAB 1 MG                                       | 59070035000310 | Brand   |
| FANAPT                      | ILOPERIDONE TAB 2 MG                                       | 59070035000320 | Brand   |
| FANAPT                      | ILOPERIDONE TAB 4 MG                                       | 59070035000340 | Brand   |
| FANAPT                      | ILOPERIDONE TAB 6 MG                                       | 59070035000360 | Brand   |
| FANAPT                      | ILOPERIDONE TAB 8 MG                                       | 59070035000380 | Brand   |
| FANAPT                      | ILOPERIDONE TAB 10 MG                                      | 59070035000385 | Brand   |
| FANAPT                      | ILOPERIDONE TAB 12 MG                                      | 59070035000390 | Brand   |
| FANAPT<br>TITRATION PACK    | ILOPERIDONE TAB 1 MG & 2 MG & 4 MG & 6 MG<br>TITRATION PAK | 59070035006320 | Brand   |
| CAPLYTA                     | LUMATEPERONE TOSYLATE CAP 10.5 MG                          | 59400022400110 | Brand   |
| CAPLYTA                     | LUMATEPERONE TOSYLATE CAP 21 MG                            | 59400022400115 | Brand   |
| CAPLYTA                     | LUMATEPERONE TOSYLATE CAP 42 MG                            | 59400022400120 | Brand   |
| LURASIDONE<br>HYDROCHLORIDE | LURASIDONE HCL TAB 20 MG                                   | 59400023100310 | Generic |
| LURASIDONE<br>HYDROCHLORIDE | LURASIDONE HCL TAB 40 MG                                   | 59400023100320 | Generic |
| LURASIDONE<br>HYDROCHLORIDE | LURASIDONE HCL TAB 60 MG                                   | 59400023100330 | Generic |
| LURASIDONE<br>HYDROCHLORIDE | LURASIDONE HCL TAB 80 MG                                   | 59400023100340 | Generic |
| LURASIDONE<br>HYDROCHLORIDE | LURASIDONE HCL TAB 120 MG                                  | 59400023100350 | Generic |
| REXULTI                     | BREXPIPRAZOLE TAB 0.25 MG                                  | 59250020000310 | Brand   |
| REXULTI                     | BREXPIPRAZOLE TAB 0.5 MG                                   | 59250020000320 | Brand   |
| REXULTI                     | BREXPIPRAZOLE TAB 1 MG                                     | 59250020000330 | Brand   |
| REXULTI                     | BREXPIPRAZOLE TAB 2 MG                                     | 59250020000340 | Brand   |
| REXULTI                     | BREXPIPRAZOLE TAB 3 MG                                     | 59250020000350 | Brand   |
| REXULTI                     | BREXPIPRAZOLE TAB 4 MG                                     | 59250020000360 | Brand   |

1 - Trial and failure, contraindication, or intolerance of a preferred second-generation

antipsychotic (i.e., aripiprazole, olanzapine, risperidone, quetiapine, or ziprasidone).

## OR

**2** - For Minnesota Plans Only: If requested drug is prescribed for emotional disturbance or mental illness, approve if submission of medical records (e.g., chart notes) documenting that all equivalent drugs in the formulary were considered and it has been determined that the drug prescribed will best treat the member's condition

| Product Name: Generic Asenapine, Vraylar, Fanapt, Caplyta, Generic Lurasidone, Rexulti |  |  |  |
|--|--|--|--|
| Approval Length 12 month(s)  |  |  |  |
| Therapy Stage Reauthorization  |  |  |  |
| Guideline Type Step Therapy - IL and MN Plans  |  |  |  |

| Product Name            | Generic Name   | GPI            | Brand/Generic |
|-------------------------|--|----------------|---------------|
| ASENAPINE<br>MALEATE SL | ASENAPINE MALEATE SL TAB 2.5 MG (BASE EQUIV)           | 59155015100710 | Generic       |
| ASENAPINE<br>MALEATE SL | ASENAPINE MALEATE SL TAB 5 MG (BASE EQUIV)             | 59155015100720 | Generic       |
| ASENAPINE<br>MALEATE SL | ASENAPINE MALEATE SL TAB 10 MG (BASE EQUIV)            | 59155015100730 | Generic       |
| VRAYLAR                 | CARIPRAZINE HCL CAP THERAPY PACK 1.5 MG (1) & 3 MG (6) | 5940001810B220 | Brand         |
| VRAYLAR                 | CARIPRAZINE HCL CAP 1.5 MG (BASE EQUIVALENT)           | 59400018100120 | Brand         |
| VRAYLAR                 | CARIPRAZINE HCL CAP 3 MG (BASE EQUIVALENT)             | 59400018100130 | Brand         |
| VRAYLAR                 | CARIPRAZINE HCL CAP 4.5 MG (BASE EQUIVALENT)           | 59400018100140 | Brand         |
| VRAYLAR                 | CARIPRAZINE HCL CAP 6 MG (BASE EQUIVALENT)             | 59400018100150 | Brand         |
| FANAPT                  | ILOPERIDONE TAB 1 MG                                   | 59070035000310 | Brand         |
| FANAPT                  | ILOPERIDONE TAB 2 MG                                   | 59070035000320 | Brand         |
| FANAPT                  | ILOPERIDONE TAB 4 MG                                   | 59070035000340 | Brand         |
| FANAPT                  | ILOPERIDONE TAB 6 MG                                   | 59070035000360 | Brand         |
| FANAPT                  | ILOPERIDONE TAB 8 MG                                   | 59070035000380 | Brand         |
| FANAPT                  | ILOPERIDONE TAB 10 MG                                  | 59070035000385 | Brand         |
| FANAPT                  | ILOPERIDONE TAB 12 MG                                  | 59070035000390 | Brand         |
| FANAPT                  | ILOPERIDONE TAB 1 MG & 2 MG & 4 MG & 6 MG              | 59070035006320 | Brand         |

| TITRATION PACK              | TITRATION PAK                     |                |         |
|-----------------------------|-----------------------------------|----------------|---------|
| CAPLYTA                     | LUMATEPERONE TOSYLATE CAP 10.5 MG | 59400022400110 | Brand   |
| CAPLYTA                     | LUMATEPERONE TOSYLATE CAP 21 MG   | 59400022400115 | Brand   |
| CAPLYTA                     | LUMATEPERONE TOSYLATE CAP 42 MG   | 59400022400120 | Brand   |
| LURASIDONE<br>HYDROCHLORIDE | LURASIDONE HCL TAB 20 MG          | 59400023100310 | Generic |
| LURASIDONE<br>HYDROCHLORIDE | LURASIDONE HCL TAB 40 MG          | 59400023100320 | Generic |
| LURASIDONE<br>HYDROCHLORIDE | LURASIDONE HCL TAB 60 MG          | 59400023100330 | Generic |
| LURASIDONE<br>HYDROCHLORIDE | LURASIDONE HCL TAB 80 MG          | 59400023100340 | Generic |
| LURASIDONE<br>HYDROCHLORIDE | LURASIDONE HCL TAB 120 MG         | 59400023100350 | Generic |
| REXULTI                     | BREXPIPRAZOLE TAB 0.25 MG         | 59250020000310 | Brand   |
| REXULTI                     | BREXPIPRAZOLE TAB 0.5 MG          | 59250020000320 | Brand   |
| REXULTI                     | BREXPIPRAZOLE TAB 1 MG            | 59250020000330 | Brand   |
| REXULTI                     | BREXPIPRAZOLE TAB 2 MG            | 59250020000340 | Brand   |
| REXULTI                     | BREXPIPRAZOLE TAB 3 MG            | 59250020000350 | Brand   |
| REXULTI                     | BREXPIPRAZOLE TAB 4 MG            | 59250020000360 | Brand   |
|                             |                                   |                |         |

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug

## OR

- **2** For Minnesota Plans Only Both of the following for continuation of care (i.e. formulary changes or new member [(as evidenced by coverage effective date of less than or equal to 90 days]):
  - **2.1** The member has been treated with the drug for 90 days prior to the change

#### **AND**

2.2 Submission of medical records (e.g., chart notes) of documentation that the drug

prescribed will best treat the patient's condition

| Product Name: Generic Asenapine, Vraylar, Fanapt, Caplyta, Generic Lurasidone, Rexulti |  |  |  |
|--|--|--|--|
| Approval Length 12/31/2039   |  |  |  |
| Guideline Type Step Therapy - All plans except IL and MN Plans                         |  |  |  |

| Product Name                | Generic Name   | GPI            | Brand/Generic |
|-----------------------------|--|----------------|---------------|
| ASENAPINE<br>MALEATE SL     | ASENAPINE MALEATE SL TAB 2.5 MG (BASE EQUIV)               | 59155015100710 | Generic       |
| ASENAPINE<br>MALEATE SL     | ASENAPINE MALEATE SL TAB 5 MG (BASE EQUIV)                 | 59155015100720 | Generic       |
| ASENAPINE<br>MALEATE SL     | ASENAPINE MALEATE SL TAB 10 MG (BASE EQUIV)                | 59155015100730 | Generic       |
| VRAYLAR                     | CARIPRAZINE HCL CAP THERAPY PACK 1.5<br>MG (1) & 3 MG (6)  | 5940001810B220 | Brand         |
| VRAYLAR                     | CARIPRAZINE HCL CAP 1.5 MG (BASE EQUIVALENT)               | 59400018100120 | Brand         |
| VRAYLAR                     | CARIPRAZINE HCL CAP 3 MG (BASE EQUIVALENT)                 | 59400018100130 | Brand         |
| VRAYLAR                     | CARIPRAZINE HCL CAP 4.5 MG (BASE EQUIVALENT)               | 59400018100140 | Brand         |
| VRAYLAR                     | CARIPRAZINE HCL CAP 6 MG (BASE<br>EQUIVALENT)              | 59400018100150 | Brand         |
| FANAPT                      | ILOPERIDONE TAB 1 MG                                       | 59070035000310 | Brand         |
| FANAPT                      | ILOPERIDONE TAB 2 MG                                       | 59070035000320 | Brand         |
| FANAPT                      | ILOPERIDONE TAB 4 MG                                       | 59070035000340 | Brand         |
| FANAPT                      | ILOPERIDONE TAB 6 MG                                       | 59070035000360 | Brand         |
| FANAPT                      | ILOPERIDONE TAB 8 MG                                       | 59070035000380 | Brand         |
| FANAPT                      | ILOPERIDONE TAB 10 MG                                      | 59070035000385 | Brand         |
| FANAPT                      | ILOPERIDONE TAB 12 MG                                      | 59070035000390 | Brand         |
| FANAPT<br>TITRATION PACK    | ILOPERIDONE TAB 1 MG & 2 MG & 4 MG & 6 MG<br>TITRATION PAK | 59070035006320 | Brand         |
| CAPLYTA                     | LUMATEPERONE TOSYLATE CAP 10.5 MG                          | 59400022400110 | Brand         |
| CAPLYTA                     | LUMATEPERONE TOSYLATE CAP 21 MG                            | 59400022400115 | Brand         |
| CAPLYTA                     | LUMATEPERONE TOSYLATE CAP 42 MG                            | 59400022400120 | Brand         |
| LURASIDONE<br>HYDROCHLORIDE | LURASIDONE HCL TAB 20 MG                                   | 59400023100310 | Generic       |
| LURASIDONE<br>HYDROCHLORIDE | LURASIDONE HCL TAB 40 MG                                   | 59400023100320 | Generic       |

| LURASIDONE<br>HYDROCHLORIDE | LURASIDONE HCL TAB 60 MG  | 59400023100330 | Generic |
|-----------------------------|---------------------------|----------------|---------|
| LURASIDONE<br>HYDROCHLORIDE | LURASIDONE HCL TAB 80 MG  | 59400023100340 | Generic |
| LURASIDONE<br>HYDROCHLORIDE | LURASIDONE HCL TAB 120 MG | 59400023100350 | Generic |
| REXULTI                     | BREXPIPRAZOLE TAB 0.25 MG | 59250020000310 | Brand   |
| REXULTI                     | BREXPIPRAZOLE TAB 0.5 MG  | 59250020000320 | Brand   |
| REXULTI                     | BREXPIPRAZOLE TAB 1 MG    | 59250020000330 | Brand   |
| REXULTI                     | BREXPIPRAZOLE TAB 2 MG    | 59250020000340 | Brand   |
| REXULTI                     | BREXPIPRAZOLE TAB 3 MG    | 59250020000350 | Brand   |
| REXULTI                     | BREXPIPRAZOLE TAB 4 MG    | 59250020000360 | Brand   |

**1** - Trial and failure, contraindication, or intolerance of a preferred second-generation antipsychotic (i.e., aripiprazole, olanzapine, risperidone, quetiapine, or ziprasidone).

| Product Name: Generic Aripiprazole ODT        |                       |  |  |
|---|-----------------------|--|--|
| Approval Length 12 month(s)                   |                       |  |  |
| Therapy Stage                                 | Initial Authorization |  |  |
| Guideline Type Step Therapy - IL and MN Plans |                       |  |  |

| Product<br>Name     | Generic Name                                 | GPI            | Brand/Generic |
|---------------------|--|----------------|---------------|
| ARIPIPRAZOLE<br>ODT | ARIPIPRAZOLE ORALLY DISINTEGRATING TAB 10 MG | 59250015007220 | Generic       |
| ARIPIPRAZOLE<br>ODT | ARIPIPRAZOLE ORALLY DISINTEGRATING TAB 15 MG | 59250015007230 | Generic       |

# **Approval Criteria**

- 1 Both of the following:
- **1.1** Trial and failure, contraindication, or intolerance of aripiprazole tablets.

#### AND

**1.2** Trial and failure, contraindication, or intolerance of one other preferred antipsychotic (i.e., olanzapine, risperidone, quetiapine, ziprasidone).

#### OR

**2** - For Minnesota Plans Only: If requested drug is prescribed for emotional disturbance or mental illness, approve if submission of medical records (e.g., chart notes) documenting that all equivalent drugs in the formulary were considered and it has been determined that the drug prescribed will best treat the member's condition

| Product Name: Generic Aripiprazole ODT        |                 |  |  |
|---|-----------------|--|--|
| Approval Length 12 month(s)                   |                 |  |  |
| Therapy Stage                                 | Reauthorization |  |  |
| Guideline Type Step Therapy - IL and MN Plans |                 |  |  |

| Product<br>Name     | Generic Name                                 | GPI            | Brand/Generic |
|---------------------|--|----------------|---------------|
| ARIPIPRAZOLE<br>ODT | ARIPIPRAZOLE ORALLY DISINTEGRATING TAB 10 MG | 59250015007220 | Generic       |
| ARIPIPRAZOLE<br>ODT | ARIPIPRAZOLE ORALLY DISINTEGRATING TAB 15 MG | 59250015007230 | Generic       |

#### **Approval Criteria**

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug

### OR

- **2** For Minnesota Plans Only Both of the following for continuation of care (i.e. formulary changes or new member [(as evidenced by coverage effective date of less than or equal to 90 days]):
- 2.1 The member has been treated with the drug for 90 days prior to the change

## AND

**2.2** Submission of medical records (e.g., chart notes) of documentation that the drug prescribed will best treat the patient's condition

| Product Name: Generic Aripiprazole ODT                         |  |
|--|--|
| Approval Length 12/31/2039                                     |  |
| Guideline Type Step Therapy - All Plans except IL and MN Plans |  |

| Product<br>Name     | Generic Name                                 | GPI            | Brand/Generic |
|---------------------|--|----------------|---------------|
| ARIPIPRAZOLE<br>ODT | ARIPIPRAZOLE ORALLY DISINTEGRATING TAB 10 MG | 59250015007220 | Generic       |
| ARIPIPRAZOLE<br>ODT | ARIPIPRAZOLE ORALLY DISINTEGRATING TAB 15 MG | 59250015007230 | Generic       |

# **Approval Criteria**

**1** - Trial and failure, contraindication, or intolerance of aripiprazole tablets.

## **AND**

**2** - Trial and failure, contraindication, or intolerance of one other preferred antipsychotic (i.e., olanzapine, risperidone, quetiapine, ziprasidone).

# 2. Revision History

| Date      | Notes       |
|-----------|-------------|
| 8/25/2023 | New Program |

| Restricted Oral Oncology Drug   |  |
|---|--|
| (2) The formation provided to the transport of the state |  |

# **Prior Authorization Guideline**

| Guideline ID          | GL-129538                     |
|-----------------------|-------------------------------|
| <b>Guideline Name</b> | Restricted Oral Oncology Drug |
| Formulary             | Quartz                        |

# **Guideline Note:**

| Effective Date: |
|-----------------|
|-----------------|

# 1. Criteria

| Approval Length | 12 month(s)  |
|-----------------|--|
| Therapy Stage   | Initial Authorization                                  |
| Guideline Type  | Prior Authorization - ALL Plans Except IL and MN Plans |

| Product<br>Name | Generic Name                              | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| YONSA           | ABIRATERONE ACETATE MICRONIZED TAB 125 MG | 21406010250310 | Brand         |
| CALQUENCE       | ACALABRUTINIB MALEATE TAB 100 MG          | 21532103500320 | Brand         |
| KRAZATI         | ADAGRASIB TAB 200 MG                      | 21532410000320 | Brand         |

| -        |   |                |       |
|----------|---|----------------|-------|
| ERLEADA  | APALUTAMIDE TAB 60 MG                                       | 21402410000320 | Brand |
| ERLEADA  | APALUTAMIDE TAB 240 MG                                      | 21402410000360 | Brand |
| SCEMBLIX | ASCIMINIB HCL TAB 20 MG                                     | 21531806100320 | Brand |
| SCEMBLIX | ASCIMINIB HCL TAB 40 MG                                     | 21531806100340 | Brand |
| AYVAKIT  | AVAPRITINIB TAB 25 MG                                       | 21490009000310 | Brand |
| AYVAKIT  | AVAPRITINIB TAB 50 MG                                       | 21490009000315 | Brand |
| AYVAKIT  | AVAPRITINIB TAB 100 MG                                      | 21490009000320 | Brand |
| AYVAKIT  | AVAPRITINIB TAB 200 MG                                      | 21490009000330 | Brand |
| AYVAKIT  | AVAPRITINIB TAB 300 MG                                      | 21490009000340 | Brand |
| WELIREG  | BELZUTIFAN TAB 40 MG  | 21421020000320 | Brand |
| MEKTOVI  | BINIMETINIB TAB 15 MG                                       | 21533520000320 | Brand |
| ALUNBRIG | BRIGATINIB TAB INITIATION THERAPY PACK 90 MG<br>& 180 MG    | 2153051000B720 | Brand |
| ALUNBRIG | BRIGATINIB TAB 30 MG  | 21530510000330 | Brand |
| ALUNBRIG | BRIGATINIB TAB 90 MG  | 21530510000350 | Brand |
| ALUNBRIG | BRIGATINIB TAB 180 MG                                       | 21530510000365 | Brand |
| COMETRIQ | CABOZANTINIB S-MALATE CAP 3 X 20 MG (60 MG DOSE) KIT        | 21533010106460 | Brand |
| COMETRIQ | CABOZANTINIB S-MAL CAP 1 X 80 MG & 1 X 20 MG (100 DOSE) KIT | 21533010106470 | Brand |
| COMETRIQ | CABOZANTINIB S-MAL CAP 1 X 80 MG & 3 X 20 MG (140 DOSE) KIT | 21533010106480 | Brand |
| VIZIMPRO | DACOMITINIB TAB 15 MG                                       | 21360019000320 | Brand |
| VIZIMPRO | DACOMITINIB TAB 30 MG                                       | 21360019000330 | Brand |
| VIZIMPRO | DACOMITINIB TAB 45 MG                                       | 21360019000340 | Brand |
| INQOVI   | DECITABINE-CEDAZURIDINE TAB 35-100 MG                       | 21990002250320 | Brand |
| COPIKTRA | DUVELISIB CAP 15 MG   | 21538030000120 | Brand |
| COPIKTRA | DUVELISIB CAP 25 MG   | 21538030000130 | Brand |
| ORSERDU  | ELACESTRANT HYDROCHLORIDE TAB 86 MG                         | 21403720100320 | Brand |
| ORSERDU  | ELACESTRANT HYDROCHLORIDE TAB 345 MG                        | 21403720100340 | Brand |
| IDHIFA   | ENASIDENIB MESYLATE TAB 50 MG (BASE EQUIVALENT)             | 21535030200320 | Brand |
| IDHIFA   | ENASIDENIB MESYLATE TAB 100 MG (BASE EQUIVALENT)            | 21535030200340 | Brand |
| BRAFTOVI | ENCORAFENIB CAP 75 MG                                       | 21532040000130 | Brand |
| BALVERSA | ERDAFITINIB TAB 3 MG  | 21532225000320 | Brand |

| BALVERSA                       | ERDAFITINIB TAB 4 MG   | 21532225000325 | Brand |
|--------------------------------|--|----------------|-------|
| BALVERSA                       | ERDAFITINIB TAB 5 MG   | 21532225000323 | Brand |
| LYTGOBI                        | FUTIBATINIB TAB THERAPY PACK 4 MG (12 MG DAILY DOSE)         | 2153222800B720 | Brand |
| LYTGOBI                        | FUTIBATINIB TAB THERAPY PACK 4 MG (16 MG DAILY DOSE)         | 2153222800B725 | Brand |
| LYTGOBI                        | FUTIBATINIB TAB THERAPY PACK 4 MG (20 MG DAILY DOSE)         | 2153222800B730 | Brand |
| XOSPATA                        | GILTERITINIB FUMARATE TABLET 40 MG (BASE EQUIVALENT)         | 21533020200320 | Brand |
| DAURISMO                       | GLASDEGIB MALEATE TAB 25 MG (BASE EQUIVALENT)                | 21370030300320 | Brand |
| DAURISMO                       | GLASDEGIB MALEATE TAB 100 MG (BASE EQUIVALENT)               | 21370030300335 | Brand |
| TIBSOVO                        | IVOSIDENIB TAB 250 MG  | 21534940000320 | Brand |
| VITRAKVI                       | LAROTRECTINIB SULFATE CAP 25 MG (BASE EQUIVALENT)            | 21533835200120 | Brand |
| VITRAKVI                       | LAROTRECTINIB SULFATE CAP 100 MG (BASE EQUIVALENT)           | 21533835200150 | Brand |
| VITRAKVI                       | LAROTRECTINIB SULFATE ORAL SOLN 20 MG/ML (BASE EQUIVALENT)   | 21533835202020 | Brand |
| LENVIMA 4<br>MG DAILY<br>DOSE  | LENVATINIB CAP THERAPY PACK 4 MG (4 MG DAILY DOSE)           | 2133505420B210 | Brand |
| LENVIMA 8<br>MG DAILY<br>DOSE  | LENVATINIB CAP THERAPY PACK 2 X 4 MG (8 MG DAILY DOSE)       | 2133505420B215 | Brand |
| LENVIMA 10<br>MG DAILY<br>DOSE | LENVATINIB CAP THERAPY PACK 10 MG (10 MG DAILY DOSE)         | 2133505420B220 | Brand |
| LENVIMA<br>12MG DAILY<br>DOSE  | LENVATINIB CAP THERAPY PACK 3 X 4 MG (12 MG DAILY DOSE)      | 2133505420B223 | Brand |
| LENVIMA 20<br>MG DAILY<br>DOSE | LENVATINIB CAP THERAPY PACK 2 X 10 MG (20 MG DAILY DOSE)     | 2133505420B230 | Brand |
| LENVIMA 14<br>MG DAILY<br>DOSE | LENVATINIB CAP THERAPY PACK 10 & 4 MG (14 MG DAILY DOSE)     | 2133505420B240 | Brand |
| LENVIMA 18<br>MG DAILY<br>DOSE | LENVATINIB CAP THER PACK 10 MG & 2 X 4 MG (18 MG DAILY DOSE) | 2133505420B244 | Brand |
| LENVIMA 24<br>MG DAILY<br>DOSE | LENVATINIB CAP THER PACK 2 X 10 MG & 4 MG (24 MG DAILY DOSE) | 2133505420B250 | Brand |
| LORBRENA                       | LORLATINIB TAB 25 MG   | 21530556000320 | Brand |

| LORBRENA                        | LORLATINIB TAB 100 MG                                    | 21530556000330 | Brand |
|---------------------------------|--|----------------|-------|
| RYDAPT                          | MIDOSTAURIN CAP 25 MG                                    | 21533030000130 | Brand |
| NERLYNX                         | NERATINIB MALEATE TAB 40 MG (BASE EQUIVALENT)            | 21533035100320 | Brand |
| REZLIDHIA                       | OLUTASIDENIB CAP 150 MG                                  | 21534960000120 | Brand |
| VONJO                           | PACRITINIB CITRATE CAP 100 MG                            | 21537550100120 | Brand |
| PEMAZYRE                        | PEMIGATINIB TAB 4.5 MG                                   | 21532260000320 | Brand |
| PEMAZYRE                        | PEMIGATINIB TAB 9 MG                                     | 21532260000330 | Brand |
| PEMAZYRE                        | PEMIGATINIB TAB 13.5 MG                                  | 21532260000340 | Brand |
| TURALIO                         | PEXIDARTINIB HCL CAP 125 MG (BASE EQUIVALENT)            | 21533045010110 | Brand |
| JAYPIRCA                        | PIRTOBRUTINIB TAB 50 MG                                  | 21532165000320 | Brand |
| JAYPIRCA                        | PIRTOBRUTINIB TAB 100 MG                                 | 21532165000330 | Brand |
| ICLUSIG                         | PONATINIB HCL TAB 10 MG (BASE EQUIV)                     | 21531875100315 | Brand |
| ICLUSIG                         | PONATINIB HCL TAB 15 MG (BASE EQUIV)                     | 21531875100320 | Brand |
| ICLUSIG                         | PONATINIB HCL TAB 30 MG (BASE EQUIV)                     | 21531875100330 | Brand |
| ICLUSIG                         | PONATINIB HCL TAB 45 MG (BASE EQUIV)                     | 21531875100340 | Brand |
| GAVRETO                         | PRALSETINIB CAP 100 MG                                   | 21535750000120 | Brand |
| ORGOVYX                         | RELUGOLIX TAB 120 MG                                     | 21405570000320 | Brand |
| QINLOCK                         | RIPRETINIB TAB 50 MG                                     | 21533053000320 | Brand |
| XPOVIO 80<br>MG TWICE<br>WEEKLY | SELINEXOR TAB THERAPY PACK 20 MG (80 MG<br>TWICE WEEKLY) | 2156006000B720 | Brand |
| XPOVIO 60<br>MG TWICE<br>WEEKLY | SELINEXOR TAB THERAPY PACK 20 MG (60 MG<br>TWICE WEEKLY) | 2156006000B755 | Brand |
| XPOVIO                          | SELINEXOR TAB THERAPY PACK 40 MG (40 MG ONCE WEEKLY)     | 2156006000B760 | Brand |
| XPOVIO                          | SELINEXOR TAB THERAPY PACK 40 MG (40 MG<br>TWICE WEEKLY) | 2156006000B765 | Brand |
| XPOVIO                          | SELINEXOR TAB THERAPY PACK 40 MG (80 MG ONCE WEEKLY)     | 2156006000B770 | Brand |
| XPOVIO                          | SELINEXOR TAB THERAPY PACK 50 MG (100 MG ONCE WEEKLY)    | 2156006000B775 | Brand |
| XPOVIO                          | SELINEXOR TAB THERAPY PACK 60 MG (60 MG ONCE WEEKLY)     | 2156006000B780 | Brand |
| LUMAKRAS                        | SOTORASIB TAB 120 MG                                     | 21532480000320 | Brand |
| LUMAKRAS                        | SOTORASIB TAB 320 MG                                     | 21532480000340 | Brand |

| TALZENNA | TALAZOPARIB TOSYLATE CAP 0.1 MG (BASE EQUIVALENT)     | 21535580400105 | Brand |
|----------|---|----------------|-------|
| TALZENNA | TALAZOPARIB TOSYLATE CAP 0.25 MG (BASE EQUIVALENT)    | 21535580400110 | Brand |
| TALZENNA | TALAZOPARIB TOSYLATE CAP 0.35 MG (BASE EQUIVALENT)    | 21535580400112 | Brand |
| TALZENNA | TALAZOPARIB TOSYLATE CAP 0.5 MG (BASE EQUIVALENT)     | 21535580400114 | Brand |
| TALZENNA | TALAZOPARIB TOSYLATE CAP 0.75 MG (BASE EQUIVALENT)    | 21535580400118 | Brand |
| TALZENNA | TALAZOPARIB TOSYLATE CAP 1 MG (BASE EQUIVALENT)       | 21535580400120 | Brand |
| ТЕРМЕТКО | TEPOTINIB HCL TAB 225 MG                              | 21533773100320 | Brand |
| FOTIVDA  | TIVOZANIB HCL CAP 0.89 MG (BASE EQUIVALENT)           | 21533076250120 | Brand |
| FOTIVDA  | TIVOZANIB HCL CAP 1.34 MG (BASE EQUIVALENT)           | 21533076250130 | Brand |
| CAPRELSA | VANDETANIB TAB 100 MG                                 | 21533085000320 | Brand |
| CAPRELSA | VANDETANIB TAB 300 MG                                 | 21533085000340 | Brand |
| BRUKINSA | ZANUBRUTINIB CAP 80 MG                                | 21532195000120 | Brand |
| AKEEGA   | NIRAPARIB TOSYLATE-ABIRATERONE ACETATE TAB 50-500 MG  | 21409902120320 | Brand |
| AKEEGA   | NIRAPARIB TOSYLATE-ABIRATERONE ACETATE TAB 100-500 MG | 21409902120330 | Brand |
| VANFLYTA | QUIZARTINIB DIHYDROCHLORIDE TAB 17.7 MG               | 21533047100320 | Brand |
| VANFLYTA | QUIZARTINIB DIHYDROCHLORIDE TAB 26.5 MG               | 21533047100325 | Brand |
|          |   |                |       |

- **1** One of the following:
- **1.1** The requested drug is being used alone or in a combination regimen that is FDA-labeled for the treatment of the specific condition the member presents with\*

## OR

**1.2** The requested drug is being used alone or in a combination regimen that has a class 1 or 2 recommendation for use from the National Comprehensive Cancer Network (NCCN) in the specific condition of the member\*

#### **AND**

- **2** Prescribed by or in consultation with one of the following:
  - oncologist
  - hematologist
  - other specialist in the treatment of malignancy

| Notes | *Includes any relevant genetic testing, mutations, etc. |
|-------|---|
|-------|---|

| Approval Length | 12 month(s)  |
|-----------------|--|
| Therapy Stage   | Reauthorization  |
| Guideline Type  | Prior Authorization - ALL Plans Except IL and MN Plans |

| Product<br>Name | Generic Name   | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| YONSA           | ABIRATERONE ACETATE MICRONIZED TAB 125 MG                | 21406010250310 | Brand         |
| CALQUENCE       | ACALABRUTINIB MALEATE TAB 100 MG                         | 21532103500320 | Brand         |
| KRAZATI         | ADAGRASIB TAB 200 MG                                     | 21532410000320 | Brand         |
| ERLEADA         | APALUTAMIDE TAB 60 MG                                    | 21402410000320 | Brand         |
| ERLEADA         | APALUTAMIDE TAB 240 MG                                   | 21402410000360 | Brand         |
| SCEMBLIX        | ASCIMINIB HCL TAB 20 MG                                  | 21531806100320 | Brand         |
| SCEMBLIX        | ASCIMINIB HCL TAB 40 MG                                  | 21531806100340 | Brand         |
| AYVAKIT         | AVAPRITINIB TAB 25 MG                                    | 21490009000310 | Brand         |
| AYVAKIT         | AVAPRITINIB TAB 50 MG                                    | 21490009000315 | Brand         |
| AYVAKIT         | AVAPRITINIB TAB 100 MG                                   | 21490009000320 | Brand         |
| AYVAKIT         | AVAPRITINIB TAB 200 MG                                   | 21490009000330 | Brand         |
| AYVAKIT         | AVAPRITINIB TAB 300 MG                                   | 21490009000340 | Brand         |
| WELIREG         | BELZUTIFAN TAB 40 MG                                     | 21421020000320 | Brand         |
| MEKTOVI         | BINIMETINIB TAB 15 MG                                    | 21533520000320 | Brand         |
| ALUNBRIG        | BRIGATINIB TAB INITIATION THERAPY PACK 90 MG<br>& 180 MG | 2153051000B720 | Brand         |
| ALUNBRIG        | BRIGATINIB TAB 30 MG                                     | 21530510000330 | Brand         |

| ALUNBRIG | BRIGATINIB TAB 90 MG  | 21530510000350 | Brand |
|----------|---|----------------|-------|
| ALUNBRIG | BRIGATINIB TAB 180 MG                                       | 21530510000365 | Brand |
| COMETRIQ | CABOZANTINIB S-MALATE CAP 3 X 20 MG (60 MG DOSE) KIT        | 21533010106460 | Brand |
| COMETRIQ | CABOZANTINIB S-MAL CAP 1 X 80 MG & 1 X 20 MG (100 DOSE) KIT | 21533010106470 | Brand |
| COMETRIQ | CABOZANTINIB S-MAL CAP 1 X 80 MG & 3 X 20 MG (140 DOSE) KIT | 21533010106480 | Brand |
| VIZIMPRO | DACOMITINIB TAB 15 MG                                       | 21360019000320 | Brand |
| VIZIMPRO | DACOMITINIB TAB 30 MG                                       | 21360019000330 | Brand |
| VIZIMPRO | DACOMITINIB TAB 45 MG                                       | 21360019000340 | Brand |
| INQOVI   | DECITABINE-CEDAZURIDINE TAB 35-100 MG                       | 21990002250320 | Brand |
| COPIKTRA | DUVELISIB CAP 15 MG   | 21538030000120 | Brand |
| COPIKTRA | DUVELISIB CAP 25 MG   | 21538030000130 | Brand |
| ORSERDU  | ELACESTRANT HYDROCHLORIDE TAB 86 MG                         | 21403720100320 | Brand |
| ORSERDU  | ELACESTRANT HYDROCHLORIDE TAB 345 MG                        | 21403720100340 | Brand |
| IDHIFA   | ENASIDENIB MESYLATE TAB 50 MG (BASE EQUIVALENT)             | 21535030200320 | Brand |
| IDHIFA   | ENASIDENIB MESYLATE TAB 100 MG (BASE EQUIVALENT)            | 21535030200340 | Brand |
| BRAFTOVI | ENCORAFENIB CAP 75 MG                                       | 21532040000130 | Brand |
| BALVERSA | ERDAFITINIB TAB 3 MG  | 21532225000320 | Brand |
| BALVERSA | ERDAFITINIB TAB 4 MG  | 21532225000325 | Brand |
| BALVERSA | ERDAFITINIB TAB 5 MG  | 21532225000330 | Brand |
| LYTGOBI  | FUTIBATINIB TAB THERAPY PACK 4 MG (12 MG DAILY DOSE)        | 2153222800B720 | Brand |
| LYTGOBI  | FUTIBATINIB TAB THERAPY PACK 4 MG (16 MG DAILY DOSE)        | 2153222800B725 | Brand |
| LYTGOBI  | FUTIBATINIB TAB THERAPY PACK 4 MG (20 MG DAILY DOSE)        | 2153222800B730 | Brand |
| XOSPATA  | GILTERITINIB FUMARATE TABLET 40 MG (BASE EQUIVALENT)        | 21533020200320 | Brand |
| DAURISMO | GLASDEGIB MALEATE TAB 25 MG (BASE EQUIVALENT)               | 21370030300320 | Brand |
| DAURISMO | GLASDEGIB MALEATE TAB 100 MG (BASE EQUIVALENT)              | 21370030300335 | Brand |
| TIBSOVO  | IVOSIDENIB TAB 250 MG                                       | 21534940000320 | Brand |
| VITRAKVI | LAROTRECTINIB SULFATE CAP 25 MG (BASE EQUIVALENT)           | 21533835200120 | Brand |

|                                | <u> </u>  |                | Ī     |
|--------------------------------|---|----------------|-------|
| VITRAKVI                       | LAROTRECTINIB SULFATE CAP 100 MG (BASE EQUIVALENT)            | 21533835200150 | Brand |
| VITRAKVI                       | LAROTRECTINIB SULFATE ORAL SOLN 20 MG/ML<br>(BASE EQUIVALENT) | 21533835202020 | Brand |
| LENVIMA 4<br>MG DAILY<br>DOSE  | LENVATINIB CAP THERAPY PACK 4 MG (4 MG DAILY DOSE)            | 2133505420B210 | Brand |
| LENVIMA 8<br>MG DAILY<br>DOSE  | LENVATINIB CAP THERAPY PACK 2 X 4 MG (8 MG DAILY DOSE)        | 2133505420B215 | Brand |
| LENVIMA 10<br>MG DAILY<br>DOSE | LENVATINIB CAP THERAPY PACK 10 MG (10 MG DAILY DOSE)          | 2133505420B220 | Brand |
| LENVIMA<br>12MG DAILY<br>DOSE  | LENVATINIB CAP THERAPY PACK 3 X 4 MG (12 MG DAILY DOSE)       | 2133505420B223 | Brand |
| LENVIMA 20<br>MG DAILY<br>DOSE | LENVATINIB CAP THERAPY PACK 2 X 10 MG (20 MG DAILY DOSE)      | 2133505420B230 | Brand |
| LENVIMA 14<br>MG DAILY<br>DOSE | LENVATINIB CAP THERAPY PACK 10 & 4 MG (14 MG DAILY DOSE)      | 2133505420B240 | Brand |
| LENVIMA 18<br>MG DAILY<br>DOSE | LENVATINIB CAP THER PACK 10 MG & 2 X 4 MG (18 MG DAILY DOSE)  | 2133505420B244 | Brand |
| LENVIMA 24<br>MG DAILY<br>DOSE | LENVATINIB CAP THER PACK 2 X 10 MG & 4 MG (24 MG DAILY DOSE)  | 2133505420B250 | Brand |
| LORBRENA                       | LORLATINIB TAB 25 MG  | 21530556000320 | Brand |
| LORBRENA                       | LORLATINIB TAB 100 MG   | 21530556000330 | Brand |
| RYDAPT                         | MIDOSTAURIN CAP 25 MG   | 21533030000130 | Brand |
| NERLYNX                        | NERATINIB MALEATE TAB 40 MG (BASE EQUIVALENT)                 | 21533035100320 | Brand |
| REZLIDHIA                      | OLUTASIDENIB CAP 150 MG                                       | 21534960000120 | Brand |
| VONJO                          | PACRITINIB CITRATE CAP 100 MG                                 | 21537550100120 | Brand |
| PEMAZYRE                       | PEMIGATINIB TAB 4.5 MG  | 21532260000320 | Brand |
| PEMAZYRE                       | PEMIGATINIB TAB 9 MG  | 21532260000330 | Brand |
| PEMAZYRE                       | PEMIGATINIB TAB 13.5 MG                                       | 21532260000340 | Brand |
| TURALIO                        | PEXIDARTINIB HCL CAP 125 MG (BASE EQUIVALENT)                 | 21533045010110 | Brand |
| JAYPIRCA                       | PIRTOBRUTINIB TAB 50 MG                                       | 21532165000320 | Brand |
| JAYPIRCA                       | PIRTOBRUTINIB TAB 100 MG                                      | 21532165000330 | Brand |
| ICLUSIG                        | PONATINIB HCL TAB 10 MG (BASE EQUIV)                          | 21531875100315 | Brand |

| ICLUSIG                         | PONATINIB HCL TAB 15 MG (BASE EQUIV)                  | 21531875100320 | Brand |
|---------------------------------|---|----------------|-------|
| ICLUSIG                         | PONATINIB HCL TAB 30 MG (BASE EQUIV)                  | 21531875100330 | Brand |
| ICLUSIG                         | PONATINIB HCL TAB 45 MG (BASE EQUIV)                  | 21531875100340 | Brand |
| GAVRETO                         | PRALSETINIB CAP 100 MG                                | 21535750000120 | Brand |
| ORGOVYX                         | RELUGOLIX TAB 120 MG                                  | 21405570000320 | Brand |
| QINLOCK                         | RIPRETINIB TAB 50 MG                                  | 21533053000320 | Brand |
| XPOVIO 80<br>MG TWICE<br>WEEKLY | SELINEXOR TAB THERAPY PACK 20 MG (80 MG TWICE WEEKLY) | 2156006000B720 | Brand |
| XPOVIO 60<br>MG TWICE<br>WEEKLY | SELINEXOR TAB THERAPY PACK 20 MG (60 MG TWICE WEEKLY) | 2156006000B755 | Brand |
| XPOVIO                          | SELINEXOR TAB THERAPY PACK 40 MG (40 MG ONCE WEEKLY)  | 2156006000B760 | Brand |
| XPOVIO                          | SELINEXOR TAB THERAPY PACK 40 MG (40 MG TWICE WEEKLY) | 2156006000B765 | Brand |
| XPOVIO                          | SELINEXOR TAB THERAPY PACK 40 MG (80 MG ONCE WEEKLY)  | 2156006000B770 | Brand |
| XPOVIO                          | SELINEXOR TAB THERAPY PACK 50 MG (100 MG ONCE WEEKLY) | 2156006000B775 | Brand |
| XPOVIO                          | SELINEXOR TAB THERAPY PACK 60 MG (60 MG ONCE WEEKLY)  | 2156006000B780 | Brand |
| LUMAKRAS                        | SOTORASIB TAB 120 MG                                  | 21532480000320 | Brand |
| LUMAKRAS                        | SOTORASIB TAB 320 MG                                  | 21532480000340 | Brand |
| TALZENNA                        | TALAZOPARIB TOSYLATE CAP 0.1 MG (BASE EQUIVALENT)     | 21535580400105 | Brand |
| TALZENNA                        | TALAZOPARIB TOSYLATE CAP 0.25 MG (BASE EQUIVALENT)    | 21535580400110 | Brand |
| TALZENNA                        | TALAZOPARIB TOSYLATE CAP 0.35 MG (BASE EQUIVALENT)    | 21535580400112 | Brand |
| TALZENNA                        | TALAZOPARIB TOSYLATE CAP 0.5 MG (BASE EQUIVALENT)     | 21535580400114 | Brand |
| TALZENNA                        | TALAZOPARIB TOSYLATE CAP 0.75 MG (BASE EQUIVALENT)    | 21535580400118 | Brand |
| TALZENNA                        | TALAZOPARIB TOSYLATE CAP 1 MG (BASE EQUIVALENT)       | 21535580400120 | Brand |
| TEPMETKO                        | TEPOTINIB HCL TAB 225 MG                              | 21533773100320 | Brand |
| FOTIVDA                         | TIVOZANIB HCL CAP 0.89 MG (BASE EQUIVALENT)           | 21533076250120 | Brand |
| FOTIVDA                         | TIVOZANIB HCL CAP 1.34 MG (BASE EQUIVALENT)           | 21533076250130 | Brand |
| CAPRELSA                        | VANDETANIB TAB 100 MG                                 | 21533085000320 | Brand |
| CAPRELSA                        | VANDETANIB TAB 300 MG                                 | 21533085000340 | Brand |

| BRUKINSA | ZANUBRUTINIB CAP 80 MG                                   | 21532195000120 | Brand |
|----------|--|----------------|-------|
| AKEEGA   | NIRAPARIB TOSYLATE-ABIRATERONE ACETATE<br>TAB 50-500 MG  | 21409902120320 | Brand |
| AKEEGA   | NIRAPARIB TOSYLATE-ABIRATERONE ACETATE<br>TAB 100-500 MG | 21409902120330 | Brand |
| VANFLYTA | QUIZARTINIB DIHYDROCHLORIDE TAB 17.7 MG                  | 21533047100320 | Brand |
| VANFLYTA | QUIZARTINIB DIHYDROCHLORIDE TAB 26.5 MG                  | 21533047100325 | Brand |

- **1** One of the following:
- **1.1** The requested drug is being used alone or in a combination regimen that is FDA-labeled for the treatment of the specific condition the member presents with\*

#### OR

**1.2** The requested drug is being used alone or in a combination regimen that has a class 1 or 2 recommendation for use from the National Comprehensive Cancer Network (NCCN) in the specific condition of the member\*

#### AND

- 2 Prescribed by or in consultation with one of the following:
  - oncologist
  - hematologist
  - other specialist in the treatment of malignancy

| Notes | *Includes any relevant genetic testing, mutations, etc. |
|-------|---|
|-------|---|

| Approval Length | 12 month(s)           |
|-----------------|-----------------------|
| Therapy Stage   | Initial Authorization |

| Guideline Type Prior Authorization - MN Plans |                        |   |                |               |
|---|------------------------|---|----------------|---------------|
| Product<br>Name                               | Generic Name           |   | GPI            | Brand/Generic |
| YONSA   | ABIRATERO              | ONE ACETATE MICRONIZED TAB 125 MG           | 21406010250310 | Brand         |
| CALQUENCE                                     | ACALABRU               | TINIB MALEATE TAB 100 MG                    | 21532103500320 | Brand         |
| KRAZATI                                       | ADAGRASII              | 3 TAB 200 MG                                | 21532410000320 | Brand         |
| ERLEADA                                       | APALUTAM               | IDE TAB 60 MG                               | 21402410000320 | Brand         |
| ERLEADA                                       | APALUTAM               | IDE TAB 240 MG                              | 21402410000360 | Brand         |
| SCEMBLIX                                      | ASCIMINIB              | HCL TAB 20 MG                               | 21531806100320 | Brand         |
| SCEMBLIX                                      | ASCIMINIB              | HCL TAB 40 MG                               | 21531806100340 | Brand         |
| AYVAKIT                                       | AVAPRITIN              | B TAB 25 MG                                 | 21490009000310 | Brand         |
| AYVAKIT                                       | AVAPRITIN              | B TAB 50 MG                                 | 21490009000315 | Brand         |
| AYVAKIT                                       | AVAPRITIN              | B TAB 100 MG                                | 21490009000320 | Brand         |
| AYVAKIT                                       | AVAPRITIN              | AVAPRITINIB TAB 200 MG                      |                | Brand         |
| AYVAKIT                                       | AVAPRITIN              | AVAPRITINIB TAB 300 MG                      |                | Brand         |
| WELIREG                                       | BELZUTIFAN TAB 40 MG   |   | 21421020000320 | Brand         |
| MEKTOVI                                       | BINIMETINI             | BINIMETINIB TAB 15 MG                       |                | Brand         |
| ALUNBRIG                                      | BRIGATINIE<br>& 180 MG | TAB INITIATION THERAPY PACK 90 MG           | 2153051000B720 | Brand         |
| ALUNBRIG                                      | BRIGATINIE             | 3 TAB 30 MG                                 | 21530510000330 | Brand         |
| ALUNBRIG                                      | BRIGATINIE             | 3 TAB 90 MG                                 | 21530510000350 | Brand         |
| ALUNBRIG                                      | BRIGATINIE             | 3 TAB 180 MG                                | 21530510000365 | Brand         |
| COMETRIQ                                      | CABOZANT<br>DOSE) KIT  | INIB S-MALATE CAP 3 X 20 MG (60 MG          | 21533010106460 | Brand         |
| COMETRIQ                                      | CABOZANT<br>(100 DOSE) | INIB S-MAL CAP 1 X 80 MG & 1 X 20 MG<br>KIT | 21533010106470 | Brand         |
| COMETRIQ                                      | CABOZANT<br>(140 DOSE) | INIB S-MAL CAP 1 X 80 MG & 3 X 20 MG<br>KIT | 21533010106480 | Brand         |
| VIZIMPRO                                      | DACOMITIN              | IIB TAB 15 MG                               | 21360019000320 | Brand         |
| VIZIMPRO                                      | DACOMITINIB TAB 30 MG  |   | 21360019000330 | Brand         |
| VIZIMPRO                                      | DACOMITIN              | IIB TAB 45 MG                               | 21360019000340 | Brand         |
| INQOVI  | DECITABIN              | E-CEDAZURIDINE TAB 35-100 MG                | 21990002250320 | Brand         |
| COPIKTRA                                      | DUVELISIB              | CAP 15 MG                                   | 21538030000120 | Brand         |
| COPIKTRA                                      | DUVELISIB              | CAP 25 MG                                   | 21538030000130 | Brand         |
| ORSERDU                                       | ELACESTR               | ANT HYDROCHLORIDE TAB 86 MG                 | 21403720100320 | Brand         |

| ORSERDU                        | ELACESTRANT HYDROCHLORIDE TAB 345 MG                       | 21403720100340 | Brand |
|--------------------------------|--|----------------|-------|
| IDHIFA                         | ENASIDENIB MESYLATE TAB 50 MG (BASE EQUIVALENT)            | 21535030200320 | Brand |
| IDHIFA                         | ENASIDENIB MESYLATE TAB 100 MG (BASE EQUIVALENT)           | 21535030200340 | Brand |
| BRAFTOVI                       | ENCORAFENIB CAP 75 MG                                      | 21532040000130 | Brand |
| BALVERSA                       | ERDAFITINIB TAB 3 MG                                       | 21532225000320 | Brand |
| BALVERSA                       | ERDAFITINIB TAB 4 MG                                       | 21532225000325 | Brand |
| BALVERSA                       | ERDAFITINIB TAB 5 MG                                       | 21532225000330 | Brand |
| LYTGOBI                        | FUTIBATINIB TAB THERAPY PACK 4 MG (12 MG DAILY DOSE)       | 2153222800B720 | Brand |
| LYTGOBI                        | FUTIBATINIB TAB THERAPY PACK 4 MG (16 MG DAILY DOSE)       | 2153222800B725 | Brand |
| LYTGOBI                        | FUTIBATINIB TAB THERAPY PACK 4 MG (20 MG DAILY DOSE)       | 2153222800B730 | Brand |
| XOSPATA                        | GILTERITINIB FUMARATE TABLET 40 MG (BASE EQUIVALENT)       | 21533020200320 | Brand |
| DAURISMO                       | GLASDEGIB MALEATE TAB 25 MG (BASE EQUIVALENT)              | 21370030300320 | Brand |
| DAURISMO                       | GLASDEGIB MALEATE TAB 100 MG (BASE EQUIVALENT)             | 21370030300335 | Brand |
| TIBSOVO                        | IVOSIDENIB TAB 250 MG                                      | 21534940000320 | Brand |
| VITRAKVI                       | LAROTRECTINIB SULFATE CAP 25 MG (BASE EQUIVALENT)          | 21533835200120 | Brand |
| VITRAKVI                       | LAROTRECTINIB SULFATE CAP 100 MG (BASE EQUIVALENT)         | 21533835200150 | Brand |
| VITRAKVI                       | LAROTRECTINIB SULFATE ORAL SOLN 20 MG/ML (BASE EQUIVALENT) | 21533835202020 | Brand |
| LENVIMA 4<br>MG DAILY<br>DOSE  | LENVATINIB CAP THERAPY PACK 4 MG (4 MG DAILY DOSE)         | 2133505420B210 | Brand |
| LENVIMA 8<br>MG DAILY<br>DOSE  | LENVATINIB CAP THERAPY PACK 2 X 4 MG (8 MG DAILY DOSE)     | 2133505420B215 | Brand |
| LENVIMA 10<br>MG DAILY<br>DOSE | LENVATINIB CAP THERAPY PACK 10 MG (10 MG DAILY DOSE)       | 2133505420B220 | Brand |
| LENVIMA<br>12MG DAILY<br>DOSE  | LENVATINIB CAP THERAPY PACK 3 X 4 MG (12 MG DAILY DOSE)    | 2133505420B223 | Brand |
| LENVIMA 20<br>MG DAILY<br>DOSE | LENVATINIB CAP THERAPY PACK 2 X 10 MG (20 MG DAILY DOSE)   | 2133505420B230 | Brand |
| LENVIMA 14                     | LENVATINIB CAP THERAPY PACK 10 & 4 MG (14 MG               | 2133505420B240 | Brand |

| MG DAILY<br>DOSE                | DAILY DOSE)  |                |       |
|---------------------------------|--|----------------|-------|
| LENVIMA 18<br>MG DAILY<br>DOSE  | LENVATINIB CAP THER PACK 10 MG & 2 X 4 MG (18 MG DAILY DOSE) | 2133505420B244 | Brand |
| LENVIMA 24<br>MG DAILY<br>DOSE  | LENVATINIB CAP THER PACK 2 X 10 MG & 4 MG (24 MG DAILY DOSE) | 2133505420B250 | Brand |
| LORBRENA                        | LORLATINIB TAB 25 MG   | 21530556000320 | Brand |
| LORBRENA                        | LORLATINIB TAB 100 MG  | 21530556000330 | Brand |
| RYDAPT                          | MIDOSTAURIN CAP 25 MG  | 21533030000130 | Brand |
| NERLYNX                         | NERATINIB MALEATE TAB 40 MG (BASE EQUIVALENT)                | 21533035100320 | Brand |
| REZLIDHIA                       | OLUTASIDENIB CAP 150 MG                                      | 21534960000120 | Brand |
| VONJO                           | PACRITINIB CITRATE CAP 100 MG                                | 21537550100120 | Brand |
| PEMAZYRE                        | PEMIGATINIB TAB 4.5 MG                                       | 21532260000320 | Brand |
| PEMAZYRE                        | PEMIGATINIB TAB 9 MG   | 21532260000330 | Brand |
| PEMAZYRE                        | PEMIGATINIB TAB 13.5 MG                                      | 21532260000340 | Brand |
| TURALIO                         | PEXIDARTINIB HCL CAP 125 MG (BASE EQUIVALENT)                | 21533045010110 | Brand |
| JAYPIRCA                        | PIRTOBRUTINIB TAB 50 MG                                      | 21532165000320 | Brand |
| JAYPIRCA                        | PIRTOBRUTINIB TAB 100 MG                                     | 21532165000330 | Brand |
| ICLUSIG                         | PONATINIB HCL TAB 10 MG (BASE EQUIV)                         | 21531875100315 | Brand |
| ICLUSIG                         | PONATINIB HCL TAB 15 MG (BASE EQUIV)                         | 21531875100320 | Brand |
| ICLUSIG                         | PONATINIB HCL TAB 30 MG (BASE EQUIV)                         | 21531875100330 | Brand |
| ICLUSIG                         | PONATINIB HCL TAB 45 MG (BASE EQUIV)                         | 21531875100340 | Brand |
| GAVRETO                         | PRALSETINIB CAP 100 MG                                       | 21535750000120 | Brand |
| ORGOVYX                         | RELUGOLIX TAB 120 MG   | 21405570000320 | Brand |
| QINLOCK                         | RIPRETINIB TAB 50 MG   | 21533053000320 | Brand |
| XPOVIO 80<br>MG TWICE<br>WEEKLY | SELINEXOR TAB THERAPY PACK 20 MG (80 MG<br>TWICE WEEKLY)     | 2156006000B720 | Brand |
| XPOVIO 60<br>MG TWICE<br>WEEKLY | SELINEXOR TAB THERAPY PACK 20 MG (60 MG<br>TWICE WEEKLY)     | 2156006000B755 | Brand |
| XPOVIO                          | SELINEXOR TAB THERAPY PACK 40 MG (40 MG ONCE WEEKLY)         | 2156006000B760 | Brand |
| XPOVIO                          | SELINEXOR TAB THERAPY PACK 40 MG (40 MG TWICE WEEKLY)        | 2156006000B765 | Brand |

| XPOVIO   | SELINEXOR TAB THERAPY PACK 40 MG (80 MG ONCE WEEKLY)  | 2156006000B770 | Brand |
|----------|---|----------------|-------|
| XPOVIO   | SELINEXOR TAB THERAPY PACK 50 MG (100 MG ONCE WEEKLY) | 2156006000B775 | Brand |
| XPOVIO   | SELINEXOR TAB THERAPY PACK 60 MG (60 MG ONCE WEEKLY)  | 2156006000B780 | Brand |
| LUMAKRAS | SOTORASIB TAB 120 MG                                  | 21532480000320 | Brand |
| LUMAKRAS | SOTORASIB TAB 320 MG                                  | 21532480000340 | Brand |
| TALZENNA | TALAZOPARIB TOSYLATE CAP 0.1 MG (BASE EQUIVALENT)     | 21535580400105 | Brand |
| TALZENNA | TALAZOPARIB TOSYLATE CAP 0.25 MG (BASE EQUIVALENT)    | 21535580400110 | Brand |
| TALZENNA | TALAZOPARIB TOSYLATE CAP 0.35 MG (BASE EQUIVALENT)    | 21535580400112 | Brand |
| TALZENNA | TALAZOPARIB TOSYLATE CAP 0.5 MG (BASE EQUIVALENT)     | 21535580400114 | Brand |
| TALZENNA | TALAZOPARIB TOSYLATE CAP 0.75 MG (BASE EQUIVALENT)    | 21535580400118 | Brand |
| TALZENNA | TALAZOPARIB TOSYLATE CAP 1 MG (BASE EQUIVALENT)       | 21535580400120 | Brand |
| TEPMETKO | TEPOTINIB HCL TAB 225 MG                              | 21533773100320 | Brand |
| FOTIVDA  | TIVOZANIB HCL CAP 0.89 MG (BASE EQUIVALENT)           | 21533076250120 | Brand |
| FOTIVDA  | TIVOZANIB HCL CAP 1.34 MG (BASE EQUIVALENT)           | 21533076250130 | Brand |
| CAPRELSA | VANDETANIB TAB 100 MG                                 | 21533085000320 | Brand |
| CAPRELSA | VANDETANIB TAB 300 MG                                 | 21533085000340 | Brand |
| BRUKINSA | ZANUBRUTINIB CAP 80 MG                                | 21532195000120 | Brand |
| AKEEGA   | NIRAPARIB TOSYLATE-ABIRATERONE ACETATE TAB 50-500 MG  | 21409902120320 | Brand |
| AKEEGA   | NIRAPARIB TOSYLATE-ABIRATERONE ACETATE TAB 100-500 MG | 21409902120330 | Brand |
| VANFLYTA | QUIZARTINIB DIHYDROCHLORIDE TAB 17.7 MG               | 21533047100320 | Brand |
| VANFLYTA | QUIZARTINIB DIHYDROCHLORIDE TAB 26.5 MG               | 21533047100325 | Brand |
|          | -   | •              |       |

- **1** One of the following:
- **1.1** The requested drug is being used alone or in a combination regimen that is FDA-labeled for the treatment of the specific condition the member presents with\*

OR

**1.2** The requested drug being used alone or in a combination regimen that has a class 1 or 2 recommendation for use from the National Comprehensive Cancer Network (NCCN) in the specific condition of the member

OR

- **1.3** The requested drug is being used alone or in a combination regimen that is recommended for use in the specific condition of the member in one of the following:\*
  - United States Pharmacopeia Drug Information
  - American Hospital Formulary Service Drug Information
  - One article in a major peer-reviewed medical journal that recognizes the safety and efficacy of the requested drug, in the member's specific condition

#### **AND**

- **2** Prescribed by or in consultation with one of the following:
  - oncologist
  - hematologist
  - other specialist in the treatment of malignancy

| Notes | *Includes any relevant genetic testing, mutations, etc. |
|-------|---|

| Approval Length | 12 month(s)                    |
|-----------------|--------------------------------|
| Therapy Stage   | Reauthorization                |
| Guideline Type  | Prior Authorization - MN Plans |

| Product<br>Name | Generic Name                              | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| YONSA           | ABIRATERONE ACETATE MICRONIZED TAB 125 MG | 21406010250310 | Brand         |

| CALOUENCE | ACALABRUTINIB MALEATE TAB 100 MG                            | 0450040050005  | Brand |
|-----------|---|----------------|-------|
|           |   | 21532103500320 |       |
| KRAZATI   | ADAGRASIB TAB 200 MG  | 21532410000320 | Brand |
| ERLEADA   | APALUTAMIDE TAB 60 MG                                       | 21402410000320 | Brand |
| ERLEADA   | APALUTAMIDE TAB 240 MG                                      | 21402410000360 | Brand |
| SCEMBLIX  | ASCIMINIB HCL TAB 20 MG                                     | 21531806100320 | Brand |
| SCEMBLIX  | ASCIMINIB HCL TAB 40 MG                                     | 21531806100340 | Brand |
| AYVAKIT   | AVAPRITINIB TAB 25 MG                                       | 21490009000310 | Brand |
| AYVAKIT   | AVAPRITINIB TAB 50 MG                                       | 21490009000315 | Brand |
| AYVAKIT   | AVAPRITINIB TAB 100 MG                                      | 21490009000320 | Brand |
| AYVAKIT   | AVAPRITINIB TAB 200 MG                                      | 21490009000330 | Brand |
| AYVAKIT   | AVAPRITINIB TAB 300 MG                                      | 21490009000340 | Brand |
| WELIREG   | BELZUTIFAN TAB 40 MG  | 21421020000320 | Brand |
| MEKTOVI   | BINIMETINIB TAB 15 MG                                       | 21533520000320 | Brand |
| ALUNBRIG  | BRIGATINIB TAB INITIATION THERAPY PACK 90 MG<br>& 180 MG    | 2153051000B720 | Brand |
| ALUNBRIG  | BRIGATINIB TAB 30 MG  | 21530510000330 | Brand |
| ALUNBRIG  | BRIGATINIB TAB 90 MG  | 21530510000350 | Brand |
| ALUNBRIG  | BRIGATINIB TAB 180 MG                                       | 21530510000365 | Brand |
| COMETRIQ  | CABOZANTINIB S-MALATE CAP 3 X 20 MG (60 MG DOSE) KIT        | 21533010106460 | Brand |
| COMETRIQ  | CABOZANTINIB S-MAL CAP 1 X 80 MG & 1 X 20 MG (100 DOSE) KIT | 21533010106470 | Brand |
| COMETRIQ  | CABOZANTINIB S-MAL CAP 1 X 80 MG & 3 X 20 MG (140 DOSE) KIT | 21533010106480 | Brand |
| VIZIMPRO  | DACOMITINIB TAB 15 MG                                       | 21360019000320 | Brand |
| VIZIMPRO  | DACOMITINIB TAB 30 MG                                       | 21360019000330 | Brand |
| VIZIMPRO  | DACOMITINIB TAB 45 MG                                       | 21360019000340 | Brand |
| INQOVI    | DECITABINE-CEDAZURIDINE TAB 35-100 MG                       | 21990002250320 | Brand |
| COPIKTRA  | DUVELISIB CAP 15 MG   | 21538030000120 | Brand |
| COPIKTRA  | DUVELISIB CAP 25 MG   | 21538030000130 | Brand |
| ORSERDU   | ELACESTRANT HYDROCHLORIDE TAB 86 MG                         | 21403720100320 | Brand |
| ORSERDU   | ELACESTRANT HYDROCHLORIDE TAB 345 MG                        | 21403720100340 | Brand |
| IDHIFA    | ENASIDENIB MESYLATE TAB 50 MG (BASE<br>EQUIVALENT)          | 21535030200320 | Brand |
| IDHIFA    | ENASIDENIB MESYLATE TAB 100 MG (BASE EQUIVALENT)            | 21535030200340 | Brand |

| BRAFTOVI                       | ENCORAFENIB CAP 75 MG  | 21532040000130 | Brand |
|--------------------------------|--|----------------|-------|
| BALVERSA                       | ERDAFITINIB TAB 3 MG   | 21532225000320 | Brand |
| BALVERSA                       | ERDAFITINIB TAB 4 MG   | 21532225000325 | Brand |
| BALVERSA                       | ERDAFITINIB TAB 5 MG   | 21532225000330 | Brand |
| LYTGOBI                        | FUTIBATINIB TAB THERAPY PACK 4 MG (12 MG DAILY DOSE)         | 2153222800B720 | Brand |
| LYTGOBI                        | FUTIBATINIB TAB THERAPY PACK 4 MG (16 MG DAILY DOSE)         | 2153222800B725 | Brand |
| LYTGOBI                        | FUTIBATINIB TAB THERAPY PACK 4 MG (20 MG DAILY DOSE)         | 2153222800B730 | Brand |
| XOSPATA                        | GILTERITINIB FUMARATE TABLET 40 MG (BASE EQUIVALENT)         | 21533020200320 | Brand |
| DAURISMO                       | GLASDEGIB MALEATE TAB 25 MG (BASE EQUIVALENT)                | 21370030300320 | Brand |
| DAURISMO                       | GLASDEGIB MALEATE TAB 100 MG (BASE EQUIVALENT)               | 21370030300335 | Brand |
| TIBSOVO                        | IVOSIDENIB TAB 250 MG  | 21534940000320 | Brand |
| VITRAKVI                       | LAROTRECTINIB SULFATE CAP 25 MG (BASE EQUIVALENT)            | 21533835200120 | Brand |
| VITRAKVI                       | LAROTRECTINIB SULFATE CAP 100 MG (BASE EQUIVALENT)           | 21533835200150 | Brand |
| VITRAKVI                       | LAROTRECTINIB SULFATE ORAL SOLN 20 MG/ML (BASE EQUIVALENT)   | 21533835202020 | Brand |
| LENVIMA 4<br>MG DAILY<br>DOSE  | LENVATINIB CAP THERAPY PACK 4 MG (4 MG DAILY DOSE)           | 2133505420B210 | Brand |
| LENVIMA 8<br>MG DAILY<br>DOSE  | LENVATINIB CAP THERAPY PACK 2 X 4 MG (8 MG DAILY DOSE)       | 2133505420B215 | Brand |
| LENVIMA 10<br>MG DAILY<br>DOSE | LENVATINIB CAP THERAPY PACK 10 MG (10 MG DAILY DOSE)         | 2133505420B220 | Brand |
| LENVIMA<br>12MG DAILY<br>DOSE  | LENVATINIB CAP THERAPY PACK 3 X 4 MG (12 MG DAILY DOSE)      | 2133505420B223 | Brand |
| LENVIMA 20<br>MG DAILY<br>DOSE | LENVATINIB CAP THERAPY PACK 2 X 10 MG (20 MG DAILY DOSE)     | 2133505420B230 | Brand |
| LENVIMA 14<br>MG DAILY<br>DOSE | LENVATINIB CAP THERAPY PACK 10 & 4 MG (14 MG DAILY DOSE)     | 2133505420B240 | Brand |
| LENVIMA 18<br>MG DAILY<br>DOSE | LENVATINIB CAP THER PACK 10 MG & 2 X 4 MG (18 MG DAILY DOSE) | 2133505420B244 | Brand |
| LENVIMA 24                     | LENVATINIB CAP THER PACK 2 X 10 MG & 4 MG (24                | 2133505420B250 | Brand |

| MG DAILY<br>DOSE                | MG DAILY DOSE)  |                |       |
|---------------------------------|---|----------------|-------|
| LORBRENA                        | LORLATINIB TAB 25 MG                                  | 21530556000320 | Brand |
| LORBRENA                        | LORLATINIB TAB 100 MG                                 | 21530556000330 | Brand |
| RYDAPT                          | MIDOSTAURIN CAP 25 MG                                 | 21533030000130 | Brand |
| NERLYNX                         | NERATINIB MALEATE TAB 40 MG (BASE EQUIVALENT)         | 21533035100320 | Brand |
| REZLIDHIA                       | OLUTASIDENIB CAP 150 MG                               | 21534960000120 | Brand |
| VONJO                           | PACRITINIB CITRATE CAP 100 MG                         | 21537550100120 | Brand |
| PEMAZYRE                        | PEMIGATINIB TAB 4.5 MG                                | 21532260000320 | Brand |
| PEMAZYRE                        | PEMIGATINIB TAB 9 MG                                  | 21532260000330 | Brand |
| PEMAZYRE                        | PEMIGATINIB TAB 13.5 MG                               | 21532260000340 | Brand |
| TURALIO                         | PEXIDARTINIB HCL CAP 125 MG (BASE EQUIVALENT)         | 21533045010110 | Brand |
| JAYPIRCA                        | PIRTOBRUTINIB TAB 50 MG                               | 21532165000320 | Brand |
| JAYPIRCA                        | PIRTOBRUTINIB TAB 100 MG                              | 21532165000330 | Brand |
| ICLUSIG                         | PONATINIB HCL TAB 10 MG (BASE EQUIV)                  | 21531875100315 | Brand |
| ICLUSIG                         | PONATINIB HCL TAB 15 MG (BASE EQUIV)                  | 21531875100320 | Brand |
| ICLUSIG                         | PONATINIB HCL TAB 30 MG (BASE EQUIV)                  | 21531875100330 | Brand |
| ICLUSIG                         | PONATINIB HCL TAB 45 MG (BASE EQUIV)                  | 21531875100340 | Brand |
| GAVRETO                         | PRALSETINIB CAP 100 MG                                | 21535750000120 | Brand |
| ORGOVYX                         | RELUGOLIX TAB 120 MG                                  | 21405570000320 | Brand |
| QINLOCK                         | RIPRETINIB TAB 50 MG                                  | 21533053000320 | Brand |
| XPOVIO 80<br>MG TWICE<br>WEEKLY | SELINEXOR TAB THERAPY PACK 20 MG (80 MG TWICE WEEKLY) | 2156006000B720 | Brand |
| XPOVIO 60<br>MG TWICE<br>WEEKLY | SELINEXOR TAB THERAPY PACK 20 MG (60 MG TWICE WEEKLY) | 2156006000B755 | Brand |
| XPOVIO                          | SELINEXOR TAB THERAPY PACK 40 MG (40 MG ONCE WEEKLY)  | 2156006000B760 | Brand |
| XPOVIO                          | SELINEXOR TAB THERAPY PACK 40 MG (40 MG TWICE WEEKLY) | 2156006000B765 | Brand |
| XPOVIO                          | SELINEXOR TAB THERAPY PACK 40 MG (80 MG ONCE WEEKLY)  | 2156006000B770 | Brand |
| XPOVIO                          | SELINEXOR TAB THERAPY PACK 50 MG (100 MG ONCE WEEKLY) | 2156006000B775 | Brand |
| XPOVIO                          | SELINEXOR TAB THERAPY PACK 60 MG (60 MG ONCE WEEKLY)  | 2156006000B780 | Brand |

| LUMAKRAS | SOTORASIB TAB 120 MG                                  | 21532480000320 | Brand |
|----------|---|----------------|-------|
| LUMAKRAS | SOTORASIB TAB 320 MG                                  | 21532480000340 | Brand |
| TALZENNA | TALAZOPARIB TOSYLATE CAP 0.1 MG (BASE EQUIVALENT)     | 21535580400105 | Brand |
| TALZENNA | TALAZOPARIB TOSYLATE CAP 0.25 MG (BASE EQUIVALENT)    | 21535580400110 | Brand |
| TALZENNA | TALAZOPARIB TOSYLATE CAP 0.35 MG (BASE EQUIVALENT)    | 21535580400112 | Brand |
| TALZENNA | TALAZOPARIB TOSYLATE CAP 0.5 MG (BASE EQUIVALENT)     | 21535580400114 | Brand |
| TALZENNA | TALAZOPARIB TOSYLATE CAP 0.75 MG (BASE EQUIVALENT)    | 21535580400118 | Brand |
| TALZENNA | TALAZOPARIB TOSYLATE CAP 1 MG (BASE EQUIVALENT)       | 21535580400120 | Brand |
| ТЕРМЕТКО | TEPOTINIB HCL TAB 225 MG                              | 21533773100320 | Brand |
| FOTIVDA  | TIVOZANIB HCL CAP 0.89 MG (BASE EQUIVALENT)           | 21533076250120 | Brand |
| FOTIVDA  | TIVOZANIB HCL CAP 1.34 MG (BASE EQUIVALENT)           | 21533076250130 | Brand |
| CAPRELSA | VANDETANIB TAB 100 MG                                 | 21533085000320 | Brand |
| CAPRELSA | VANDETANIB TAB 300 MG                                 | 21533085000340 | Brand |
| BRUKINSA | ZANUBRUTINIB CAP 80 MG                                | 21532195000120 | Brand |
| AKEEGA   | NIRAPARIB TOSYLATE-ABIRATERONE ACETATE TAB 50-500 MG  | 21409902120320 | Brand |
| AKEEGA   | NIRAPARIB TOSYLATE-ABIRATERONE ACETATE TAB 100-500 MG | 21409902120330 | Brand |
| VANFLYTA | QUIZARTINIB DIHYDROCHLORIDE TAB 17.7 MG               | 21533047100320 | Brand |
| VANFLYTA | QUIZARTINIB DIHYDROCHLORIDE TAB 26.5 MG               | 21533047100325 | Brand |
|          |   |                |       |

- 1 One of the following:
- **1.1** The requested drug is being used alone or in a combination regimen that is FDA-labeled for the treatment of the specific condition the member presents with\*

OR

**1.2** The requested drug being used alone or in a combination regimen that has a class 1 or 2 recommendation for use from the National Comprehensive Cancer Network (NCCN) in the specific condition of the member

#### OR

- **1.3** The requested drug is being used alone or in a combination regimen that is recommended for use in the specific condition of the member in one of the following\*:
  - United States Pharmacopeia Drug Information
  - American Hospital Formulary Service Drug Information
  - One article in a major peer-reviewed medical journal that recognizes the safety and efficacy of the requested drug, in the member's specific condition

#### **AND**

- 2 Prescribed by or in consultation with one of the following:
  - oncologist
  - hematologist
  - other specialist in the treatment of malignancy

| Notes | *Includes any relevant genetic testing, mutations, etc. |
|-------|---|
|-------|---|

| Approval Length | 12 month(s)                    |
|-----------------|--------------------------------|
| Therapy Stage   | Initial Authorization          |
| Guideline Type  | Prior Authorization - IL Plans |

| Product<br>Name | Generic Name                              | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| YONSA           | ABIRATERONE ACETATE MICRONIZED TAB 125 MG | 21406010250310 | Brand         |
| CALQUENCE       | ACALABRUTINIB MALEATE TAB 100 MG          | 21532103500320 | Brand         |
| KRAZATI         | ADAGRASIB TAB 200 MG                      | 21532410000320 | Brand         |
| ERLEADA         | APALUTAMIDE TAB 60 MG                     | 21402410000320 | Brand         |
| ERLEADA         | APALUTAMIDE TAB 240 MG                    | 21402410000360 | Brand         |
| SCEMBLIX        | ASCIMINIB HCL TAB 20 MG                   | 21531806100320 | Brand         |

| SCEMBLIX | ASCIMINIB HCL TAB 40 MG                                     | 21531806100340 | Brand |
|----------|---|----------------|-------|
| AYVAKIT  | AVAPRITINIB TAB 25 MG                                       | 21490009000310 | Brand |
| AYVAKIT  | AVAPRITINIB TAB 50 MG                                       | 21490009000315 | Brand |
| AYVAKIT  | AVAPRITINIB TAB 100 MG                                      | 21490009000320 | Brand |
| AYVAKIT  | AVAPRITINIB TAB 200 MG                                      | 21490009000330 | Brand |
| AYVAKIT  | AVAPRITINIB TAB 300 MG                                      | 21490009000340 | Brand |
| WELIREG  | BELZUTIFAN TAB 40 MG  | 21421020000320 | Brand |
| MEKTOVI  | BINIMETINIB TAB 15 MG                                       | 21533520000320 | Brand |
| ALUNBRIG | BRIGATINIB TAB INITIATION THERAPY PACK 90 MG<br>& 180 MG    | 2153051000B720 | Brand |
| ALUNBRIG | BRIGATINIB TAB 30 MG  | 21530510000330 | Brand |
| ALUNBRIG | BRIGATINIB TAB 90 MG  | 21530510000350 | Brand |
| ALUNBRIG | BRIGATINIB TAB 180 MG                                       | 21530510000365 | Brand |
| COMETRIQ | CABOZANTINIB S-MALATE CAP 3 X 20 MG (60 MG DOSE) KIT        | 21533010106460 | Brand |
| COMETRIQ | CABOZANTINIB S-MAL CAP 1 X 80 MG & 1 X 20 MG (100 DOSE) KIT | 21533010106470 | Brand |
| COMETRIQ | CABOZANTINIB S-MAL CAP 1 X 80 MG & 3 X 20 MG (140 DOSE) KIT | 21533010106480 | Brand |
| VIZIMPRO | DACOMITINIB TAB 15 MG                                       | 21360019000320 | Brand |
| VIZIMPRO | DACOMITINIB TAB 30 MG                                       | 21360019000330 | Brand |
| VIZIMPRO | DACOMITINIB TAB 45 MG                                       | 21360019000340 | Brand |
| INQOVI   | DECITABINE-CEDAZURIDINE TAB 35-100 MG                       | 21990002250320 | Brand |
| COPIKTRA | DUVELISIB CAP 15 MG   | 21538030000120 | Brand |
| COPIKTRA | DUVELISIB CAP 25 MG   | 21538030000130 | Brand |
| ORSERDU  | ELACESTRANT HYDROCHLORIDE TAB 86 MG                         | 21403720100320 | Brand |
| ORSERDU  | ELACESTRANT HYDROCHLORIDE TAB 345 MG                        | 21403720100340 | Brand |
| IDHIFA   | ENASIDENIB MESYLATE TAB 50 MG (BASE EQUIVALENT)             | 21535030200320 | Brand |
| IDHIFA   | ENASIDENIB MESYLATE TAB 100 MG (BASE EQUIVALENT)            | 21535030200340 | Brand |
| BRAFTOVI | ENCORAFENIB CAP 75 MG                                       | 21532040000130 | Brand |
| BALVERSA | ERDAFITINIB TAB 3 MG  | 21532225000320 | Brand |
| BALVERSA | ERDAFITINIB TAB 4 MG  | 21532225000325 | Brand |
| BALVERSA | ERDAFITINIB TAB 5 MG  | 21532225000330 | Brand |
| LYTGOBI  | FUTIBATINIB TAB THERAPY PACK 4 MG (12 MG                    | 2153222800B720 | Brand |

|                                | DAILY DOSE)  |                |       |
|--------------------------------|--|----------------|-------|
| LYTGOBI                        | FUTIBATINIB TAB THERAPY PACK 4 MG (16 MG DAILY DOSE)         | 2153222800B725 | Brand |
| LYTGOBI                        | FUTIBATINIB TAB THERAPY PACK 4 MG (20 MG DAILY DOSE)         | 2153222800B730 | Brand |
| XOSPATA                        | GILTERITINIB FUMARATE TABLET 40 MG (BASE EQUIVALENT)         | 21533020200320 | Brand |
| DAURISMO                       | GLASDEGIB MALEATE TAB 25 MG (BASE EQUIVALENT)                | 21370030300320 | Brand |
| DAURISMO                       | GLASDEGIB MALEATE TAB 100 MG (BASE EQUIVALENT)               | 21370030300335 | Brand |
| TIBSOVO                        | IVOSIDENIB TAB 250 MG  | 21534940000320 | Brand |
| VITRAKVI                       | LAROTRECTINIB SULFATE CAP 25 MG (BASE EQUIVALENT)            | 21533835200120 | Brand |
| VITRAKVI                       | LAROTRECTINIB SULFATE CAP 100 MG (BASE EQUIVALENT)           | 21533835200150 | Brand |
| VITRAKVI                       | LAROTRECTINIB SULFATE ORAL SOLN 20 MG/ML (BASE EQUIVALENT)   | 21533835202020 | Brand |
| LENVIMA 4<br>MG DAILY<br>DOSE  | LENVATINIB CAP THERAPY PACK 4 MG (4 MG DAILY DOSE)           | 2133505420B210 | Brand |
| LENVIMA 8<br>MG DAILY<br>DOSE  | LENVATINIB CAP THERAPY PACK 2 X 4 MG (8 MG DAILY DOSE)       | 2133505420B215 | Brand |
| LENVIMA 10<br>MG DAILY<br>DOSE | LENVATINIB CAP THERAPY PACK 10 MG (10 MG DAILY DOSE)         | 2133505420B220 | Brand |
| LENVIMA<br>12MG DAILY<br>DOSE  | LENVATINIB CAP THERAPY PACK 3 X 4 MG (12 MG DAILY DOSE)      | 2133505420B223 | Brand |
| LENVIMA 20<br>MG DAILY<br>DOSE | LENVATINIB CAP THERAPY PACK 2 X 10 MG (20 MG DAILY DOSE)     | 2133505420B230 | Brand |
| LENVIMA 14<br>MG DAILY<br>DOSE | LENVATINIB CAP THERAPY PACK 10 & 4 MG (14 MG DAILY DOSE)     | 2133505420B240 | Brand |
| LENVIMA 18<br>MG DAILY<br>DOSE | LENVATINIB CAP THER PACK 10 MG & 2 X 4 MG (18 MG DAILY DOSE) | 2133505420B244 | Brand |
| LENVIMA 24<br>MG DAILY<br>DOSE | LENVATINIB CAP THER PACK 2 X 10 MG & 4 MG (24 MG DAILY DOSE) | 2133505420B250 | Brand |
| LORBRENA                       | LORLATINIB TAB 25 MG   | 21530556000320 | Brand |
| LORBRENA                       | LORLATINIB TAB 100 MG  | 21530556000330 | Brand |
| RYDAPT                         | MIDOSTAURIN CAP 25 MG  | 21533030000130 | Brand |

| NERLYNX                         | NERATINIB MALEATE TAB 40 MG (BASE                        | 21533035100320 | Brand |
|---------------------------------|--|----------------|-------|
| REZLIDHIA                       | EQUIVALENT) OLUTASIDENIB CAP 150 MG                      | 2452406000400  | Brand |
| VONJO                           | PACRITINIB CITRATE CAP 100 MG                            | 21534960000120 | Brand |
| PEMAZYRE                        | PEMIGATINIB TAB 4.5 MG                                   | 21537550100120 | Brand |
|                                 |  | 21532260000320 |       |
| PEMAZYRE                        | PEMIGATINIB TAB 9 MG                                     | 21532260000330 | Brand |
| PEMAZYRE                        | PEMIGATINIB TAB 13.5 MG                                  | 21532260000340 | Brand |
| TURALIO                         | PEXIDARTINIB HCL CAP 125 MG (BASE EQUIVALENT)            | 21533045010110 | Brand |
| JAYPIRCA                        | PIRTOBRUTINIB TAB 50 MG                                  | 21532165000320 | Brand |
| JAYPIRCA                        | PIRTOBRUTINIB TAB 100 MG                                 | 21532165000330 | Brand |
| ICLUSIG                         | PONATINIB HCL TAB 10 MG (BASE EQUIV)                     | 21531875100315 | Brand |
| ICLUSIG                         | PONATINIB HCL TAB 15 MG (BASE EQUIV)                     | 21531875100320 | Brand |
| ICLUSIG                         | PONATINIB HCL TAB 30 MG (BASE EQUIV)                     | 21531875100330 | Brand |
| ICLUSIG                         | PONATINIB HCL TAB 45 MG (BASE EQUIV)                     | 21531875100340 | Brand |
| GAVRETO                         | PRALSETINIB CAP 100 MG                                   | 21535750000120 | Brand |
| ORGOVYX                         | RELUGOLIX TAB 120 MG                                     | 21405570000320 | Brand |
| QINLOCK                         | RIPRETINIB TAB 50 MG                                     | 21533053000320 | Brand |
| XPOVIO 80<br>MG TWICE<br>WEEKLY | SELINEXOR TAB THERAPY PACK 20 MG (80 MG<br>TWICE WEEKLY) | 2156006000B720 | Brand |
| XPOVIO 60<br>MG TWICE<br>WEEKLY | SELINEXOR TAB THERAPY PACK 20 MG (60 MG<br>TWICE WEEKLY) | 2156006000B755 | Brand |
| XPOVIO                          | SELINEXOR TAB THERAPY PACK 40 MG (40 MG ONCE WEEKLY)     | 2156006000B760 | Brand |
| XPOVIO                          | SELINEXOR TAB THERAPY PACK 40 MG (40 MG<br>TWICE WEEKLY) | 2156006000B765 | Brand |
| XPOVIO                          | SELINEXOR TAB THERAPY PACK 40 MG (80 MG ONCE WEEKLY)     | 2156006000B770 | Brand |
| XPOVIO                          | SELINEXOR TAB THERAPY PACK 50 MG (100 MG ONCE WEEKLY)    | 2156006000B775 | Brand |
| XPOVIO                          | SELINEXOR TAB THERAPY PACK 60 MG (60 MG ONCE WEEKLY)     | 2156006000B780 | Brand |
| LUMAKRAS                        | SOTORASIB TAB 120 MG                                     | 21532480000320 | Brand |
| LUMAKRAS                        | SOTORASIB TAB 320 MG                                     | 21532480000340 | Brand |
| TALZENNA                        | TALAZOPARIB TOSYLATE CAP 0.1 MG (BASE EQUIVALENT)        | 21535580400105 | Brand |

| TALZENNA | TALAZOPARIB TOSYLATE CAP 0.25 MG (BASE EQUIVALENT)    | 21535580400110 | Brand |
|----------|---|----------------|-------|
| TALZENNA | TALAZOPARIB TOSYLATE CAP 0.35 MG (BASE EQUIVALENT)    | 21535580400112 | Brand |
| TALZENNA | TALAZOPARIB TOSYLATE CAP 0.5 MG (BASE EQUIVALENT)     | 21535580400114 | Brand |
| TALZENNA | TALAZOPARIB TOSYLATE CAP 0.75 MG (BASE EQUIVALENT)    | 21535580400118 | Brand |
| TALZENNA | TALAZOPARIB TOSYLATE CAP 1 MG (BASE EQUIVALENT)       | 21535580400120 | Brand |
| ТЕРМЕТКО | TEPOTINIB HCL TAB 225 MG                              | 21533773100320 | Brand |
| FOTIVDA  | TIVOZANIB HCL CAP 0.89 MG (BASE EQUIVALENT)           | 21533076250120 | Brand |
| FOTIVDA  | TIVOZANIB HCL CAP 1.34 MG (BASE EQUIVALENT)           | 21533076250130 | Brand |
| CAPRELSA | VANDETANIB TAB 100 MG                                 | 21533085000320 | Brand |
| CAPRELSA | VANDETANIB TAB 300 MG                                 | 21533085000340 | Brand |
| BRUKINSA | ZANUBRUTINIB CAP 80 MG                                | 21532195000120 | Brand |
| AKEEGA   | NIRAPARIB TOSYLATE-ABIRATERONE ACETATE TAB 50-500 MG  | 21409902120320 | Brand |
| AKEEGA   | NIRAPARIB TOSYLATE-ABIRATERONE ACETATE TAB 100-500 MG | 21409902120330 | Brand |
| VANFLYTA | QUIZARTINIB DIHYDROCHLORIDE TAB 17.7 MG               | 21533047100320 | Brand |
| VANFLYTA | QUIZARTINIB DIHYDROCHLORIDE TAB 26.5 MG               | 21533047100325 | Brand |

- **1** One of the following:
- **1.1** The requested drug is being used alone or in a combination regimen that is FDA-labeled for the treatment of the specific condition the member presents with\*

OR

**1.2** The requested drug being used alone or in a combination regimen that has a class 1 or 2 recommendation for use from the National Comprehensive Cancer Network (NCCN) in the specific condition of the member

OR

- **1.3** The requested drug is being used alone or in a combination regimen that is recommended for use in the specific condition of the member in one of the following\*:
  - American Hospital Formulary Service Drug Information
  - Thompson Micromedex's Drug Dex
  - Elsevier Gold Standard's Clinical Pharmacology
  - Two articles in a major peer-reviewed medical journal from the United States or Great Britain that recognizes the safety and efficacy of the requested drug, in the member's specific condition

#### AND

- 2 Prescribed by or in consultation with one of the following:
  - oncologist
  - hematologist
  - other specialist in the treatment of malignancy

| Notes | *Includes any relevant genetic testing, mutations, etc. |
|-------|---|
|       | · ·   |

| Approval Length | 12 month(s)                    |
|-----------------|--------------------------------|
| Therapy Stage   | Reauthorization                |
| Guideline Type  | Prior Authorization - IL Plans |

| Product<br>Name | Generic Name                              | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| YONSA           | ABIRATERONE ACETATE MICRONIZED TAB 125 MG | 21406010250310 | Brand         |
| CALQUENCE       | ACALABRUTINIB MALEATE TAB 100 MG          | 21532103500320 | Brand         |
| KRAZATI         | ADAGRASIB TAB 200 MG                      | 21532410000320 | Brand         |
| ERLEADA         | APALUTAMIDE TAB 60 MG                     | 21402410000320 | Brand         |
| ERLEADA         | APALUTAMIDE TAB 240 MG                    | 21402410000360 | Brand         |
| SCEMBLIX        | ASCIMINIB HCL TAB 20 MG                   | 21531806100320 | Brand         |
| SCEMBLIX        | ASCIMINIB HCL TAB 40 MG                   | 21531806100340 | Brand         |
| AYVAKIT         | AVAPRITINIB TAB 25 MG                     | 21490009000310 | Brand         |

| AYVAKIT  | AVAPRITINIB TAB 50 MG                                       | 21490009000315 | Brand |
|----------|---|----------------|-------|
| AYVAKIT  | AVAPRITINIB TAB 100 MG                                      | 21490009000320 | Brand |
| AYVAKIT  | AVAPRITINIB TAB 200 MG                                      | 21490009000330 | Brand |
| AYVAKIT  | AVAPRITINIB TAB 300 MG                                      | 21490009000340 | Brand |
| WELIREG  | BELZUTIFAN TAB 40 MG  | 21421020000320 | Brand |
| MEKTOVI  | BINIMETINIB TAB 15 MG                                       | 21533520000320 | Brand |
| ALUNBRIG | BRIGATINIB TAB INITIATION THERAPY PACK 90 MG<br>& 180 MG    | 2153051000B720 | Brand |
| ALUNBRIG | BRIGATINIB TAB 30 MG  | 21530510000330 | Brand |
| ALUNBRIG | BRIGATINIB TAB 90 MG  | 21530510000350 | Brand |
| ALUNBRIG | BRIGATINIB TAB 180 MG                                       | 21530510000365 | Brand |
| COMETRIQ | CABOZANTINIB S-MALATE CAP 3 X 20 MG (60 MG DOSE) KIT        | 21533010106460 | Brand |
| COMETRIQ | CABOZANTINIB S-MAL CAP 1 X 80 MG & 1 X 20 MG (100 DOSE) KIT | 21533010106470 | Brand |
| COMETRIQ | CABOZANTINIB S-MAL CAP 1 X 80 MG & 3 X 20 MG (140 DOSE) KIT | 21533010106480 | Brand |
| VIZIMPRO | DACOMITINIB TAB 15 MG                                       | 21360019000320 | Brand |
| VIZIMPRO | DACOMITINIB TAB 30 MG                                       | 21360019000330 | Brand |
| VIZIMPRO | DACOMITINIB TAB 45 MG                                       | 21360019000340 | Brand |
| INQOVI   | DECITABINE-CEDAZURIDINE TAB 35-100 MG                       | 21990002250320 | Brand |
| COPIKTRA | DUVELISIB CAP 15 MG   | 21538030000120 | Brand |
| COPIKTRA | DUVELISIB CAP 25 MG   | 21538030000130 | Brand |
| ORSERDU  | ELACESTRANT HYDROCHLORIDE TAB 86 MG                         | 21403720100320 | Brand |
| ORSERDU  | ELACESTRANT HYDROCHLORIDE TAB 345 MG                        | 21403720100340 | Brand |
| IDHIFA   | ENASIDENIB MESYLATE TAB 50 MG (BASE EQUIVALENT)             | 21535030200320 | Brand |
| IDHIFA   | ENASIDENIB MESYLATE TAB 100 MG (BASE EQUIVALENT)            | 21535030200340 | Brand |
| BRAFTOVI | ENCORAFENIB CAP 75 MG                                       | 21532040000130 | Brand |
| BALVERSA | ERDAFITINIB TAB 3 MG  | 21532225000320 | Brand |
| BALVERSA | ERDAFITINIB TAB 4 MG  | 21532225000325 | Brand |
| BALVERSA | ERDAFITINIB TAB 5 MG  | 21532225000330 | Brand |
| LYTGOBI  | FUTIBATINIB TAB THERAPY PACK 4 MG (12 MG DAILY DOSE)        | 2153222800B720 | Brand |
| LYTGOBI  | FUTIBATINIB TAB THERAPY PACK 4 MG (16 MG DAILY DOSE)        | 2153222800B725 | Brand |

| LYTGOBI  | FUTIBATINIB TAB THERAPY PACK 4 MG (20 MG DAILY DOSE)         | 2153222800B730 | Brand |
|--|--|----------------|-------|
| XOSPATA GILTERITINIB FUMARATE TABLET 40 MG (BASE EQUIVALENT) |  | 21533020200320 | Brand |
| DAURISMO   | GLASDEGIB MALEATE TAB 25 MG (BASE EQUIVALENT)                | 21370030300320 | Brand |
| DAURISMO   | GLASDEGIB MALEATE TAB 100 MG (BASE EQUIVALENT)               | 21370030300335 | Brand |
| TIBSOVO  | IVOSIDENIB TAB 250 MG  | 21534940000320 | Brand |
| VITRAKVI   | LAROTRECTINIB SULFATE CAP 25 MG (BASE EQUIVALENT)            | 21533835200120 | Brand |
| VITRAKVI   | LAROTRECTINIB SULFATE CAP 100 MG (BASE EQUIVALENT)           | 21533835200150 | Brand |
| VITRAKVI   | LAROTRECTINIB SULFATE ORAL SOLN 20 MG/ML (BASE EQUIVALENT)   | 21533835202020 | Brand |
| LENVIMA 4<br>MG DAILY<br>DOSE                                | LENVATINIB CAP THERAPY PACK 4 MG (4 MG DAILY DOSE)           | 2133505420B210 | Brand |
| LENVIMA 8<br>MG DAILY<br>DOSE                                | LENVATINIB CAP THERAPY PACK 2 X 4 MG (8 MG DAILY DOSE)       | 2133505420B215 | Brand |
| LENVIMA 10<br>MG DAILY<br>DOSE                               | LENVATINIB CAP THERAPY PACK 10 MG (10 MG DAILY DOSE)         | 2133505420B220 | Brand |
| LENVIMA<br>12MG DAILY<br>DOSE                                | LENVATINIB CAP THERAPY PACK 3 X 4 MG (12 MG DAILY DOSE)      | 2133505420B223 | Brand |
| LENVIMA 20<br>MG DAILY<br>DOSE                               | LENVATINIB CAP THERAPY PACK 2 X 10 MG (20 MG DAILY DOSE)     | 2133505420B230 | Brand |
| LENVIMA 14<br>MG DAILY<br>DOSE                               | LENVATINIB CAP THERAPY PACK 10 & 4 MG (14 MG DAILY DOSE)     | 2133505420B240 | Brand |
| LENVIMA 18<br>MG DAILY<br>DOSE                               | LENVATINIB CAP THER PACK 10 MG & 2 X 4 MG (18 MG DAILY DOSE) | 2133505420B244 | Brand |
| LENVIMA 24<br>MG DAILY<br>DOSE                               | LENVATINIB CAP THER PACK 2 X 10 MG & 4 MG (24 MG DAILY DOSE) | 2133505420B250 | Brand |
| LORBRENA   | LORLATINIB TAB 25 MG   | 21530556000320 | Brand |
| LORBRENA   | LORLATINIB TAB 100 MG  | 21530556000330 | Brand |
| RYDAPT   | MIDOSTAURIN CAP 25 MG  | 21533030000130 | Brand |
| NERLYNX  | NERATINIB MALEATE TAB 40 MG (BASE EQUIVALENT)                | 21533035100320 | Brand |
| REZLIDHIA  | OLUTASIDENIB CAP 150 MG                                      | 21534960000120 | Brand |

| VONJO                           | PACRITINIB CITRATE CAP 100 MG                            | 04507550400400 | Brand |
|---------------------------------|--|----------------|-------|
|                                 |  | 21537550100120 |       |
| PEMAZYRE                        | PEMIGATINIB TAB 4.5 MG                                   | 21532260000320 | Brand |
| PEMAZYRE                        | PEMIGATINIB TAB 9 MG                                     | 21532260000330 | Brand |
| PEMAZYRE                        | PEMIGATINIB TAB 13.5 MG                                  | 21532260000340 | Brand |
| TURALIO                         | PEXIDARTINIB HCL CAP 125 MG (BASE EQUIVALENT)            | 21533045010110 | Brand |
| JAYPIRCA                        | PIRTOBRUTINIB TAB 50 MG                                  | 21532165000320 | Brand |
| JAYPIRCA                        | PIRTOBRUTINIB TAB 100 MG                                 | 21532165000330 | Brand |
| ICLUSIG                         | PONATINIB HCL TAB 10 MG (BASE EQUIV)                     | 21531875100315 | Brand |
| ICLUSIG                         | PONATINIB HCL TAB 15 MG (BASE EQUIV)                     | 21531875100320 | Brand |
| ICLUSIG                         | PONATINIB HCL TAB 30 MG (BASE EQUIV)                     | 21531875100330 | Brand |
| ICLUSIG                         | PONATINIB HCL TAB 45 MG (BASE EQUIV)                     | 21531875100340 | Brand |
| GAVRETO                         | PRALSETINIB CAP 100 MG                                   | 21535750000120 | Brand |
| ORGOVYX                         | RELUGOLIX TAB 120 MG                                     | 21405570000320 | Brand |
| QINLOCK                         | RIPRETINIB TAB 50 MG                                     | 21533053000320 | Brand |
| XPOVIO 80<br>MG TWICE<br>WEEKLY | SELINEXOR TAB THERAPY PACK 20 MG (80 MG<br>TWICE WEEKLY) | 2156006000B720 | Brand |
| XPOVIO 60<br>MG TWICE<br>WEEKLY | SELINEXOR TAB THERAPY PACK 20 MG (60 MG<br>TWICE WEEKLY) | 2156006000B755 | Brand |
| XPOVIO                          | SELINEXOR TAB THERAPY PACK 40 MG (40 MG ONCE WEEKLY)     | 2156006000B760 | Brand |
| XPOVIO                          | SELINEXOR TAB THERAPY PACK 40 MG (40 MG<br>TWICE WEEKLY) | 2156006000B765 | Brand |
| XPOVIO                          | SELINEXOR TAB THERAPY PACK 40 MG (80 MG ONCE WEEKLY)     | 2156006000B770 | Brand |
| XPOVIO                          | SELINEXOR TAB THERAPY PACK 50 MG (100 MG ONCE WEEKLY)    | 2156006000B775 | Brand |
| XPOVIO                          | SELINEXOR TAB THERAPY PACK 60 MG (60 MG ONCE WEEKLY)     | 2156006000B780 | Brand |
| LUMAKRAS                        | SOTORASIB TAB 120 MG                                     | 21532480000320 | Brand |
| LUMAKRAS                        | SOTORASIB TAB 320 MG                                     | 21532480000340 | Brand |
| TALZENNA                        | TALAZOPARIB TOSYLATE CAP 0.1 MG (BASE EQUIVALENT)        | 21535580400105 | Brand |
| TALZENNA                        | TALAZOPARIB TOSYLATE CAP 0.25 MG (BASE EQUIVALENT)       | 21535580400110 | Brand |
| TALZENNA                        | TALAZOPARIB TOSYLATE CAP 0.35 MG (BASE EQUIVALENT)       | 21535580400112 | Brand |

| TALZENNA | TALAZOPARIB TOSYLATE CAP 0.5 MG (BASE EQUIVALENT)        | 21535580400114 | Brand |
|----------|--|----------------|-------|
| TALZENNA | TALAZOPARIB TOSYLATE CAP 0.75 MG (BASE EQUIVALENT)       | 21535580400118 | Brand |
| TALZENNA | TALAZOPARIB TOSYLATE CAP 1 MG (BASE EQUIVALENT)          | 21535580400120 | Brand |
| TEPMETKO | TEPOTINIB HCL TAB 225 MG                                 | 21533773100320 | Brand |
| FOTIVDA  | TIVOZANIB HCL CAP 0.89 MG (BASE EQUIVALENT)              | 21533076250120 | Brand |
| FOTIVDA  | TIVOZANIB HCL CAP 1.34 MG (BASE EQUIVALENT)              | 21533076250130 | Brand |
| CAPRELSA | VANDETANIB TAB 100 MG                                    | 21533085000320 | Brand |
| CAPRELSA | VANDETANIB TAB 300 MG                                    | 21533085000340 | Brand |
| BRUKINSA | ZANUBRUTINIB CAP 80 MG                                   | 21532195000120 | Brand |
| AKEEGA   | NIRAPARIB TOSYLATE-ABIRATERONE ACETATE<br>TAB 50-500 MG  | 21409902120320 | Brand |
| AKEEGA   | NIRAPARIB TOSYLATE-ABIRATERONE ACETATE<br>TAB 100-500 MG | 21409902120330 | Brand |
| VANFLYTA | QUIZARTINIB DIHYDROCHLORIDE TAB 17.7 MG                  | 21533047100320 | Brand |
| VANFLYTA | QUIZARTINIB DIHYDROCHLORIDE TAB 26.5 MG                  | 21533047100325 | Brand |

- **1** One of the following:
- **1.1** The requested drug is being used alone or in a combination regimen that is FDA-labeled for the treatment of the specific condition the member presents with\*

OR

**1.2** The requested drug being used alone or in a combination regimen that has a class 1 or 2 recommendation for use from the National Comprehensive Cancer Network (NCCN) in the specific condition of the member

OR

- **1.3** The requested drug is being used alone or in a combination regimen that is recommended for use in the specific condition of the member in one of the following\*:
  - American Hospital Formulary Service Drug Information

- Thompson Micromedex's Drug Dex
- Elsevier Gold Standard's Clinical Pharmacology
- Two articles in a major peer-reviewed medical journal from the United States or Great Britain that recognizes the safety and efficacy of the requested drug, in the member's specific condition

### **AND**

- **2** Prescribed by or in consultation with one of the following:
  - oncologist
  - hematologist
  - other specialist in the treatment of malignancy

| Notes *Includes any relevant genetic testing, mutations, etc. |
|---|
|---|

## 2. Revision History

| Date       | Notes                   |
|------------|-------------------------|
| 10/25/2023 | 2024 New Implementation |

| Restricted Oral Oncology Drugs Quartz Specialty Pharmacy I |  |  |  |
|--|--|--|--|
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## **Prior Authorization Guideline**

| Guideline ID   | GL-141300  |
|----------------|--|
| Guideline Name | Restricted Oral Oncology Drugs Quartz Specialty Pharmacy Network |
| Formulary      | Quartz   |

## **Guideline Note:**

| Effective Date: |
|-----------------|
|-----------------|

### 1. Criteria

| Approval Length | 12 month(s)  |
|-----------------|--|
| Therapy Stage   | Initial Authorization                                  |
| Guideline Type  | Prior Authorization - ALL Plans Except IL and MN Plans |

| Product<br>Name | Generic Name                                      | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| GILOTRIF        | AFATINIB DIMALEATE TAB 20 MG (BASE EQUIVALENT)    | 21360006100320 | Brand         |
| GILOTRIF        | AFATINIB DIMALEATE TAB 30 MG (BASE EQUIVALENT)    | 21360006100330 | Brand         |
| GILOTRIF        | AFATINIB DIMALEATE TAB 40 MG (BASE<br>EQUIVALENT) | 21360006100340 | Brand         |

| ALECENSA                | ALECTINIB HCL CAP 150 MG (BASE EQUIVALENT)               | 21530507100120 | Brand   |
|-------------------------|--|----------------|---------|
| ONUREG                  | AZACITIDINE TAB 200 MG                                   | 21300003000320 | Brand   |
| ONUREG                  | AZACITIDINE TAB 300 MG                                   | 21300003000330 | Brand   |
| TABRECTA                | CAPMATINIB HCL TAB 150 MG                                | 21533716200320 | Brand   |
| TABRECTA                | CAPMATINIB HCL TAB 200 MG                                | 21533716200330 | Brand   |
| COTELLIC                | COBIMETINIB FUMARATE TAB 20 MG (BASE EQUIVALENT)         | 21533530200320 | Brand   |
| TAFINLAR                | DABRAFENIB MESYLATE CAP 50 MG (BASE<br>EQUIVALENT)       | 21532025100120 | Brand   |
| TAFINLAR                | DABRAFENIB MESYLATE CAP 75 MG (BASE EQUIVALENT)          | 21532025100130 | Brand   |
| TAFINLAR                | DABRAFENIB MESYLATE TAB FOR ORAL SUSP 10 MG (BASE EQUIV) | 21532025107320 | Brand   |
| ROZLYTREK               | ENTRECTINIB CAP 100 MG                                   | 21533820000120 | Brand   |
| ROZLYTREK               | ENTRECTINIB CAP 200 MG                                   | 21533820000130 | Brand   |
| IMBRUVICA               | IBRUTINIB CAP 70 MG                                      | 21532133000110 | Brand   |
| IMBRUVICA               | IBRUTINIB CAP 140 MG                                     | 21532133000120 | Brand   |
| IMBRUVICA               | IBRUTINIB TAB 420 MG                                     | 21532133000340 | Brand   |
| IMBRUVICA               | IBRUTINIB ORAL SUSP 70 MG/ML                             | 21532133001820 | Brand   |
| ZYDELIG                 | IDELALISIB TAB 100 MG                                    | 21538040000320 | Brand   |
| ZYDELIG                 | IDELALISIB TAB 150 MG                                    | 21538040000330 | Brand   |
| NINLARO                 | IXAZOMIB CITRATE CAP 2.3 MG (BASE EQUIVALENT)            | 21536045100120 | Brand   |
| NINLARO                 | IXAZOMIB CITRATE CAP 3 MG (BASE<br>EQUIVALENT)           | 21536045100130 | Brand   |
| NINLARO                 | IXAZOMIB CITRATE CAP 4 MG (BASE<br>EQUIVALENT)           | 21536045100140 | Brand   |
| LAPATINIB<br>DITOSYLATE | LAPATINIB DITOSYLATE TAB 250 MG (BASE EQUIV)             | 21533026100320 | Generic |
| LENALIDOMIDE            | LENALIDOMIDE CAPS 2.5 MG                                 | 99394050000110 | Generic |
| LENALIDOMIDE            | LENALIDOMIDE CAP 5 MG                                    | 99394050000120 | Generic |
| LENALIDOMIDE            | LENALIDOMIDE CAP 10 MG                                   | 99394050000130 | Generic |
| LENALIDOMIDE            | LENALIDOMIDE CAP 15 MG                                   | 99394050000140 | Generic |
| LENALIDOMIDE            | LENALIDOMIDE CAP 20 MG                                   | 99394050000145 | Generic |
| LENALIDOMIDE            | LENALIDOMIDE CAP 25 MG                                   | 99394050000150 | Generic |
| EXKIVITY                | MOBOCERTINIB SUCCINATE CAP 40 MG                         | 21360050600120 | Brand   |
| POMALYST                | POMALIDOMIDE CAP 1 MG                                    | 21450080000110 | Brand   |

| POMALYST                      | POMALIDOMIDE CAP 2 MG                                       | 21450000000445 | Brand |
|-------------------------------|---|----------------|-------|
| POMALYST                      | POMALIDOMIDE CAP 3 MG                                       | 21450080000115 | Brand |
| _                             | POMALIDOMIDE CAP 3 MG                                       | 21450080000120 |       |
| POMALYST                      |   | 21450080000125 | Brand |
| STIVARGA                      | REGORAFENIB TAB 40 MG                                       | 21533050000320 | Brand |
| KOSELUGO                      | SELUMETINIB SULFATE CAP 10 MG                               | 21533565500110 | Brand |
| KOSELUGO                      | SELUMETINIB SULFATE CAP 25 MG                               | 21533565500125 | Brand |
| ODOMZO                        | SONIDEGIB PHOSPHATE CAP 200 MG (BASE EQUIVALENT)            | 21370060200120 | Brand |
| HYCAMTIN                      | TOPOTECAN HCL CAP 0.25 MG (BASE EQUIV)                      | 21550080100120 | Brand |
| HYCAMTIN                      | TOPOTECAN HCL CAP 1 MG (BASE EQUIV)                         | 21550080100140 | Brand |
| MEKINIST                      | TRAMETINIB DIMETHYL SULFOXIDE TAB 0.5 MG (BASE EQUIVALENT)  | 21533570100310 | Brand |
| MEKINIST                      | TRAMETINIB DIMETHYL SULFOXIDE TAB 2 MG (BASE EQUIVALENT)    | 21533570100330 | Brand |
| MEKINIST                      | TRAMETINIB DIMETHYL SULFOXIDE FOR SOLN 0.05 MG/ML (BASE EQ) | 21533570102120 | Brand |
| LONSURF                       | TRIFLURIDINE-TIPIRACIL TAB 15-6.14 MG                       | 21990002750320 | Brand |
| LONSURF                       | TRIFLURIDINE-TIPIRACIL TAB 20-8.19 MG                       | 21990002750330 | Brand |
| TUKYSA                        | TUCATINIB TAB 50 MG   | 21170080000320 | Brand |
| TUKYSA                        | TUCATINIB TAB 150 MG  | 21170080000340 | Brand |
| VENCLEXTA<br>STARTING<br>PACK | VENETOCLAX TAB THERAPY STARTER PACK 10 & 50 & 100 MG        | 2147008000B720 | Brand |
| VENCLEXTA                     | VENETOCLAX TAB 10 MG  | 21470080000320 | Brand |
| VENCLEXTA                     | VENETOCLAX TAB 50 MG  | 21470080000340 | Brand |
| VENCLEXTA                     | VENETOCLAX TAB 100 MG                                       | 21470080000360 | Brand |
| ERIVEDGE                      | VISMODEGIB CAP 150 MG                                       | 21370070000120 | Brand |
| ZOLINZA                       | VORINOSTAT CAP 100 MG                                       | 21531575000120 | Brand |
| IBRANCE                       | PALBOCICLIB CAP 75 MG                                       | 21531060000120 | Brand |
| IBRANCE                       | PALBOCICLIB CAP 100 MG                                      | 21531060000130 | Brand |
| IBRANCE                       | PALBOCICLIB CAP 125 MG                                      | 21531060000140 | Brand |
| IBRANCE                       | PALBOCICLIB TAB 75 MG                                       | 21531060000320 | Brand |
| IBRANCE                       | PALBOCICLIB TAB 100 MG                                      | 21531060000330 | Brand |
| IBRANCE                       | PALBOCICLIB TAB 125 MG                                      | 21531060000340 | Brand |
| KISQALI                       | RIBOCICLIB SUCCINATE TAB PACK 200 MG DAILY DOSE             | 2153107050B720 | Brand |

| KISQALI                       | RIBOCICLIB SUCCINATE TAB PACK 400 MG DAILY DOSE (200 MG TAB) | 2153107050B740 | Brand |
|-------------------------------|--|----------------|-------|
| KISQALI                       | RIBOCICLIB SUCCINATE TAB PACK 600 MG DAILY DOSE (200 MG TAB) | 2153107050B760 | Brand |
| KISQALI<br>FEMARA 200<br>DOSE | RIBOCICLIB 200 MG DOSE (200 MG TAB) & LETROZOLE 2.5 MG TBPK  | 2199000260B730 | Brand |
| KISQALI<br>FEMARA 400<br>DOSE | RIBOCICLIB 400 MG DOSE (200 MG TAB) & LETROZOLE 2.5 MG TBPK  | 2199000260B740 | Brand |
| KISQALI<br>FEMARA 600<br>DOSE | RIBOCICLIB 600 MG DOSE (200 MG TAB) & LETROZOLE 2.5 MG TBPK  | 2199000260B760 | Brand |
| VERZENIO                      | ABEMACICLIB TAB 50 MG  | 21531010000305 | Brand |
| VERZENIO                      | ABEMACICLIB TAB 100 MG                                       | 21531010000310 | Brand |
| VERZENIO                      | ABEMACICLIB TAB 150 MG                                       | 21531010000315 | Brand |
| VERZENIO                      | ABEMACICLIB TAB 200 MG                                       | 21531010000320 | Brand |

- **1** One of the following:
- **1.1** The requested drug is being used alone or in a combination regimen that is FDA-labeled for the treatment of the specific condition the member presents with\*

### OR

**1.2** The requested drug is being used alone or in a combination regimen that has a class 1 or 2 recommendation for use from the National Comprehensive Cancer Network (NCCN) in the specific condition of the member\*

### **AND**

- **2** Prescribed by or in consultation with one of the following:
  - oncologist
  - hematologist
  - other specialist in the treatment of malignancy

| includes any relevant genetic testing, mutations, etc. | Notes | *Includes any relevant genetic testing, mutations, etc. |
|--|-------|---|
|--|-------|---|

| Approval Length | 12 month(s)  |
|-----------------|--|
| Therapy Stage   | Reauthorization  |
| Guideline Type  | Prior Authorization - ALL Plans Except IL and MN Plans |

| Product<br>Name | Generic Name   | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| GILOTRIF        | AFATINIB DIMALEATE TAB 20 MG (BASE EQUIVALENT)           | 21360006100320 | Brand         |
| GILOTRIF        | AFATINIB DIMALEATE TAB 30 MG (BASE EQUIVALENT)           | 21360006100330 | Brand         |
| GILOTRIF        | AFATINIB DIMALEATE TAB 40 MG (BASE EQUIVALENT)           | 21360006100340 | Brand         |
| ALECENSA        | ALECTINIB HCL CAP 150 MG (BASE EQUIVALENT)               | 21530507100120 | Brand         |
| ONUREG          | AZACITIDINE TAB 200 MG                                   | 21300003000320 | Brand         |
| ONUREG          | AZACITIDINE TAB 300 MG                                   | 21300003000330 | Brand         |
| TABRECTA        | CAPMATINIB HCL TAB 150 MG                                | 21533716200320 | Brand         |
| TABRECTA        | CAPMATINIB HCL TAB 200 MG                                | 21533716200330 | Brand         |
| COTELLIC        | COBIMETINIB FUMARATE TAB 20 MG (BASE EQUIVALENT)         | 21533530200320 | Brand         |
| TAFINLAR        | DABRAFENIB MESYLATE CAP 50 MG (BASE EQUIVALENT)          | 21532025100120 | Brand         |
| TAFINLAR        | DABRAFENIB MESYLATE CAP 75 MG (BASE EQUIVALENT)          | 21532025100130 | Brand         |
| TAFINLAR        | DABRAFENIB MESYLATE TAB FOR ORAL SUSP 10 MG (BASE EQUIV) | 21532025107320 | Brand         |
| ROZLYTREK       | ENTRECTINIB CAP 100 MG                                   | 21533820000120 | Brand         |
| ROZLYTREK       | ENTRECTINIB CAP 200 MG                                   | 21533820000130 | Brand         |
| IMBRUVICA       | IBRUTINIB CAP 70 MG                                      | 21532133000110 | Brand         |
| IMBRUVICA       | IBRUTINIB CAP 140 MG                                     | 21532133000120 | Brand         |
| IMBRUVICA       | IBRUTINIB TAB 420 MG                                     | 21532133000340 | Brand         |
| IMBRUVICA       | IBRUTINIB ORAL SUSP 70 MG/ML                             | 21532133001820 | Brand         |
| ZYDELIG         | IDELALISIB TAB 100 MG                                    | 21538040000320 | Brand         |
| ZYDELIG         | IDELALISIB TAB 150 MG                                    | 21538040000330 | Brand         |

| NINLARO                 | IXAZOMIB CITRATE CAP 2.3 MG (BASE EQUIVALENT)               | 21536045100120 | Brand   |
|-------------------------|---|----------------|---------|
| NINLARO                 | IXAZOMIB CITRATE CAP 3 MG (BASE<br>EQUIVALENT)              | 21536045100130 | Brand   |
| NINLARO                 | IXAZOMIB CITRATE CAP 4 MG (BASE<br>EQUIVALENT)              | 21536045100140 | Brand   |
| LAPATINIB<br>DITOSYLATE | LAPATINIB DITOSYLATE TAB 250 MG (BASE EQUIV)                | 21533026100320 | Generic |
| LENALIDOMIDE            | LENALIDOMIDE CAPS 2.5 MG                                    | 99394050000110 | Generic |
| LENALIDOMIDE            | LENALIDOMIDE CAP 5 MG                                       | 99394050000120 | Generic |
| LENALIDOMIDE            | LENALIDOMIDE CAP 10 MG                                      | 99394050000130 | Generic |
| LENALIDOMIDE            | LENALIDOMIDE CAP 15 MG                                      | 99394050000140 | Generic |
| LENALIDOMIDE            | LENALIDOMIDE CAP 20 MG                                      | 99394050000145 | Generic |
| LENALIDOMIDE            | LENALIDOMIDE CAP 25 MG                                      | 99394050000150 | Generic |
| EXKIVITY                | MOBOCERTINIB SUCCINATE CAP 40 MG                            | 21360050600120 | Brand   |
| POMALYST                | POMALIDOMIDE CAP 1 MG                                       | 21450080000110 | Brand   |
| POMALYST                | POMALIDOMIDE CAP 2 MG                                       | 21450080000115 | Brand   |
| POMALYST                | POMALIDOMIDE CAP 3 MG                                       | 21450080000120 | Brand   |
| POMALYST                | POMALIDOMIDE CAP 4 MG                                       | 21450080000125 | Brand   |
| STIVARGA                | REGORAFENIB TAB 40 MG                                       | 21533050000320 | Brand   |
| KOSELUGO                | SELUMETINIB SULFATE CAP 10 MG                               | 21533565500110 | Brand   |
| KOSELUGO                | SELUMETINIB SULFATE CAP 25 MG                               | 21533565500125 | Brand   |
| ODOMZO                  | SONIDEGIB PHOSPHATE CAP 200 MG (BASE EQUIVALENT)            | 21370060200120 | Brand   |
| HYCAMTIN                | TOPOTECAN HCL CAP 0.25 MG (BASE EQUIV)                      | 21550080100120 | Brand   |
| HYCAMTIN                | TOPOTECAN HCL CAP 1 MG (BASE EQUIV)                         | 21550080100140 | Brand   |
| MEKINIST                | TRAMETINIB DIMETHYL SULFOXIDE TAB 0.5 MG (BASE EQUIVALENT)  | 21533570100310 | Brand   |
| MEKINIST                | TRAMETINIB DIMETHYL SULFOXIDE TAB 2 MG (BASE EQUIVALENT)    | 21533570100330 | Brand   |
| MEKINIST                | TRAMETINIB DIMETHYL SULFOXIDE FOR SOLN 0.05 MG/ML (BASE EQ) | 21533570102120 | Brand   |
| LONSURF                 | TRIFLURIDINE-TIPIRACIL TAB 15-6.14 MG                       | 21990002750320 | Brand   |
| LONSURF                 | TRIFLURIDINE-TIPIRACIL TAB 20-8.19 MG                       | 21990002750330 | Brand   |
| TUKYSA                  | TUCATINIB TAB 50 MG   | 21170080000320 | Brand   |
| TUKYSA                  | TUCATINIB TAB 150 MG  | 21170080000340 | Brand   |
| VENCLEXTA               | VENETOCLAX TAB THERAPY STARTER PACK 10                      | 2147008000B720 | Brand   |

| STARTING<br>PACK              | & 50 & 100 MG  |                |       |
|-------------------------------|--|----------------|-------|
| VENCLEXTA                     | VENETOCLAX TAB 10 MG   | 21470080000320 | Brand |
| VENCLEXTA                     | VENETOCLAX TAB 50 MG   | 21470080000340 | Brand |
| VENCLEXTA                     | VENETOCLAX TAB 100 MG  | 21470080000360 | Brand |
| ERIVEDGE                      | VISMODEGIB CAP 150 MG  | 21370070000120 | Brand |
| ZOLINZA                       | VORINOSTAT CAP 100 MG  | 21531575000120 | Brand |
| IBRANCE                       | PALBOCICLIB CAP 75 MG  | 21531060000120 | Brand |
| IBRANCE                       | PALBOCICLIB CAP 100 MG                                       | 21531060000130 | Brand |
| IBRANCE                       | PALBOCICLIB CAP 125 MG                                       | 21531060000140 | Brand |
| IBRANCE                       | PALBOCICLIB TAB 75 MG  | 21531060000320 | Brand |
| IBRANCE                       | PALBOCICLIB TAB 100 MG                                       | 21531060000330 | Brand |
| IBRANCE                       | PALBOCICLIB TAB 125 MG                                       | 21531060000340 | Brand |
| KISQALI                       | RIBOCICLIB SUCCINATE TAB PACK 200 MG DAILY DOSE              | 2153107050B720 | Brand |
| KISQALI                       | RIBOCICLIB SUCCINATE TAB PACK 400 MG DAILY DOSE (200 MG TAB) | 2153107050B740 | Brand |
| KISQALI                       | RIBOCICLIB SUCCINATE TAB PACK 600 MG DAILY DOSE (200 MG TAB) | 2153107050B760 | Brand |
| KISQALI<br>FEMARA 200<br>DOSE | RIBOCICLIB 200 MG DOSE (200 MG TAB) & LETROZOLE 2.5 MG TBPK  | 2199000260B730 | Brand |
| KISQALI<br>FEMARA 400<br>DOSE | RIBOCICLIB 400 MG DOSE (200 MG TAB) & LETROZOLE 2.5 MG TBPK  | 2199000260B740 | Brand |
| KISQALI<br>FEMARA 600<br>DOSE | RIBOCICLIB 600 MG DOSE (200 MG TAB) & LETROZOLE 2.5 MG TBPK  | 2199000260B760 | Brand |
| VERZENIO                      | ABEMACICLIB TAB 50 MG  | 21531010000305 | Brand |
| VERZENIO                      | ABEMACICLIB TAB 100 MG                                       | 21531010000310 | Brand |
| VERZENIO                      | ABEMACICLIB TAB 150 MG                                       | 21531010000315 | Brand |
| VERZENIO                      | ABEMACICLIB TAB 200 MG                                       | 21531010000320 | Brand |
|                               |  |                |       |

- **1** One of the following:
- **1.1** The requested drug is being used alone or in a combination regimen that is FDA-labeled for the treatment of the specific condition the member presents with\*

OR

**1.2** The requested drug is being used alone or in a combination regimen that has a class 1 or 2 recommendation for use from the National Comprehensive Cancer Network (NCCN) in the specific condition of the member\*

### AND

- 2 Prescribed by or in consultation with one of the following:
  - oncologist
  - hematologist
  - other specialist in the treatment of malignancy

| Notes | *Includes any relevant genetic testing, mutations, etc. |
|-------|---|
|-------|---|

Product Name: Alecensa, Bosulif, Cabometyx, Cotellic, Erivedge, Exkivity, Generic abiraterone, Generic erlotinib, Generic everolimus, Generic gefitinib, Generic lapatinib, Generic lenalidomide, Generic sorafenib, Generic sunitinib, Gilotrif, Hycamtin, Ibrance, Imbruvica, Inlyta, Inrebic, Jakafi, Kisqali, Kisqali Femara, Koselugo, Lonsurf, Lynparza, Mekinist, Ninlaro, Nubeqa, Odomzo, Onureg, Piqray, Pomalyst, Retevmo, Rozlytrek, Rubraca, Sprycel, Stivarga, Tabrecta, Tafinlar, Tagrisso, Tasigna, Tazverik, Tukysa, Venclexta, Verzenio, Votrient, Xalkori, Xtandi, Zejula, Zelboraf, Zolinza, Zydelig, Zykadia

| Approval Length | 12 month(s)                    |
|-----------------|--------------------------------|
| Therapy Stage   | Initial Authorization          |
| Guideline Type  | Prior Authorization - IL Plans |

| Product Name | Generic Name                                   | GPI            | Brand/Generic |
|--------------|--|----------------|---------------|
| GILOTRIF     | AFATINIB DIMALEATE TAB 20 MG (BASE EQUIVALENT) | 21360006100320 | Brand         |
| GILOTRIF     | AFATINIB DIMALEATE TAB 30 MG (BASE EQUIVALENT) | 21360006100330 | Brand         |
| GILOTRIF     | AFATINIB DIMALEATE TAB 40 MG (BASE EQUIVALENT) | 21360006100340 | Brand         |
| ALECENSA     | ALECTINIB HCL CAP 150 MG (BASE EQUIVALENT)     | 21530507100120 | Brand         |
| ONUREG       | AZACITIDINE TAB 200 MG                         | 21300003000320 | Brand         |
| ONUREG       | AZACITIDINE TAB 300 MG                         | 21300003000330 | Brand         |

| TABRECTA                | CAPMATINIB HCL TAB 150 MG                                | 21533716200320 | Brand   |
|-------------------------|--|----------------|---------|
| TABRECTA                | CAPMATINIB HCL TAB 200 MG                                | 21533716200330 | Brand   |
| COTELLIC                | COBIMETINIB FUMARATE TAB 20 MG (BASE EQUIVALENT)         | 21533530200320 | Brand   |
| TAFINLAR                | DABRAFENIB MESYLATE CAP 50 MG (BASE EQUIVALENT)          | 21532025100120 | Brand   |
| TAFINLAR                | DABRAFENIB MESYLATE CAP 75 MG (BASE EQUIVALENT)          | 21532025100130 | Brand   |
| TAFINLAR                | DABRAFENIB MESYLATE TAB FOR ORAL SUSP 10 MG (BASE EQUIV) | 21532025107320 | Brand   |
| ROZLYTREK               | ENTRECTINIB CAP 100 MG                                   | 21533820000120 | Brand   |
| ROZLYTREK               | ENTRECTINIB CAP 200 MG                                   | 21533820000130 | Brand   |
| IMBRUVICA               | IBRUTINIB CAP 70 MG                                      | 21532133000110 | Brand   |
| IMBRUVICA               | IBRUTINIB CAP 140 MG                                     | 21532133000120 | Brand   |
| IMBRUVICA               | IBRUTINIB TAB 420 MG                                     | 21532133000340 | Brand   |
| IMBRUVICA               | IBRUTINIB ORAL SUSP 70 MG/ML                             | 21532133001820 | Brand   |
| ZYDELIG                 | IDELALISIB TAB 100 MG                                    | 21538040000320 | Brand   |
| ZYDELIG                 | IDELALISIB TAB 150 MG                                    | 21538040000330 | Brand   |
| NINLARO                 | IXAZOMIB CITRATE CAP 2.3 MG (BASE EQUIVALENT)            | 21536045100120 | Brand   |
| NINLARO                 | IXAZOMIB CITRATE CAP 3 MG (BASE EQUIVALENT)              | 21536045100130 | Brand   |
| NINLARO                 | IXAZOMIB CITRATE CAP 4 MG (BASE EQUIVALENT)              | 21536045100140 | Brand   |
| LAPATINIB<br>DITOSYLATE | LAPATINIB DITOSYLATE TAB 250 MG (BASE EQUIV)             | 21533026100320 | Generic |
| LENALIDOMIDE            | LENALIDOMIDE CAPS 2.5 MG                                 | 99394050000110 | Generic |
| LENALIDOMIDE            | LENALIDOMIDE CAP 5 MG                                    | 99394050000120 | Generic |
| LENALIDOMIDE            | LENALIDOMIDE CAP 10 MG                                   | 99394050000130 | Generic |
| LENALIDOMIDE            | LENALIDOMIDE CAP 15 MG                                   | 99394050000140 | Generic |
| LENALIDOMIDE            | LENALIDOMIDE CAP 20 MG                                   | 99394050000145 | Generic |
| LENALIDOMIDE            | LENALIDOMIDE CAP 25 MG                                   | 99394050000150 | Generic |
| EXKIVITY                | MOBOCERTINIB SUCCINATE CAP 40 MG                         | 21360050600120 | Brand   |
| POMALYST                | POMALIDOMIDE CAP 1 MG                                    | 21450080000110 | Brand   |
| POMALYST                | POMALIDOMIDE CAP 2 MG                                    | 21450080000115 | Brand   |
| POMALYST                | POMALIDOMIDE CAP 3 MG                                    | 21450080000120 | Brand   |
| POMALYST                | POMALIDOMIDE CAP 4 MG                                    | 21450080000125 | Brand   |

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|----------------------------|---|----------------|-------|
| STIVARGA                   | REGORAFENIB TAB 40 MG   | 21533050000320 | Brand |
| KOSELUGO                   | SELUMETINIB SULFATE CAP 10 MG                                   | 21533565500110 | Brand |
| KOSELUGO                   | SELUMETINIB SULFATE CAP 25 MG                                   | 21533565500125 | Brand |
| ODOMZO                     | SONIDEGIB PHOSPHATE CAP 200 MG (BASE EQUIVALENT)                | 21370060200120 | Brand |
| HYCAMTIN                   | TOPOTECAN HCL CAP 0.25 MG (BASE EQUIV)                          | 21550080100120 | Brand |
| HYCAMTIN                   | TOPOTECAN HCL CAP 1 MG (BASE EQUIV)                             | 21550080100140 | Brand |
| MEKINIST                   | TRAMETINIB DIMETHYL SULFOXIDE TAB 0.5 MG (BASE EQUIVALENT)      | 21533570100310 | Brand |
| MEKINIST                   | TRAMETINIB DIMETHYL SULFOXIDE TAB 2 MG (BASE EQUIVALENT)        | 21533570100330 | Brand |
| MEKINIST                   | TRAMETINIB DIMETHYL SULFOXIDE FOR SOLN 0.05 MG/ML (BASE EQ)     | 21533570102120 | Brand |
| LONSURF                    | TRIFLURIDINE-TIPIRACIL TAB 15-6.14 MG                           | 21990002750320 | Brand |
| LONSURF                    | TRIFLURIDINE-TIPIRACIL TAB 20-8.19 MG                           | 21990002750330 | Brand |
| TUKYSA                     | TUCATINIB TAB 50 MG   | 21170080000320 | Brand |
| TUKYSA                     | TUCATINIB TAB 150 MG  | 21170080000340 | Brand |
| VENCLEXTA<br>STARTING PACK | VENETOCLAX TAB THERAPY STARTER PACK<br>10 & 50 & 100 MG         | 2147008000B720 | Brand |
| VENCLEXTA                  | VENETOCLAX TAB 10 MG  | 21470080000320 | Brand |
| VENCLEXTA                  | VENETOCLAX TAB 50 MG  | 21470080000340 | Brand |
| VENCLEXTA                  | VENETOCLAX TAB 100 MG   | 21470080000360 | Brand |
| ERIVEDGE                   | VISMODEGIB CAP 150 MG   | 21370070000120 | Brand |
| ZOLINZA                    | VORINOSTAT CAP 100 MG   | 21531575000120 | Brand |
| IBRANCE                    | PALBOCICLIB CAP 75 MG   | 21531060000120 | Brand |
| IBRANCE                    | PALBOCICLIB CAP 100 MG  | 21531060000130 | Brand |
| IBRANCE                    | PALBOCICLIB CAP 125 MG  | 21531060000140 | Brand |
| IBRANCE                    | PALBOCICLIB TAB 75 MG   | 21531060000320 | Brand |
| IBRANCE                    | PALBOCICLIB TAB 100 MG  | 21531060000330 | Brand |
| IBRANCE                    | PALBOCICLIB TAB 125 MG  | 21531060000340 | Brand |
| KISQALI                    | RIBOCICLIB SUCCINATE TAB PACK 200 MG<br>DAILY DOSE              | 2153107050B720 | Brand |
| KISQALI                    | RIBOCICLIB SUCCINATE TAB PACK 400 MG<br>DAILY DOSE (200 MG TAB) | 2153107050B740 | Brand |
| KISQALI                    | RIBOCICLIB SUCCINATE TAB PACK 600 MG<br>DAILY DOSE (200 MG TAB) | 2153107050B760 | Brand |
| KISQALI FEMARA             | RIBOCICLIB 200 MG DOSE (200 MG TAB) &                           | 2199000260B730 | Brand |

| 200 DOSE                   | LETROZOLE 2.5 MG TBPK                                       |                |       |
|----------------------------|---|----------------|-------|
| KISQALI FEMARA             | RIBOCICLIB 400 MG DOSE (200 MG TAB) &                       | 2199000260B740 | Brand |
| 400 DOSE                   | LETROZOLE 2.5 MG TBPK                                       |                |       |
| KISQALI FEMARA<br>600 DOSE | RIBOCICLIB 600 MG DOSE (200 MG TAB) & LETROZOLE 2.5 MG TBPK | 2199000260B760 | Brand |
| VERZENIO                   | ABEMACICLIB TAB 50 MG                                       | 21531010000305 | Brand |
| VERZENIO                   | ABEMACICLIB TAB 100 MG                                      | 21531010000310 | Brand |
| VERZENIO                   | ABEMACICLIB TAB 150 MG                                      | 21531010000315 | Brand |
| VERZENIO                   | ABEMACICLIB TAB 200 MG                                      | 21531010000320 | Brand |
| PIQRAY 200MG<br>DAILY DOSE | ALPELISIB TAB THERAPY PACK 200 MG DAILY<br>DOSE             | 2153801000B720 | Brand |
| PIQRAY 250MG<br>DAILY DOSE | ALPELISIB TAB PACK 250 MG DAILY DOSE (200 MG & 50 MG TABS)  | 2153801000B725 | Brand |
| PIQRAY 300MG<br>DAILY DOSE | ALPELISIB TAB PACK 300 MG DAILY DOSE (2X150 MG TAB)         | 2153801000B730 | Brand |
| INLYTA                     | AXITINIB TAB 1 MG   | 21335013000320 | Brand |
| INLYTA                     | AXITINIB TAB 5 MG   | 21335013000340 | Brand |
| BOSULIF                    | BOSUTINIB TAB 100 MG  | 21531812000320 | Brand |
| BOSULIF                    | BOSUTINIB TAB 400 MG  | 21531812000327 | Brand |
| BOSULIF                    | BOSUTINIB TAB 500 MG  | 21531812000340 | Brand |
| CABOMETYX                  | CABOZANTINIB S-MALATE TAB 20 MG (BASE EQUIVALENT)           | 21533010100320 | Brand |
| CABOMETYX                  | CABOZANTINIB S-MALATE TAB 40 MG (BASE EQUIVALENT)           | 21533010100330 | Brand |
| CABOMETYX                  | CABOZANTINIB S-MALATE TAB 60 MG (BASE EQUIVALENT)           | 21533010100340 | Brand |
| ZYKADIA                    | CERITINIB TAB 150 MG  | 21530514000330 | Brand |
| XALKORI                    | CRIZOTINIB CAP 200 MG                                       | 21530517000120 | Brand |
| XALKORI                    | CRIZOTINIB CAP 250 MG                                       | 21530517000125 | Brand |
| NUBEQA                     | DAROLUTAMIDE TAB 300 MG                                     | 21402425000320 | Brand |
| SPRYCEL                    | DASATINIB TAB 20 MG   | 21531820000320 | Brand |
| SPRYCEL                    | DASATINIB TAB 50 MG   | 21531820000340 | Brand |
| SPRYCEL                    | DASATINIB TAB 70 MG   | 21531820000350 | Brand |
| SPRYCEL                    | DASATINIB TAB 80 MG   | 21531820000354 | Brand |
| SPRYCEL                    | DASATINIB TAB 100 MG  | 21531820000360 | Brand |
| SPRYCEL                    | DASATINIB TAB 140 MG  | 21531820000380 | Brand |
| XTANDI                     | ENZALUTAMIDE CAP 40 MG                                      | 21402430000120 | Brand |

| XTANDI                     | ENZALUTAMIDE TAB 40 MG                           | 24.402.420.02020 | Brand   |
|----------------------------|--|------------------|---------|
|                            | FNZALUTAMIDE TAB 40 MG                           | 21402430000320   |         |
| XTANDI                     |  | 21402430000340   | Brand   |
| ERLOTINIB<br>HYDROCHLORIDE | ERLOTINIB HCL TAB 25 MG (BASE<br>EQUIVALENT)     | 21360025100320   | Generic |
| ERLOTINIB<br>HYDROCHLORIDE | ERLOTINIB HCL TAB 100 MG (BASE<br>EQUIVALENT)    | 21360025100330   | Generic |
| ERLOTINIB<br>HYDROCHLORIDE | ERLOTINIB HCL TAB 150 MG (BASE EQUIVALENT)       | 21360025100360   | Generic |
| EVEROLIMUS                 | EVEROLIMUS TAB 2.5 MG                            | 21532530000310   | Generic |
| EVEROLIMUS                 | EVEROLIMUS TAB 5 MG                              | 21532530000320   | Generic |
| EVEROLIMUS                 | EVEROLIMUS TAB 7.5 MG                            | 21532530000325   | Generic |
| EVEROLIMUS                 | EVEROLIMUS TAB 10 MG                             | 21532530000330   | Generic |
| EVEROLIMUS                 | EVEROLIMUS TAB FOR ORAL SUSP 2 MG                | 21532530007310   | Generic |
| EVEROLIMUS                 | EVEROLIMUS TAB FOR ORAL SUSP 3 MG                | 21532530007320   | Generic |
| EVEROLIMUS                 | EVEROLIMUS TAB FOR ORAL SUSP 5 MG                | 21532530007340   | Generic |
| INREBIC                    | FEDRATINIB HCL CAP 100 MG                        | 21537520200120   | Brand   |
| GEFITINIB                  | GEFITINIB TAB 250 MG                             | 21360030000320   | Generic |
| TASIGNA                    | NILOTINIB HCL CAP 50 MG (BASE<br>EQUIVALENT)     | 21531860200110   | Brand   |
| TASIGNA                    | NILOTINIB HCL CAP 150 MG (BASE<br>EQUIVALENT)    | 21531860200115   | Brand   |
| TASIGNA                    | NILOTINIB HCL CAP 200 MG (BASE<br>EQUIVALENT)    | 21531860200125   | Brand   |
| ZEJULA                     | NIRAPARIB TOSYLATE TAB 100 MG (BASE EQUIVALENT)  | 21535550200320   | Brand   |
| ZEJULA                     | NIRAPARIB TOSYLATE TAB 200 MG (BASE EQUIVALENT)  | 21535550200330   | Brand   |
| ZEJULA                     | NIRAPARIB TOSYLATE TAB 300 MG (BASE EQUIVALENT)  | 21535550200340   | Brand   |
| LYNPARZA                   | OLAPARIB TAB 100 MG                              | 21535560000330   | Brand   |
| LYNPARZA                   | OLAPARIB TAB 150 MG                              | 21535560000340   | Brand   |
| TAGRISSO                   | OSIMERTINIB MESYLATE TAB 40 MG (BASE EQUIVALENT) | 21360068200320   | Brand   |
| TAGRISSO                   | OSIMERTINIB MESYLATE TAB 80 MG (BASE EQUIVALENT) | 21360068200330   | Brand   |
| VOTRIENT                   | PAZOPANIB HCL TAB 200 MG (BASE EQUIV)            | 21533042100320   | Brand   |
| RUBRACA                    | RUCAPARIB CAMSYLATE TAB 200 MG (BASE EQUIVALENT) | 21535570200320   | Brand   |
| RUBRACA                    | RUCAPARIB CAMSYLATE TAB 250 MG (BASE EQUIVALENT) | 21535570200325   | Brand   |

| RUBRACA               | RUCAPARIB CAMSYLATE TAB 300 MG (BASE EQUIVALENT)  | 21535570200330 | Brand   |
|-----------------------|---|----------------|---------|
| JAKAFI                | RUXOLITINIB PHOSPHATE TAB 5 MG (BASE EQUIVALENT)  | 21537560200310 | Brand   |
| JAKAFI                | RUXOLITINIB PHOSPHATE TAB 10 MG (BASE EQUIVALENT) | 21537560200320 | Brand   |
| JAKAFI                | RUXOLITINIB PHOSPHATE TAB 15 MG (BASE EQUIVALENT) | 21537560200325 | Brand   |
| JAKAFI                | RUXOLITINIB PHOSPHATE TAB 20 MG (BASE EQUIVALENT) | 21537560200330 | Brand   |
| JAKAFI                | RUXOLITINIB PHOSPHATE TAB 25 MG (BASE EQUIVALENT) | 21537560200335 | Brand   |
| RETEVMO               | SELPERCATINIB CAP 40 MG                           | 21535779000120 | Brand   |
| RETEVMO               | SELPERCATINIB CAP 80 MG                           | 21535779000140 | Brand   |
| SORAFENIB             | SORAFENIB TOSYLATE TAB 200 MG (BASE EQUIVALENT)   | 21533060400320 | Generic |
| SORAFENIB<br>TOSYLATE | SORAFENIB TOSYLATE TAB 200 MG (BASE EQUIVALENT)   | 21533060400320 | Generic |
| SUNITINIB<br>MALATE   | SUNITINIB MALATE CAP 12.5 MG (BASE EQUIVALENT)    | 21533070300120 | Generic |
| SUNITINIB<br>MALATE   | SUNITINIB MALATE CAP 25 MG (BASE EQUIVALENT)      | 21533070300130 | Generic |
| SUNITINIB<br>MALATE   | SUNITINIB MALATE CAP 37.5 MG (BASE EQUIVALENT)    | 21533070300135 | Generic |
| SUNITINIB<br>MALATE   | SUNITINIB MALATE CAP 50 MG (BASE EQUIVALENT)      | 21533070300140 | Generic |
| TAZVERIK              | TAZEMETOSTAT HBR TAB 200 MG                       | 21533675200320 | Brand   |
| ZELBORAF              | VEMURAFENIB TAB 240 MG                            | 21532080000320 | Brand   |
| BOSULIF               | BOSUTINIB CAP 100 MG                              | 21531812000130 | Brand   |
| BOSULIF               | BOSUTINIB CAP 50 MG                               | 21531812000120 | Brand   |
|                       | •   |                |         |

- 1 One of the following:
- **1.1** The requested drug is being used alone or in a combination regimen that is FDA-labeled for the treatment of the specific condition the member presents with\*

OR

**1.2** The requested drug being used alone or in a combination regimen that has a class 1 or 2 recommendation for use from the National Comprehensive Cancer Network (NCCN) in the specific condition of the member

#### OR

- **1.3** The requested drug is being used alone or in a combination regimen that is recommended for use in the specific condition of the member\* in one of the following:
  - American Hospital Formulary Service Drug Information
  - Thompson Micromedex's Drug Dex
  - Elsevier Gold Standard's Clinical Pharmacology
  - Two articles in peer-reviewed professional medical journals from the United States or Great Britain that recognize the safety and efficacy of the requested drug in the member's specific condition

#### AND

- 2 Prescribed by or in consultation with one of the following:
  - oncologist
  - hematologist
  - other specialist in the treatment of malignancy

| Notes | *Includes any relevant genetic testing, mutations, etc. |
|-------|---|

Product Name: Alecensa, Bosulif, Cabometyx, Cotellic, Erivedge, Exkivity, Generic abiraterone, Generic erlotinib, Generic everolimus, Generic gefitinib, Generic lapatinib, Generic lenalidomide, Generic sorafenib, Generic sunitinib, Gilotrif, Hycamtin, Ibrance, Imbruvica, Inlyta, Inrebic, Jakafi, Kisqali, Kisqali Femara, Koselugo, Lonsurf, Lynparza, Mekinist, Ninlaro, Nubeqa, Odomzo, Onureg, Piqray, Pomalyst, Retevmo, Rozlytrek, Rubraca, Sprycel, Stivarga, Tabrecta, Tafinlar, Tagrisso, Tasigna, Tazverik, Tukysa, Venclexta, Verzenio, Votrient, Xalkori, Xtandi, Zejula, Zelboraf, Zolinza, Zydelig, Zykadia

| Approval Length | 12 month(s)                    |
|-----------------|--------------------------------|
| Therapy Stage   | Reauthorization                |
| Guideline Type  | Prior Authorization - IL Plans |

| Product Name | Generic Name                                   | GPI            | Brand/Generic |
|--------------|--|----------------|---------------|
| GILOTRIF     | AFATINIB DIMALEATE TAB 20 MG (BASE EQUIVALENT) | 21360006100320 | Brand         |
| GILOTRIF     | AFATINIB DIMALEATE TAB 30 MG (BASE             | 21360006100330 | Brand         |

|                         | EQUIVALENT)   |                |         |
|-------------------------|---|----------------|---------|
| GILOTRIF                | AFATINIB DIMALEATE TAB 40 MG (BASE EQUIVALENT)              | 21360006100340 | Brand   |
| ALECENSA                | ALECTINIB HCL CAP 150 MG (BASE EQUIVALENT)                  | 21530507100120 | Brand   |
| ONUREG                  | AZACITIDINE TAB 200 MG                                      | 21300003000320 | Brand   |
| ONUREG                  | AZACITIDINE TAB 300 MG                                      | 21300003000330 | Brand   |
| TABRECTA                | CAPMATINIB HCL TAB 150 MG                                   | 21533716200320 | Brand   |
| TABRECTA                | CAPMATINIB HCL TAB 200 MG                                   | 21533716200330 | Brand   |
| COTELLIC                | COBIMETINIB FUMARATE TAB 20 MG (BASE EQUIVALENT)            | 21533530200320 | Brand   |
| TAFINLAR                | DABRAFENIB MESYLATE CAP 50 MG (BASE EQUIVALENT)             | 21532025100120 | Brand   |
| TAFINLAR                | DABRAFENIB MESYLATE CAP 75 MG (BASE EQUIVALENT)             | 21532025100130 | Brand   |
| TAFINLAR                | DABRAFENIB MESYLATE TAB FOR ORAL SUSP<br>10 MG (BASE EQUIV) | 21532025107320 | Brand   |
| ROZLYTREK               | ENTRECTINIB CAP 100 MG                                      | 21533820000120 | Brand   |
| ROZLYTREK               | ENTRECTINIB CAP 200 MG                                      | 21533820000130 | Brand   |
| IMBRUVICA               | IBRUTINIB CAP 70 MG   | 21532133000110 | Brand   |
| IMBRUVICA               | IBRUTINIB CAP 140 MG  | 21532133000120 | Brand   |
| IMBRUVICA               | IBRUTINIB TAB 420 MG  | 21532133000340 | Brand   |
| IMBRUVICA               | IBRUTINIB ORAL SUSP 70 MG/ML                                | 21532133001820 | Brand   |
| ZYDELIG                 | IDELALISIB TAB 100 MG                                       | 21538040000320 | Brand   |
| ZYDELIG                 | IDELALISIB TAB 150 MG                                       | 21538040000330 | Brand   |
| NINLARO                 | IXAZOMIB CITRATE CAP 2.3 MG (BASE EQUIVALENT)               | 21536045100120 | Brand   |
| NINLARO                 | IXAZOMIB CITRATE CAP 3 MG (BASE EQUIVALENT)                 | 21536045100130 | Brand   |
| NINLARO                 | IXAZOMIB CITRATE CAP 4 MG (BASE EQUIVALENT)                 | 21536045100140 | Brand   |
| LAPATINIB<br>DITOSYLATE | LAPATINIB DITOSYLATE TAB 250 MG (BASE EQUIV)                | 21533026100320 | Generic |
| LENALIDOMIDE            | LENALIDOMIDE CAPS 2.5 MG                                    | 99394050000110 | Generic |
| LENALIDOMIDE            | LENALIDOMIDE CAP 5 MG                                       | 99394050000120 | Generic |
| LENALIDOMIDE            | LENALIDOMIDE CAP 10 MG                                      | 99394050000130 | Generic |
| LENALIDOMIDE            | LENALIDOMIDE CAP 15 MG                                      | 99394050000140 | Generic |
| LENALIDOMIDE            | LENALIDOMIDE CAP 20 MG                                      | 99394050000145 | Generic |

| LENALIDOMIDE               | LENALIDOMIDE CAP 25 MG                                      | 99394050000150 | Generic |
|----------------------------|---|----------------|---------|
| EXKIVITY                   | MOBOCERTINIB SUCCINATE CAP 40 MG                            | 21360050600120 | Brand   |
| POMALYST                   | POMALIDOMIDE CAP 1 MG                                       | 21450080000110 | Brand   |
| POMALYST                   | POMALIDOMIDE CAP 2 MG                                       | 21450080000115 | Brand   |
| POMALYST                   | POMALIDOMIDE CAP 3 MG                                       | 21450080000120 | Brand   |
| POMALYST                   | POMALIDOMIDE CAP 4 MG                                       | 21450080000125 | Brand   |
| STIVARGA                   | REGORAFENIB TAB 40 MG                                       | 21533050000320 | Brand   |
| KOSELUGO                   | SELUMETINIB SULFATE CAP 10 MG                               | 21533565500110 | Brand   |
| KOSELUGO                   | SELUMETINIB SULFATE CAP 25 MG                               | 21533565500125 | Brand   |
| ODOMZO                     | SONIDEGIB PHOSPHATE CAP 200 MG (BASE EQUIVALENT)            | 21370060200120 | Brand   |
| HYCAMTIN                   | TOPOTECAN HCL CAP 0.25 MG (BASE EQUIV)                      | 21550080100120 | Brand   |
| HYCAMTIN                   | TOPOTECAN HCL CAP 1 MG (BASE EQUIV)                         | 21550080100140 | Brand   |
| MEKINIST                   | TRAMETINIB DIMETHYL SULFOXIDE TAB 0.5 MG (BASE EQUIVALENT)  | 21533570100310 | Brand   |
| MEKINIST                   | TRAMETINIB DIMETHYL SULFOXIDE TAB 2 MG (BASE EQUIVALENT)    | 21533570100330 | Brand   |
| MEKINIST                   | TRAMETINIB DIMETHYL SULFOXIDE FOR SOLN 0.05 MG/ML (BASE EQ) | 21533570102120 | Brand   |
| LONSURF                    | TRIFLURIDINE-TIPIRACIL TAB 15-6.14 MG                       | 21990002750320 | Brand   |
| LONSURF                    | TRIFLURIDINE-TIPIRACIL TAB 20-8.19 MG                       | 21990002750330 | Brand   |
| TUKYSA                     | TUCATINIB TAB 50 MG   | 21170080000320 | Brand   |
| TUKYSA                     | TUCATINIB TAB 150 MG  | 21170080000340 | Brand   |
| VENCLEXTA<br>STARTING PACK | VENETOCLAX TAB THERAPY STARTER PACK 10 & 50 & 100 MG        | 2147008000B720 | Brand   |
| VENCLEXTA                  | VENETOCLAX TAB 10 MG  | 21470080000320 | Brand   |
| VENCLEXTA                  | VENETOCLAX TAB 50 MG  | 21470080000340 | Brand   |
| VENCLEXTA                  | VENETOCLAX TAB 100 MG                                       | 21470080000360 | Brand   |
| ERIVEDGE                   | VISMODEGIB CAP 150 MG                                       | 21370070000120 | Brand   |
| ZOLINZA                    | VORINOSTAT CAP 100 MG                                       | 21531575000120 | Brand   |
| IBRANCE                    | PALBOCICLIB CAP 75 MG                                       | 21531060000120 | Brand   |
| IBRANCE                    | PALBOCICLIB CAP 100 MG                                      | 21531060000130 | Brand   |
| IBRANCE                    | PALBOCICLIB CAP 125 MG                                      | 21531060000140 | Brand   |
| IBRANCE                    | PALBOCICLIB TAB 75 MG                                       | 21531060000320 | Brand   |
| IBRANCE                    | PALBOCICLIB TAB 100 MG                                      | 21531060000330 | Brand   |

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|----------------------------|---|----------------|-------|
| IBRANCE                    | PALBOCICLIB TAB 125 MG  | 21531060000340 | Brand |
| KISQALI                    | RIBOCICLIB SUCCINATE TAB PACK 200 MG<br>DAILY DOSE              | 2153107050B720 | Brand |
| KISQALI                    | RIBOCICLIB SUCCINATE TAB PACK 400 MG<br>DAILY DOSE (200 MG TAB) | 2153107050B740 | Brand |
| KISQALI                    | RIBOCICLIB SUCCINATE TAB PACK 600 MG<br>DAILY DOSE (200 MG TAB) | 2153107050B760 | Brand |
| KISQALI FEMARA<br>200 DOSE | RIBOCICLIB 200 MG DOSE (200 MG TAB) & LETROZOLE 2.5 MG TBPK     | 2199000260B730 | Brand |
| KISQALI FEMARA<br>400 DOSE | RIBOCICLIB 400 MG DOSE (200 MG TAB) & LETROZOLE 2.5 MG TBPK     | 2199000260B740 | Brand |
| KISQALI FEMARA<br>600 DOSE | RIBOCICLIB 600 MG DOSE (200 MG TAB) & LETROZOLE 2.5 MG TBPK     | 2199000260B760 | Brand |
| VERZENIO                   | ABEMACICLIB TAB 50 MG   | 21531010000305 | Brand |
| VERZENIO                   | ABEMACICLIB TAB 100 MG  | 21531010000310 | Brand |
| VERZENIO                   | ABEMACICLIB TAB 150 MG  | 21531010000315 | Brand |
| VERZENIO                   | ABEMACICLIB TAB 200 MG  | 21531010000320 | Brand |
| PIQRAY 200MG<br>DAILY DOSE | ALPELISIB TAB THERAPY PACK 200 MG DAILY DOSE                    | 2153801000B720 | Brand |
| PIQRAY 250MG<br>DAILY DOSE | ALPELISIB TAB PACK 250 MG DAILY DOSE (200 MG & 50 MG TABS)      | 2153801000B725 | Brand |
| PIQRAY 300MG<br>DAILY DOSE | ALPELISIB TAB PACK 300 MG DAILY DOSE<br>(2X150 MG TAB)          | 2153801000B730 | Brand |
| INLYTA                     | AXITINIB TAB 1 MG   | 21335013000320 | Brand |
| INLYTA                     | AXITINIB TAB 5 MG   | 21335013000340 | Brand |
| BOSULIF                    | BOSUTINIB TAB 100 MG  | 21531812000320 | Brand |
| BOSULIF                    | BOSUTINIB TAB 400 MG  | 21531812000327 | Brand |
| BOSULIF                    | BOSUTINIB TAB 500 MG  | 21531812000340 | Brand |
| CABOMETYX                  | CABOZANTINIB S-MALATE TAB 20 MG (BASE EQUIVALENT)               | 21533010100320 | Brand |
| CABOMETYX                  | CABOZANTINIB S-MALATE TAB 40 MG (BASE EQUIVALENT)               | 21533010100330 | Brand |
| CABOMETYX                  | CABOZANTINIB S-MALATE TAB 60 MG (BASE EQUIVALENT)               | 21533010100340 | Brand |
| ZYKADIA                    | CERITINIB TAB 150 MG  | 21530514000330 | Brand |
| XALKORI                    | CRIZOTINIB CAP 200 MG   | 21530517000120 | Brand |
| XALKORI                    | CRIZOTINIB CAP 250 MG   | 21530517000125 | Brand |
| NUBEQA                     | DAROLUTAMIDE TAB 300 MG   | 21402425000320 | Brand |
| SPRYCEL                    | DASATINIB TAB 20 MG   | 21531820000320 | Brand |

| SPRYCEL                    | DASATINIB TAB 50 MG                             | 21531820000340 | Brand   |
|----------------------------|---|----------------|---------|
| SPRYCEL                    | DASATINIB TAB 70 MG                             | 21531820000350 | Brand   |
| SPRYCEL                    | DASATINIB TAB 80 MG                             | 21531820000354 | Brand   |
| SPRYCEL                    | DASATINIB TAB 100 MG                            | 21531820000360 | Brand   |
| SPRYCEL                    | DASATINIB TAB 140 MG                            | 21531820000380 | Brand   |
| XTANDI                     | ENZALUTAMIDE CAP 40 MG                          | 21402430000120 | Brand   |
| XTANDI                     | ENZALUTAMIDE TAB 40 MG                          | 21402430000320 | Brand   |
| XTANDI                     | ENZALUTAMIDE TAB 80 MG                          | 21402430000340 | Brand   |
| ERLOTINIB<br>HYDROCHLORIDE | ERLOTINIB HCL TAB 25 MG (BASE<br>EQUIVALENT)    | 21360025100320 | Generic |
| ERLOTINIB<br>HYDROCHLORIDE | ERLOTINIB HCL TAB 100 MG (BASE EQUIVALENT)      | 21360025100330 | Generic |
| ERLOTINIB<br>HYDROCHLORIDE | ERLOTINIB HCL TAB 150 MG (BASE EQUIVALENT)      | 21360025100360 | Generic |
| EVEROLIMUS                 | EVEROLIMUS TAB 2.5 MG                           | 21532530000310 | Generic |
| EVEROLIMUS                 | EVEROLIMUS TAB 5 MG                             | 21532530000320 | Generic |
| EVEROLIMUS                 | EVEROLIMUS TAB 7.5 MG                           | 21532530000325 | Generic |
| EVEROLIMUS                 | EVEROLIMUS TAB 10 MG                            | 21532530000330 | Generic |
| EVEROLIMUS                 | EVEROLIMUS TAB FOR ORAL SUSP 2 MG               | 21532530007310 | Generic |
| EVEROLIMUS                 | EVEROLIMUS TAB FOR ORAL SUSP 3 MG               | 21532530007320 | Generic |
| EVEROLIMUS                 | EVEROLIMUS TAB FOR ORAL SUSP 5 MG               | 21532530007340 | Generic |
| INREBIC                    | FEDRATINIB HCL CAP 100 MG                       | 21537520200120 | Brand   |
| GEFITINIB                  | GEFITINIB TAB 250 MG                            | 21360030000320 | Generic |
| TASIGNA                    | NILOTINIB HCL CAP 50 MG (BASE EQUIVALENT)       | 21531860200110 | Brand   |
| TASIGNA                    | NILOTINIB HCL CAP 150 MG (BASE EQUIVALENT)      | 21531860200115 | Brand   |
| TASIGNA                    | NILOTINIB HCL CAP 200 MG (BASE EQUIVALENT)      | 21531860200125 | Brand   |
| ZEJULA                     | NIRAPARIB TOSYLATE TAB 100 MG (BASE EQUIVALENT) | 21535550200320 | Brand   |
| ZEJULA                     | NIRAPARIB TOSYLATE TAB 200 MG (BASE EQUIVALENT) | 21535550200330 | Brand   |
| ZEJULA                     | NIRAPARIB TOSYLATE TAB 300 MG (BASE EQUIVALENT) | 21535550200340 | Brand   |
| LYNPARZA                   | OLAPARIB TAB 100 MG                             | 21535560000330 | Brand   |
| LYNPARZA                   | OLAPARIB TAB 150 MG                             | 21535560000340 | Brand   |

| TAGRISSO              | OSIMERTINIB MESYLATE TAB 40 MG (BASE EQUIVALENT)  | 21360068200320 | Brand   |
|-----------------------|---|----------------|---------|
| TAGRISSO              | OSIMERTINIB MESYLATE TAB 80 MG (BASE EQUIVALENT)  | 21360068200330 | Brand   |
| VOTRIENT              | PAZOPANIB HCL TAB 200 MG (BASE EQUIV)             | 21533042100320 | Brand   |
| RUBRACA               | RUCAPARIB CAMSYLATE TAB 200 MG (BASE EQUIVALENT)  | 21535570200320 | Brand   |
| RUBRACA               | RUCAPARIB CAMSYLATE TAB 250 MG (BASE EQUIVALENT)  | 21535570200325 | Brand   |
| RUBRACA               | RUCAPARIB CAMSYLATE TAB 300 MG (BASE EQUIVALENT)  | 21535570200330 | Brand   |
| JAKAFI                | RUXOLITINIB PHOSPHATE TAB 5 MG (BASE EQUIVALENT)  | 21537560200310 | Brand   |
| JAKAFI                | RUXOLITINIB PHOSPHATE TAB 10 MG (BASE EQUIVALENT) | 21537560200320 | Brand   |
| JAKAFI                | RUXOLITINIB PHOSPHATE TAB 15 MG (BASE EQUIVALENT) | 21537560200325 | Brand   |
| JAKAFI                | RUXOLITINIB PHOSPHATE TAB 20 MG (BASE EQUIVALENT) | 21537560200330 | Brand   |
| JAKAFI                | RUXOLITINIB PHOSPHATE TAB 25 MG (BASE EQUIVALENT) | 21537560200335 | Brand   |
| RETEVMO               | SELPERCATINIB CAP 40 MG                           | 21535779000120 | Brand   |
| RETEVMO               | SELPERCATINIB CAP 80 MG                           | 21535779000140 | Brand   |
| SORAFENIB             | SORAFENIB TOSYLATE TAB 200 MG (BASE EQUIVALENT)   | 21533060400320 | Generic |
| SORAFENIB<br>TOSYLATE | SORAFENIB TOSYLATE TAB 200 MG (BASE EQUIVALENT)   | 21533060400320 | Generic |
| SUNITINIB<br>MALATE   | SUNITINIB MALATE CAP 12.5 MG (BASE EQUIVALENT)    | 21533070300120 | Generic |
| SUNITINIB<br>MALATE   | SUNITINIB MALATE CAP 25 MG (BASE EQUIVALENT)      | 21533070300130 | Generic |
| SUNITINIB<br>MALATE   | SUNITINIB MALATE CAP 37.5 MG (BASE EQUIVALENT)    | 21533070300135 | Generic |
| SUNITINIB<br>MALATE   | SUNITINIB MALATE CAP 50 MG (BASE EQUIVALENT)      | 21533070300140 | Generic |
| TAZVERIK              | TAZEMETOSTAT HBR TAB 200 MG                       | 21533675200320 | Brand   |
| ZELBORAF              | VEMURAFENIB TAB 240 MG                            | 21532080000320 | Brand   |
| BOSULIF               | BOSUTINIB CAP 50 MG                               | 21531812000120 | Brand   |
| BOSULIF               | BOSUTINIB CAP 100 MG                              | 21531812000130 | Brand   |

- **1** One of the following:
- **1.1** The requested drug is being used alone or in a combination regimen that is FDA-labeled for the treatment of the specific condition the member presents with\*

OR

**1.2** The requested drug being used alone or in a combination regimen that has a class 1 or 2 recommendation for use from the National Comprehensive Cancer Network (NCCN) in the specific condition of the member

OR

- **1.3** The requested drug is being used alone or in a combination regimen that is recommended for use in the specific condition of the member\* in one of the following:
  - American Hospital Formulary Service Drug Information
  - Thompson Micromedex's Drug Dex
  - Elsevier Gold Standard's Clinical Pharmacology
  - Two articles in peer-reviewed professional medical journals from the United States or Great Britain that recognize the safety and efficacy of the requested drug in the member's specific condition

#### AND

- **2** Prescribed by or in consultation with one of the following:
  - oncologist
  - hematologist
  - other specialist in the treatment of malignancy

| Notes | *Includes any relevant genetic testing, mutations, etc. |
|-------|---|
|-------|---|

| Approval Length | 12 month(s)           |
|-----------------|-----------------------|
| Therapy Stage   | Initial Authorization |

| Guideline Type          |                                | Prior Authorization - MN Plans                 |                |               |
|-------------------------|--------------------------------|--|----------------|---------------|
| Product<br>Name         | Generio                        | Name   | GPI            | Brand/Generic |
| GILOTRIF                | AFATINIE<br>EQUIVAL            | B DIMALEATE TAB 20 MG (BASE<br>ENT)            | 21360006100320 | Brand         |
| GILOTRIF                | AFATINIE<br>EQUIVAL            | B DIMALEATE TAB 30 MG (BASE<br>ENT)            | 21360006100330 | Brand         |
| GILOTRIF                | AFATINIE<br>EQUIVAL            | B DIMALEATE TAB 40 MG (BASE<br>LENT)           | 21360006100340 | Brand         |
| ALECENSA                | ALECTIN                        | IB HCL CAP 150 MG (BASE EQUIVALENT)            | 21530507100120 | Brand         |
| ONUREG                  | AZACITI                        | DINE TAB 200 MG                                | 21300003000320 | Brand         |
| ONUREG                  | AZACITI                        | DINE TAB 300 MG                                | 21300003000330 | Brand         |
| TABRECTA                | CAPMAT                         | INIB HCL TAB 150 MG                            | 21533716200320 | Brand         |
| TABRECTA                | CAPMAT                         | INIB HCL TAB 200 MG                            | 21533716200330 | Brand         |
| COTELLIC                | COBIME <sup>*</sup><br>EQUIVAL | TINIB FUMARATE TAB 20 MG (BASE<br>LENT)        | 21533530200320 | Brand         |
| TAFINLAR                | DABRAF<br>EQUIVAL              | ENIB MESYLATE CAP 50 MG (BASE<br>ENT)          | 21532025100120 | Brand         |
| TAFINLAR                | DABRAF<br>EQUIVAL              | ENIB MESYLATE CAP 75 MG (BASE<br>ENT)          | 21532025100130 | Brand         |
| TAFINLAR                |                                | ENIB MESYLATE TAB FOR ORAL SUSP 10<br>E EQUIV) | 21532025107320 | Brand         |
| ROZLYTREK               | ENTREC                         | TINIB CAP 100 MG                               | 21533820000120 | Brand         |
| ROZLYTREK               | ENTREC                         | TINIB CAP 200 MG                               | 21533820000130 | Brand         |
| IMBRUVICA               | IBRUTIN                        | B CAP 70 MG                                    | 21532133000110 | Brand         |
| IMBRUVICA               | IBRUTIN                        | B CAP 140 MG                                   | 21532133000120 | Brand         |
| IMBRUVICA               | IBRUTIN                        | B TAB 420 MG                                   | 21532133000340 | Brand         |
| IMBRUVICA               | IBRUTIN                        | B ORAL SUSP 70 MG/ML                           | 21532133001820 | Brand         |
| ZYDELIG                 | IDELALIS                       | SIB TAB 100 MG                                 | 21538040000320 | Brand         |
| ZYDELIG                 | IDELALIS                       | SIB TAB 150 MG                                 | 21538040000330 | Brand         |
| NINLARO                 | IXAZOMI<br>EQUIVAL             | B CITRATE CAP 2.3 MG (BASE<br>ENT)             | 21536045100120 | Brand         |
| NINLARO                 | IXAZOMI<br>EQUIVAL             | B CITRATE CAP 3 MG (BASE<br>ENT)               | 21536045100130 | Brand         |
| NINLARO                 | IXAZOMI<br>EQUIVAL             | B CITRATE CAP 4 MG (BASE<br>.ENT)              | 21536045100140 | Brand         |
| LAPATINIB<br>DITOSYLATE | LAPATIN<br>EQUIV)              | IB DITOSYLATE TAB 250 MG (BASE                 | 21533026100320 | Generic       |
| LENALIDOMIDE            | LENALID                        | OMIDE CAPS 2.5 MG                              | 99394050000110 | Generic       |

| LENALIDOMIDE                  | LENALIDOMIDE CAP 5 MG                                       | 99394050000120 | Generic |
|-------------------------------|---|----------------|---------|
| LENALIDOMIDE                  | LENALIDOMIDE CAP 10 MG                                      | 99394050000130 | Generic |
| LENALIDOMIDE                  | LENALIDOMIDE CAP 15 MG                                      | 99394050000140 | Generic |
| LENALIDOMIDE                  | LENALIDOMIDE CAP 20 MG                                      | 99394050000145 | Generic |
| LENALIDOMIDE                  | LENALIDOMIDE CAP 25 MG                                      | 99394050000150 | Generic |
| EXKIVITY                      | MOBOCERTINIB SUCCINATE CAP 40 MG                            | 21360050600120 | Brand   |
| POMALYST                      | POMALIDOMIDE CAP 1 MG                                       | 21450080000110 | Brand   |
| POMALYST                      | POMALIDOMIDE CAP 2 MG                                       | 21450080000115 | Brand   |
| POMALYST                      | POMALIDOMIDE CAP 3 MG                                       | 21450080000120 | Brand   |
| POMALYST                      | POMALIDOMIDE CAP 4 MG                                       | 21450080000125 | Brand   |
| STIVARGA                      | REGORAFENIB TAB 40 MG                                       | 21533050000320 | Brand   |
| KOSELUGO                      | SELUMETINIB SULFATE CAP 10 MG                               | 21533565500110 | Brand   |
| KOSELUGO                      | SELUMETINIB SULFATE CAP 25 MG                               | 21533565500125 | Brand   |
| ODOMZO                        | SONIDEGIB PHOSPHATE CAP 200 MG (BASE EQUIVALENT)            | 21370060200120 | Brand   |
| HYCAMTIN                      | TOPOTECAN HCL CAP 0.25 MG (BASE EQUIV)                      | 21550080100120 | Brand   |
| HYCAMTIN                      | TOPOTECAN HCL CAP 1 MG (BASE EQUIV)                         | 21550080100140 | Brand   |
| MEKINIST                      | TRAMETINIB DIMETHYL SULFOXIDE TAB 0.5 MG (BASE EQUIVALENT)  | 21533570100310 | Brand   |
| MEKINIST                      | TRAMETINIB DIMETHYL SULFOXIDE TAB 2 MG (BASE EQUIVALENT)    | 21533570100330 | Brand   |
| MEKINIST                      | TRAMETINIB DIMETHYL SULFOXIDE FOR SOLN 0.05 MG/ML (BASE EQ) | 21533570102120 | Brand   |
| LONSURF                       | TRIFLURIDINE-TIPIRACIL TAB 15-6.14 MG                       | 21990002750320 | Brand   |
| LONSURF                       | TRIFLURIDINE-TIPIRACIL TAB 20-8.19 MG                       | 21990002750330 | Brand   |
| TUKYSA                        | TUCATINIB TAB 50 MG   | 21170080000320 | Brand   |
| TUKYSA                        | TUCATINIB TAB 150 MG  | 21170080000340 | Brand   |
| VENCLEXTA<br>STARTING<br>PACK | VENETOCLAX TAB THERAPY STARTER PACK 10 & 50 & 100 MG        | 2147008000B720 | Brand   |
| VENCLEXTA                     | VENETOCLAX TAB 10 MG  | 21470080000320 | Brand   |
| VENCLEXTA                     | VENETOCLAX TAB 50 MG  | 21470080000340 | Brand   |
| VENCLEXTA                     | VENETOCLAX TAB 100 MG                                       | 21470080000360 | Brand   |
| ERIVEDGE                      | VISMODEGIB CAP 150 MG                                       | 21370070000120 | Brand   |
| ZOLINZA                       | VORINOSTAT CAP 100 MG                                       | 21531575000120 | Brand   |

| IBRANCE                       | PALBOCICLIB CAP 75 MG  | 21531060000120 | Brand |
|-------------------------------|--|----------------|-------|
| IBRANCE                       | PALBOCICLIB CAP 100 MG                                       | 21531060000130 | Brand |
| IBRANCE                       | PALBOCICLIB CAP 125 MG                                       | 21531060000140 | Brand |
| IBRANCE                       | PALBOCICLIB TAB 75 MG  | 21531060000320 | Brand |
| IBRANCE                       | PALBOCICLIB TAB 100 MG                                       | 21531060000330 | Brand |
| IBRANCE                       | PALBOCICLIB TAB 125 MG                                       | 21531060000340 | Brand |
| KISQALI                       | RIBOCICLIB SUCCINATE TAB PACK 200 MG DAILY DOSE              | 2153107050B720 | Brand |
| KISQALI                       | RIBOCICLIB SUCCINATE TAB PACK 400 MG DAILY DOSE (200 MG TAB) | 2153107050B740 | Brand |
| KISQALI                       | RIBOCICLIB SUCCINATE TAB PACK 600 MG DAILY DOSE (200 MG TAB) | 2153107050B760 | Brand |
| KISQALI<br>FEMARA 200<br>DOSE | RIBOCICLIB 200 MG DOSE (200 MG TAB) & LETROZOLE 2.5 MG TBPK  | 2199000260B730 | Brand |
| KISQALI<br>FEMARA 400<br>DOSE | RIBOCICLIB 400 MG DOSE (200 MG TAB) & LETROZOLE 2.5 MG TBPK  | 2199000260B740 | Brand |
| KISQALI<br>FEMARA 600<br>DOSE | RIBOCICLIB 600 MG DOSE (200 MG TAB) & LETROZOLE 2.5 MG TBPK  | 2199000260B760 | Brand |
| VERZENIO                      | ABEMACICLIB TAB 50 MG  | 21531010000305 | Brand |
| VERZENIO                      | ABEMACICLIB TAB 100 MG                                       | 21531010000310 | Brand |
| VERZENIO                      | ABEMACICLIB TAB 150 MG                                       | 21531010000315 | Brand |
| VERZENIO                      | ABEMACICLIB TAB 200 MG                                       | 21531010000320 | Brand |
|                               |  |                |       |

- 1 One of the following:
- **1.1** The requested drug is being used alone or in a combination regimen that is FDA-labeled for the treatment of the specific condition the member presents with\*

### OR

**1.2** The requested drug being used alone or in a combination regimen that has a class 1 or 2 recommendation for use from the National Comprehensive Cancer Network (NCCN) in the specific condition of the member

#### OR

- **1.3** The requested drug is being used alone or in a combination regimen that is recommended for use in the specific condition of the member\* in one of the following:
  - United States Pharmacopeia Drug Information
  - American Hospital Formulary Service Drug Information
  - One article in a major peer- reviewed medical journal that recognizes the safety and efficacy of the requested drug in the member's specific condition

#### **AND**

- 2 Prescribed by or in consultation with one of the following:
  - oncologist
  - hematologist
  - other specialist in the treatment of malignancy

| Notes | *Includes any relevant genetic testing, mutations, etc. |
|-------|---|
|-------|---|

| Approval Length | 12 month(s)                    |
|-----------------|--------------------------------|
| Therapy Stage   | Reauthorization                |
| Guideline Type  | Prior Authorization - MN Plans |

| Product<br>Name | Generic Name                                   | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| GILOTRIF        | AFATINIB DIMALEATE TAB 20 MG (BASE EQUIVALENT) | 21360006100320 | Brand         |
| GILOTRIF        | AFATINIB DIMALEATE TAB 30 MG (BASE EQUIVALENT) | 21360006100330 | Brand         |
| GILOTRIF        | AFATINIB DIMALEATE TAB 40 MG (BASE EQUIVALENT) | 21360006100340 | Brand         |
| ALECENSA        | ALECTINIB HCL CAP 150 MG (BASE EQUIVALENT)     | 21530507100120 | Brand         |
| ONUREG          | AZACITIDINE TAB 200 MG                         | 21300003000320 | Brand         |
| ONUREG          | AZACITIDINE TAB 300 MG                         | 21300003000330 | Brand         |
| TABRECTA        | CAPMATINIB HCL TAB 150 MG                      | 21533716200320 | Brand         |

| TABRECTA                | CAPMATINIB HCL TAB 200 MG                                | 21533716200330 | Brand   |
|-------------------------|--|----------------|---------|
| COTELLIC                | COBIMETINIB FUMARATE TAB 20 MG (BASE EQUIVALENT)         | 21533530200320 | Brand   |
| TAFINLAR                | DABRAFENIB MESYLATE CAP 50 MG (BASE EQUIVALENT)          | 21532025100120 | Brand   |
| TAFINLAR                | DABRAFENIB MESYLATE CAP 75 MG (BASE EQUIVALENT)          | 21532025100130 | Brand   |
| TAFINLAR                | DABRAFENIB MESYLATE TAB FOR ORAL SUSP 10 MG (BASE EQUIV) | 21532025107320 | Brand   |
| ROZLYTREK               | ENTRECTINIB CAP 100 MG                                   | 21533820000120 | Brand   |
| ROZLYTREK               | ENTRECTINIB CAP 200 MG                                   | 21533820000130 | Brand   |
| IMBRUVICA               | IBRUTINIB CAP 70 MG                                      | 21532133000110 | Brand   |
| IMBRUVICA               | IBRUTINIB CAP 140 MG                                     | 21532133000120 | Brand   |
| IMBRUVICA               | IBRUTINIB TAB 420 MG                                     | 21532133000340 | Brand   |
| IMBRUVICA               | IBRUTINIB ORAL SUSP 70 MG/ML                             | 21532133001820 | Brand   |
| ZYDELIG                 | IDELALISIB TAB 100 MG                                    | 21538040000320 | Brand   |
| ZYDELIG                 | IDELALISIB TAB 150 MG                                    | 21538040000330 | Brand   |
| NINLARO                 | IXAZOMIB CITRATE CAP 2.3 MG (BASE EQUIVALENT)            | 21536045100120 | Brand   |
| NINLARO                 | IXAZOMIB CITRATE CAP 3 MG (BASE EQUIVALENT)              | 21536045100130 | Brand   |
| NINLARO                 | IXAZOMIB CITRATE CAP 4 MG (BASE<br>EQUIVALENT)           | 21536045100140 | Brand   |
| LAPATINIB<br>DITOSYLATE | LAPATINIB DITOSYLATE TAB 250 MG (BASE EQUIV)             | 21533026100320 | Generic |
| LENALIDOMIDE            | LENALIDOMIDE CAPS 2.5 MG                                 | 99394050000110 | Generic |
| LENALIDOMIDE            | LENALIDOMIDE CAP 5 MG                                    | 99394050000120 | Generic |
| LENALIDOMIDE            | LENALIDOMIDE CAP 10 MG                                   | 99394050000130 | Generic |
| LENALIDOMIDE            | LENALIDOMIDE CAP 15 MG                                   | 99394050000140 | Generic |
| LENALIDOMIDE            | LENALIDOMIDE CAP 20 MG                                   | 99394050000145 | Generic |
| LENALIDOMIDE            | LENALIDOMIDE CAP 25 MG                                   | 99394050000150 | Generic |
| EXKIVITY                | MOBOCERTINIB SUCCINATE CAP 40 MG                         | 21360050600120 | Brand   |
| POMALYST                | POMALIDOMIDE CAP 1 MG                                    | 21450080000110 | Brand   |
| POMALYST                | POMALIDOMIDE CAP 2 MG                                    | 21450080000115 | Brand   |
| POMALYST                | POMALIDOMIDE CAP 3 MG                                    | 21450080000120 | Brand   |
| POMALYST                | POMALIDOMIDE CAP 4 MG                                    | 21450080000125 | Brand   |
| STIVARGA                | REGORAFENIB TAB 40 MG                                    | 21533050000320 | Brand   |

| KOSELUGO                      | SELUMETINIB SULFATE CAP 10 MG                                | 21533565500110 | Brand |
|-------------------------------|--|----------------|-------|
| KOSELUGO                      | SELUMETINIB SULFATE CAP 25 MG                                | 21533565500125 | Brand |
| ODOMZO                        | SONIDEGIB PHOSPHATE CAP 200 MG (BASE EQUIVALENT)             | 21370060200120 | Brand |
| HYCAMTIN                      | TOPOTECAN HCL CAP 0.25 MG (BASE EQUIV)                       | 21550080100120 | Brand |
| HYCAMTIN                      | TOPOTECAN HCL CAP 1 MG (BASE EQUIV)                          | 21550080100140 | Brand |
| MEKINIST                      | TRAMETINIB DIMETHYL SULFOXIDE TAB 0.5 MG (BASE EQUIVALENT)   | 21533570100310 | Brand |
| MEKINIST                      | TRAMETINIB DIMETHYL SULFOXIDE TAB 2 MG (BASE EQUIVALENT)     | 21533570100330 | Brand |
| MEKINIST                      | TRAMETINIB DIMETHYL SULFOXIDE FOR SOLN 0.05 MG/ML (BASE EQ)  | 21533570102120 | Brand |
| LONSURF                       | TRIFLURIDINE-TIPIRACIL TAB 15-6.14 MG                        | 21990002750320 | Brand |
| LONSURF                       | TRIFLURIDINE-TIPIRACIL TAB 20-8.19 MG                        | 21990002750330 | Brand |
| TUKYSA                        | TUCATINIB TAB 50 MG  | 21170080000320 | Brand |
| TUKYSA                        | TUCATINIB TAB 150 MG   | 21170080000340 | Brand |
| VENCLEXTA<br>STARTING<br>PACK | VENETOCLAX TAB THERAPY STARTER PACK 10 & 50 & 100 MG         | 2147008000B720 | Brand |
| VENCLEXTA                     | VENETOCLAX TAB 10 MG   | 21470080000320 | Brand |
| VENCLEXTA                     | VENETOCLAX TAB 50 MG   | 21470080000340 | Brand |
| VENCLEXTA                     | VENETOCLAX TAB 100 MG  | 21470080000360 | Brand |
| ERIVEDGE                      | VISMODEGIB CAP 150 MG  | 21370070000120 | Brand |
| ZOLINZA                       | VORINOSTAT CAP 100 MG  | 21531575000120 | Brand |
| IBRANCE                       | PALBOCICLIB CAP 75 MG  | 21531060000120 | Brand |
| IBRANCE                       | PALBOCICLIB CAP 100 MG                                       | 21531060000130 | Brand |
| IBRANCE                       | PALBOCICLIB CAP 125 MG                                       | 21531060000140 | Brand |
| IBRANCE                       | PALBOCICLIB TAB 75 MG  | 21531060000320 | Brand |
| IBRANCE                       | PALBOCICLIB TAB 100 MG                                       | 21531060000330 | Brand |
| IBRANCE                       | PALBOCICLIB TAB 125 MG                                       | 21531060000340 | Brand |
| KISQALI                       | RIBOCICLIB SUCCINATE TAB PACK 200 MG DAILY DOSE              | 2153107050B720 | Brand |
| KISQALI                       | RIBOCICLIB SUCCINATE TAB PACK 400 MG DAILY DOSE (200 MG TAB) | 2153107050B740 | Brand |
| KISQALI                       | RIBOCICLIB SUCCINATE TAB PACK 600 MG DAILY DOSE (200 MG TAB) | 2153107050B760 | Brand |
| KISQALI<br>FEMARA 200         | RIBOCICLIB 200 MG DOSE (200 MG TAB) & LETROZOLE 2.5 MG TBPK  | 2199000260B730 | Brand |

| DOSE                          |   |                |       |
|-------------------------------|---|----------------|-------|
| KISQALI<br>FEMARA 400<br>DOSE | RIBOCICLIB 400 MG DOSE (200 MG TAB) & LETROZOLE 2.5 MG TBPK | 2199000260B740 | Brand |
| KISQALI<br>FEMARA 600<br>DOSE | RIBOCICLIB 600 MG DOSE (200 MG TAB) & LETROZOLE 2.5 MG TBPK | 2199000260B760 | Brand |
| VERZENIO                      | ABEMACICLIB TAB 50 MG                                       | 21531010000305 | Brand |
| VERZENIO                      | ABEMACICLIB TAB 100 MG                                      | 21531010000310 | Brand |
| VERZENIO                      | ABEMACICLIB TAB 150 MG                                      | 21531010000315 | Brand |
| VERZENIO                      | ABEMACICLIB TAB 200 MG                                      | 21531010000320 | Brand |
| BOSULIF                       | BOSUTINIB CAP 50 MG   | 21531812000120 | Brand |
| BOSULIF                       | BOSUTINIB CAP 100 MG  | 21531812000130 | Brand |

- **1** One of the following:
- **1.1** The requested drug is being used alone or in a combination regimen that is FDA-labeled for the treatment of the specific condition the member presents with\*

OR

**1.2** The requested drug being used alone or in a combination regimen that has a class 1 or 2 recommendation for use from the National Comprehensive Cancer Network (NCCN) in the specific condition of the member

OR

- **1.3** The requested drug is being used alone or in a combination regimen that is recommended for use in the specific condition of the member\* in one of the following:
  - United States Pharmacopeia Drug Information
  - American Hospital Formulary Service Drug Information
  - One article in a major peer- reviewed medical journal that recognizes the safety and efficacy of the requested drug in the member's specific condition

**AND** 

- **2** Prescribed by or in consultation with one of the following:

  - oncologist hematologist other specialist in the treatment of malignancy

| Notes | *Includes any relevant genetic testing, mutations, etc. |
|-------|---|

# 2. Revision History

| Date      | Notes  |
|-----------|--|
| 2/14/2024 | Update program – Bosulif capsules added to IL criteria |

| Restricted Oral Oncology Drugs Split F  |  |  |
|---|--|--|
| (3) This companies delayed. The lay the loss device a make a find that the principle of control of |  |  |

## **Prior Authorization Guideline**

| Guideline ID          | GL-141303                                 |  |
|-----------------------|---|--|
| <b>Guideline Name</b> | Restricted Oral Oncology Drugs Split Fill |  |
| Formulary             | Quartz                                    |  |

## **Guideline Note:**

| Effective Date: |
|-----------------|
|-----------------|

### 1. Criteria

Product Name: Bosulif, Cabometyx, Generic erlotinib, Generic everolimus, Generic gefitinib, Generic sorafenib, Generic sunitinib, Inlyta, Inrebic, Jakafi, Lynparza, Nubeqa, Piqray, Retevmo, Rubraca, Sprycel, Tagrisso, Tasigna, Tazverik, Votrient, Xalkori, Xtandi, Zejula, Zelboraf, Zykadia

Approval Length

12 month(s)

| Approval Length | 12 month(s)  |
|-----------------|--|
| Therapy Stage   | Initial Authorization                                  |
| Guideline Type  | Prior Authorization - ALL Plans Except IL and MN Plans |

| Product Name               | Generic Name   | GPI            | Brand/Generic |
|----------------------------|--|----------------|---------------|
| PIQRAY 200MG<br>DAILY DOSE | ALPELISIB TAB THERAPY PACK 200 MG DAILY<br>DOSE            | 2153801000B720 | Brand         |
| PIQRAY 250MG<br>DAILY DOSE | ALPELISIB TAB PACK 250 MG DAILY DOSE (200 MG & 50 MG TABS) | 2153801000B725 | Brand         |
| PIQRAY 300MG<br>DAILY DOSE | ALPELISIB TAB PACK 300 MG DAILY DOSE (2X150 MG TAB)        | 2153801000B730 | Brand         |

| INLYTA                     | AXITINIB TAB 1 MG                                 | 21335013000320 | Brand   |
|----------------------------|---|----------------|---------|
| INLYTA                     | AXITINIB TAB 5 MG                                 | 21335013000340 | Brand   |
| BOSULIF                    | BOSUTINIB TAB 100 MG                              | 21531812000320 | Brand   |
| BOSULIF                    | BOSUTINIB TAB 400 MG                              | 21531812000327 | Brand   |
| BOSULIF                    | BOSUTINIB TAB 500 MG                              | 21531812000340 | Brand   |
| CABOMETYX                  | CABOZANTINIB S-MALATE TAB 20 MG (BASE EQUIVALENT) | 21533010100320 | Brand   |
| CABOMETYX                  | CABOZANTINIB S-MALATE TAB 40 MG (BASE EQUIVALENT) | 21533010100330 | Brand   |
| CABOMETYX                  | CABOZANTINIB S-MALATE TAB 60 MG (BASE EQUIVALENT) | 21533010100340 | Brand   |
| ZYKADIA                    | CERITINIB TAB 150 MG                              | 21530514000330 | Brand   |
| XALKORI                    | CRIZOTINIB CAP 200 MG                             | 21530517000120 | Brand   |
| XALKORI                    | CRIZOTINIB CAP 250 MG                             | 21530517000125 | Brand   |
| NUBEQA                     | DAROLUTAMIDE TAB 300 MG                           | 21402425000320 | Brand   |
| SPRYCEL                    | DASATINIB TAB 20 MG                               | 21531820000320 | Brand   |
| SPRYCEL                    | DASATINIB TAB 50 MG                               | 21531820000340 | Brand   |
| SPRYCEL                    | DASATINIB TAB 70 MG                               | 21531820000350 | Brand   |
| SPRYCEL                    | DASATINIB TAB 80 MG                               | 21531820000354 | Brand   |
| SPRYCEL                    | DASATINIB TAB 100 MG                              | 21531820000360 | Brand   |
| SPRYCEL                    | DASATINIB TAB 140 MG                              | 21531820000380 | Brand   |
| XTANDI                     | ENZALUTAMIDE CAP 40 MG                            | 21402430000120 | Brand   |
| XTANDI                     | ENZALUTAMIDE TAB 40 MG                            | 21402430000320 | Brand   |
| XTANDI                     | ENZALUTAMIDE TAB 80 MG                            | 21402430000340 | Brand   |
| TARCEVA                    | ERLOTINIB HCL TAB 25 MG (BASE EQUIVALENT)         | 21360025100320 | Brand   |
| ERLOTINIB<br>HYDROCHLORIDE | ERLOTINIB HCL TAB 25 MG (BASE EQUIVALENT)         | 21360025100320 | Generic |
| TARCEVA                    | ERLOTINIB HCL TAB 100 MG (BASE<br>EQUIVALENT)     | 21360025100330 | Brand   |
| ERLOTINIB<br>HYDROCHLORIDE | ERLOTINIB HCL TAB 100 MG (BASE<br>EQUIVALENT)     | 21360025100330 | Generic |
| TARCEVA                    | ERLOTINIB HCL TAB 150 MG (BASE EQUIVALENT)        | 21360025100360 | Brand   |
| ERLOTINIB<br>HYDROCHLORIDE | ERLOTINIB HCL TAB 150 MG (BASE EQUIVALENT)        | 21360025100360 | Generic |
| EVEROLIMUS                 | EVEROLIMUS TAB 2.5 MG                             | 21532530000310 | Generic |

| AFINITOR            | EVEROLIMUS TAB 2.5 MG                            | 21532530000310 | Brand   |
|---------------------|--|----------------|---------|
| EVEROLIMUS          | EVEROLIMUS TAB 5 MG                              | 21532530000320 | Generic |
| AFINITOR            | EVEROLIMUS TAB 5 MG                              | 21532530000320 | Brand   |
| EVEROLIMUS          | EVEROLIMUS TAB 7.5 MG                            | 21532530000325 | Generic |
| AFINITOR            | EVEROLIMUS TAB 7.5 MG                            | 21532530000325 | Brand   |
| EVEROLIMUS          | EVEROLIMUS TAB 10 MG                             | 21532530000330 | Generic |
| AFINITOR            | EVEROLIMUS TAB 10 MG                             | 21532530000330 | Brand   |
| AFINITOR<br>DISPERZ | EVEROLIMUS TAB FOR ORAL SUSP 2 MG                | 21532530007310 | Brand   |
| EVEROLIMUS          | EVEROLIMUS TAB FOR ORAL SUSP 2 MG                | 21532530007310 | Generic |
| AFINITOR<br>DISPERZ | EVEROLIMUS TAB FOR ORAL SUSP 3 MG                | 21532530007320 | Brand   |
| EVEROLIMUS          | EVEROLIMUS TAB FOR ORAL SUSP 3 MG                | 21532530007320 | Generic |
| AFINITOR<br>DISPERZ | EVEROLIMUS TAB FOR ORAL SUSP 5 MG                | 21532530007340 | Brand   |
| EVEROLIMUS          | EVEROLIMUS TAB FOR ORAL SUSP 5 MG                | 21532530007340 | Generic |
| INREBIC             | FEDRATINIB HCL CAP 100 MG                        | 21537520200120 | Brand   |
| IRESSA              | GEFITINIB TAB 250 MG                             | 21360030000320 | Brand   |
| GEFITINIB           | GEFITINIB TAB 250 MG                             | 21360030000320 | Generic |
| TASIGNA             | NILOTINIB HCL CAP 50 MG (BASE EQUIVALENT)        | 21531860200110 | Brand   |
| TASIGNA             | NILOTINIB HCL CAP 150 MG (BASE EQUIVALENT)       | 21531860200115 | Brand   |
| TASIGNA             | NILOTINIB HCL CAP 200 MG (BASE EQUIVALENT)       | 21531860200125 | Brand   |
| ZEJULA              | NIRAPARIB TOSYLATE CAP 100 MG (BASE EQUIVALENT)  | 21535550200120 | Brand   |
| ZEJULA              | NIRAPARIB TOSYLATE TAB 100 MG (BASE EQUIVALENT)  | 21535550200320 | Brand   |
| ZEJULA              | NIRAPARIB TOSYLATE TAB 200 MG (BASE EQUIVALENT)  | 21535550200330 | Brand   |
| ZEJULA              | NIRAPARIB TOSYLATE TAB 300 MG (BASE EQUIVALENT)  | 21535550200340 | Brand   |
| LYNPARZA            | OLAPARIB TAB 100 MG                              | 21535560000330 | Brand   |
| LYNPARZA            | OLAPARIB TAB 150 MG                              | 21535560000340 | Brand   |
| TAGRISSO            | OSIMERTINIB MESYLATE TAB 40 MG (BASE EQUIVALENT) | 21360068200320 | Brand   |
| TAGRISSO            | OSIMERTINIB MESYLATE TAB 80 MG (BASE EQUIVALENT) | 21360068200330 | Brand   |

| VOTRIENT              | PAZOPANIB HCL TAB 200 MG (BASE EQUIV)             | 21533042100320 | Brand   |
|-----------------------|---|----------------|---------|
| RUBRACA               | RUCAPARIB CAMSYLATE TAB 200 MG (BASE EQUIVALENT)  | 21535570200320 | Brand   |
| RUBRACA               | RUCAPARIB CAMSYLATE TAB 250 MG (BASE EQUIVALENT)  | 21535570200325 | Brand   |
| RUBRACA               | RUCAPARIB CAMSYLATE TAB 300 MG (BASE EQUIVALENT)  | 21535570200330 | Brand   |
| JAKAFI                | RUXOLITINIB PHOSPHATE TAB 5 MG (BASE EQUIVALENT)  | 21537560200310 | Brand   |
| JAKAFI                | RUXOLITINIB PHOSPHATE TAB 10 MG (BASE EQUIVALENT) | 21537560200320 | Brand   |
| JAKAFI                | RUXOLITINIB PHOSPHATE TAB 15 MG (BASE EQUIVALENT) | 21537560200325 | Brand   |
| JAKAFI                | RUXOLITINIB PHOSPHATE TAB 20 MG (BASE EQUIVALENT) | 21537560200330 | Brand   |
| JAKAFI                | RUXOLITINIB PHOSPHATE TAB 25 MG (BASE EQUIVALENT) | 21537560200335 | Brand   |
| RETEVMO               | SELPERCATINIB CAP 40 MG                           | 21535779000120 | Brand   |
| RETEVMO               | SELPERCATINIB CAP 80 MG                           | 21535779000140 | Brand   |
| NEXAVAR               | SORAFENIB TOSYLATE TAB 200 MG (BASE EQUIVALENT)   | 21533060400320 | Brand   |
| SORAFENIB             | SORAFENIB TOSYLATE TAB 200 MG (BASE EQUIVALENT)   | 21533060400320 | Generic |
| SORAFENIB<br>TOSYLATE | SORAFENIB TOSYLATE TAB 200 MG (BASE EQUIVALENT)   | 21533060400320 | Generic |
| SUTENT                | SUNITINIB MALATE CAP 12.5 MG (BASE EQUIVALENT)    | 21533070300120 | Brand   |
| SUNITINIB<br>MALATE   | SUNITINIB MALATE CAP 12.5 MG (BASE EQUIVALENT)    | 21533070300120 | Generic |
| SUTENT                | SUNITINIB MALATE CAP 25 MG (BASE EQUIVALENT)      | 21533070300130 | Brand   |
| SUNITINIB<br>MALATE   | SUNITINIB MALATE CAP 25 MG (BASE EQUIVALENT)      | 21533070300130 | Generic |
| SUTENT                | SUNITINIB MALATE CAP 37.5 MG (BASE EQUIVALENT)    | 21533070300135 | Brand   |
| SUNITINIB<br>MALATE   | SUNITINIB MALATE CAP 37.5 MG (BASE EQUIVALENT)    | 21533070300135 | Generic |
| SUTENT                | SUNITINIB MALATE CAP 50 MG (BASE EQUIVALENT)      | 21533070300140 | Brand   |
| SUNITINIB<br>MALATE   | SUNITINIB MALATE CAP 50 MG (BASE EQUIVALENT)      | 21533070300140 | Generic |
| TAZVERIK              | TAZEMETOSTAT HBR TAB 200 MG                       | 21533675200320 | Brand   |
| ZELBORAF              | VEMURAFENIB TAB 240 MG                            | 21532080000320 | Brand   |

| BOSULIF | BOSUTINIB CAP 50 MG  | 21531812000120 | Brand |
|---------|----------------------|----------------|-------|
| BOSULIF | BOSUTINIB CAP 100 MG | 21531812000130 | Brand |

- **1** One of the following:
- **1.1** The requested drug is being used alone or in a combination regimen that is FDA-labeled for the treatment of the specific condition the member presents with\*

#### OR

**1.2** The requested drug is being used alone or in a combination regimen that has a class 1 or 2 recommendation for use from the National Comprehensive Cancer Network (NCCN) in the specific condition of the member\*

#### **AND**

- 2 Prescribed by or in consultation with one of the following:
  - oncologist
  - hematologist
  - other specialist in the treatment of malignancy

| Notes *Includes any relevant genetic testing, mutations, etc. | Notes | *Includes any relevant genetic testing, mutations, etc. |
|---|-------|---|
|---|-------|---|

Product Name: Bosulif, Cabometyx, Generic erlotinib, Generic everolimus, Generic gefitinib, Generic sorafenib, Generic sunitinib, Inlyta, Inrebic, Jakafi, Lynparza, Nubeqa, Piqray, Retevmo, Rubraca, Sprycel, Sutent, Tagrisso, Tasigna, Tarceva, Tazverik, Votrient, Xalkori, Xtandi, Zejula, Zelboraf, Zykadia

| Approval Length | 12 month(s)  |
|-----------------|--|
| Therapy Stage   | Reauthorization  |
| Guideline Type  | Prior Authorization - ALL Plans Except IL and MN Plans |

| Product Name               | Generic Name                                 | GPI            | Brand/Generic |
|----------------------------|--|----------------|---------------|
| PIQRAY 200MG<br>DAILY DOSE | ALPELISIB TAB THERAPY PACK 200 MG DAILY DOSE | 2153801000B720 | Brand         |
| PIQRAY 250MG               | ALPELISIB TAB PACK 250 MG DAILY DOSE (200    | 2153801000B725 | Brand         |

| DAILY DOSE                 | MG & 50 MG TABS)                                    |                |         |
|----------------------------|---|----------------|---------|
| PIQRAY 300MG<br>DAILY DOSE | ALPELISIB TAB PACK 300 MG DAILY DOSE (2X150 MG TAB) | 2153801000B730 | Brand   |
| INLYTA                     | AXITINIB TAB 1 MG                                   | 21335013000320 | Brand   |
| INLYTA                     | AXITINIB TAB 5 MG                                   | 21335013000340 | Brand   |
| BOSULIF                    | BOSUTINIB TAB 100 MG                                | 21531812000320 | Brand   |
| BOSULIF                    | BOSUTINIB TAB 400 MG                                | 21531812000327 | Brand   |
| BOSULIF                    | BOSUTINIB TAB 500 MG                                | 21531812000340 | Brand   |
| CABOMETYX                  | CABOZANTINIB S-MALATE TAB 20 MG (BASE EQUIVALENT)   | 21533010100320 | Brand   |
| CABOMETYX                  | CABOZANTINIB S-MALATE TAB 40 MG (BASE EQUIVALENT)   | 21533010100330 | Brand   |
| CABOMETYX                  | CABOZANTINIB S-MALATE TAB 60 MG (BASE EQUIVALENT)   | 21533010100340 | Brand   |
| ZYKADIA                    | CERITINIB TAB 150 MG                                | 21530514000330 | Brand   |
| XALKORI                    | CRIZOTINIB CAP 200 MG                               | 21530517000120 | Brand   |
| XALKORI                    | CRIZOTINIB CAP 250 MG                               | 21530517000125 | Brand   |
| NUBEQA                     | DAROLUTAMIDE TAB 300 MG                             | 21402425000320 | Brand   |
| SPRYCEL                    | DASATINIB TAB 20 MG                                 | 21531820000320 | Brand   |
| SPRYCEL                    | DASATINIB TAB 50 MG                                 | 21531820000340 | Brand   |
| SPRYCEL                    | DASATINIB TAB 70 MG                                 | 21531820000350 | Brand   |
| SPRYCEL                    | DASATINIB TAB 80 MG                                 | 21531820000354 | Brand   |
| SPRYCEL                    | DASATINIB TAB 100 MG                                | 21531820000360 | Brand   |
| SPRYCEL                    | DASATINIB TAB 140 MG                                | 21531820000380 | Brand   |
| XTANDI                     | ENZALUTAMIDE CAP 40 MG                              | 21402430000120 | Brand   |
| XTANDI                     | ENZALUTAMIDE TAB 40 MG                              | 21402430000320 | Brand   |
| XTANDI                     | ENZALUTAMIDE TAB 80 MG                              | 21402430000340 | Brand   |
| TARCEVA                    | ERLOTINIB HCL TAB 25 MG (BASE EQUIVALENT)           | 21360025100320 | Brand   |
| ERLOTINIB<br>HYDROCHLORIDE | ERLOTINIB HCL TAB 25 MG (BASE<br>EQUIVALENT)        | 21360025100320 | Generic |
| TARCEVA                    | ERLOTINIB HCL TAB 100 MG (BASE EQUIVALENT)          | 21360025100330 | Brand   |
| ERLOTINIB<br>HYDROCHLORIDE | ERLOTINIB HCL TAB 100 MG (BASE EQUIVALENT)          | 21360025100330 | Generic |
| TARCEVA                    | ERLOTINIB HCL TAB 150 MG (BASE EQUIVALENT)          | 21360025100360 | Brand   |

| -                          |  | -              |         |
|----------------------------|--|----------------|---------|
| ERLOTINIB<br>HYDROCHLORIDE | ERLOTINIB HCL TAB 150 MG (BASE<br>EQUIVALENT)      | 21360025100360 | Generic |
| EVEROLIMUS                 | EVEROLIMUS TAB 2.5 MG                              | 21532530000310 | Generic |
| AFINITOR                   | EVEROLIMUS TAB 2.5 MG                              | 21532530000310 | Brand   |
| EVEROLIMUS                 | EVEROLIMUS TAB 5 MG                                | 21532530000320 | Generic |
| AFINITOR                   | EVEROLIMUS TAB 5 MG                                | 21532530000320 | Brand   |
| EVEROLIMUS                 | EVEROLIMUS TAB 7.5 MG                              | 21532530000325 | Generic |
| AFINITOR                   | EVEROLIMUS TAB 7.5 MG                              | 21532530000325 | Brand   |
| EVEROLIMUS                 | EVEROLIMUS TAB 10 MG                               | 21532530000330 | Generic |
| AFINITOR                   | EVEROLIMUS TAB 10 MG                               | 21532530000330 | Brand   |
| AFINITOR<br>DISPERZ        | EVEROLIMUS TAB FOR ORAL SUSP 2 MG                  | 21532530007310 | Brand   |
| EVEROLIMUS                 | EVEROLIMUS TAB FOR ORAL SUSP 2 MG                  | 21532530007310 | Generic |
| AFINITOR<br>DISPERZ        | EVEROLIMUS TAB FOR ORAL SUSP 3 MG                  | 21532530007320 | Brand   |
| EVEROLIMUS                 | EVEROLIMUS TAB FOR ORAL SUSP 3 MG                  | 21532530007320 | Generic |
| AFINITOR<br>DISPERZ        | EVEROLIMUS TAB FOR ORAL SUSP 5 MG                  | 21532530007340 | Brand   |
| EVEROLIMUS                 | EVEROLIMUS TAB FOR ORAL SUSP 5 MG                  | 21532530007340 | Generic |
| INREBIC                    | FEDRATINIB HCL CAP 100 MG                          | 21537520200120 | Brand   |
| IRESSA                     | GEFITINIB TAB 250 MG                               | 21360030000320 | Brand   |
| GEFITINIB                  | GEFITINIB TAB 250 MG                               | 21360030000320 | Generic |
| TASIGNA                    | NILOTINIB HCL CAP 50 MG (BASE<br>EQUIVALENT)       | 21531860200110 | Brand   |
| TASIGNA                    | NILOTINIB HCL CAP 150 MG (BASE<br>EQUIVALENT)      | 21531860200115 | Brand   |
| TASIGNA                    | NILOTINIB HCL CAP 200 MG (BASE<br>EQUIVALENT)      | 21531860200125 | Brand   |
| ZEJULA                     | NIRAPARIB TOSYLATE CAP 100 MG (BASE EQUIVALENT)    | 21535550200120 | Brand   |
| ZEJULA                     | NIRAPARIB TOSYLATE TAB 100 MG (BASE<br>EQUIVALENT) | 21535550200320 | Brand   |
| ZEJULA                     | NIRAPARIB TOSYLATE TAB 200 MG (BASE EQUIVALENT)    | 21535550200330 | Brand   |
| ZEJULA                     | NIRAPARIB TOSYLATE TAB 300 MG (BASE EQUIVALENT)    | 21535550200340 | Brand   |
| LYNPARZA                   | OLAPARIB TAB 100 MG                                | 21535560000330 | Brand   |
| LYNPARZA                   | OLAPARIB TAB 150 MG                                | 21535560000340 | Brand   |
| TAGRISSO                   | OSIMERTINIB MESYLATE TAB 40 MG (BASE               | 21360068200320 | Brand   |

|                       | EQUIVALENT)                                       |                |         |
|-----------------------|---|----------------|---------|
| TAGRISSO              | OSIMERTINIB MESYLATE TAB 80 MG (BASE EQUIVALENT)  | 21360068200330 | Brand   |
| VOTRIENT              | PAZOPANIB HCL TAB 200 MG (BASE EQUIV)             | 21533042100320 | Brand   |
| RUBRACA               | RUCAPARIB CAMSYLATE TAB 200 MG (BASE EQUIVALENT)  | 21535570200320 | Brand   |
| RUBRACA               | RUCAPARIB CAMSYLATE TAB 250 MG (BASE EQUIVALENT)  | 21535570200325 | Brand   |
| RUBRACA               | RUCAPARIB CAMSYLATE TAB 300 MG (BASE EQUIVALENT)  | 21535570200330 | Brand   |
| JAKAFI                | RUXOLITINIB PHOSPHATE TAB 5 MG (BASE EQUIVALENT)  | 21537560200310 | Brand   |
| JAKAFI                | RUXOLITINIB PHOSPHATE TAB 10 MG (BASE EQUIVALENT) | 21537560200320 | Brand   |
| JAKAFI                | RUXOLITINIB PHOSPHATE TAB 15 MG (BASE EQUIVALENT) | 21537560200325 | Brand   |
| JAKAFI                | RUXOLITINIB PHOSPHATE TAB 20 MG (BASE EQUIVALENT) | 21537560200330 | Brand   |
| JAKAFI                | RUXOLITINIB PHOSPHATE TAB 25 MG (BASE EQUIVALENT) | 21537560200335 | Brand   |
| RETEVMO               | SELPERCATINIB CAP 40 MG                           | 21535779000120 | Brand   |
| RETEVMO               | SELPERCATINIB CAP 80 MG                           | 21535779000140 | Brand   |
| NEXAVAR               | SORAFENIB TOSYLATE TAB 200 MG (BASE EQUIVALENT)   | 21533060400320 | Brand   |
| SORAFENIB             | SORAFENIB TOSYLATE TAB 200 MG (BASE EQUIVALENT)   | 21533060400320 | Generic |
| SORAFENIB<br>TOSYLATE | SORAFENIB TOSYLATE TAB 200 MG (BASE EQUIVALENT)   | 21533060400320 | Generic |
| SUTENT                | SUNITINIB MALATE CAP 12.5 MG (BASE EQUIVALENT)    | 21533070300120 | Brand   |
| SUNITINIB<br>MALATE   | SUNITINIB MALATE CAP 12.5 MG (BASE EQUIVALENT)    | 21533070300120 | Generic |
| SUTENT                | SUNITINIB MALATE CAP 25 MG (BASE EQUIVALENT)      | 21533070300130 | Brand   |
| SUNITINIB<br>MALATE   | SUNITINIB MALATE CAP 25 MG (BASE EQUIVALENT)      | 21533070300130 | Generic |
| SUTENT                | SUNITINIB MALATE CAP 37.5 MG (BASE EQUIVALENT)    | 21533070300135 | Brand   |
| SUNITINIB<br>MALATE   | SUNITINIB MALATE CAP 37.5 MG (BASE EQUIVALENT)    | 21533070300135 | Generic |
| SUTENT                | SUNITINIB MALATE CAP 50 MG (BASE EQUIVALENT)      | 21533070300140 | Brand   |
| SUNITINIB<br>MALATE   | SUNITINIB MALATE CAP 50 MG (BASE EQUIVALENT)      | 21533070300140 | Generic |

| TAZVERIK | TAZEMETOSTAT HBR TAB 200 MG | 21533675200320 | Brand |
|----------|-----------------------------|----------------|-------|
| ZELBORAF | VEMURAFENIB TAB 240 MG      | 21532080000320 | Brand |
| BOSULIF  | BOSUTINIB CAP 50 MG         | 21531812000120 | Brand |
| BOSULIF  | BOSUTINIB CAP 100 MG        | 21531812000130 | Brand |

- **1** One of the following:
- **1.1** The requested drug is being used alone or in a combination regimen that is FDA-labeled for the treatment of the specific condition the member presents with\*

#### OR

**1.2** The requested drug is being used alone or in a combination regimen that has a class 1 or 2 recommendation for use from the National Comprehensive Cancer Network (NCCN) in the specific condition of the member\*

#### **AND**

- 2 Prescribed by or in consultation with one of the following:
  - oncologist
  - hematologist
  - other specialist in the treatment of malignancy

| Notes | *Includes any relevant genetic testing, mutations, etc. |
|-------|---|
|-------|---|

Product Name: Bosulif, Cabometyx, Generic erlotinib, Generic everolimus, Generic gefitinib, Generic sorafenib, Generic sunitinib, Inlyta, Inrebic, Jakafi, Lynparza, Nubeqa, Piqray, Retevmo, Rubraca, Sprycel, Tagrisso, Tasigna, Tarceva, Tazverik, Votrient, Xalkori, Xtandi, Zejula, Zelboraf, Zykadia

Approval Length 12 month(s)

Therapy Stage Initial Authorization

Guideline Type Prior Authorization - MN Plans

Product Name Generic Name GPI Brand/Generic

| PIQRAY 200MG<br>DAILY DOSE | ALPELISIB TAB THERAPY PACK 200 MG DAILY<br>DOSE            | 2153801000B720 | Brand   |
|----------------------------|--|----------------|---------|
| PIQRAY 250MG<br>DAILY DOSE | ALPELISIB TAB PACK 250 MG DAILY DOSE (200 MG & 50 MG TABS) | 2153801000B725 | Brand   |
| PIQRAY 300MG<br>DAILY DOSE | ALPELISIB TAB PACK 300 MG DAILY DOSE (2X150 MG TAB)        | 2153801000B730 | Brand   |
| INLYTA                     | AXITINIB TAB 1 MG  | 21335013000320 | Brand   |
| INLYTA                     | AXITINIB TAB 5 MG  | 21335013000340 | Brand   |
| BOSULIF                    | BOSUTINIB TAB 100 MG                                       | 21531812000320 | Brand   |
| BOSULIF                    | BOSUTINIB TAB 400 MG                                       | 21531812000327 | Brand   |
| BOSULIF                    | BOSUTINIB TAB 500 MG                                       | 21531812000340 | Brand   |
| CABOMETYX                  | CABOZANTINIB S-MALATE TAB 20 MG (BASE EQUIVALENT)          | 21533010100320 | Brand   |
| CABOMETYX                  | CABOZANTINIB S-MALATE TAB 40 MG (BASE EQUIVALENT)          | 21533010100330 | Brand   |
| CABOMETYX                  | CABOZANTINIB S-MALATE TAB 60 MG (BASE EQUIVALENT)          | 21533010100340 | Brand   |
| ZYKADIA                    | CERITINIB TAB 150 MG                                       | 21530514000330 | Brand   |
| XALKORI                    | CRIZOTINIB CAP 200 MG                                      | 21530517000120 | Brand   |
| XALKORI                    | CRIZOTINIB CAP 250 MG                                      | 21530517000125 | Brand   |
| NUBEQA                     | DAROLUTAMIDE TAB 300 MG                                    | 21402425000320 | Brand   |
| SPRYCEL                    | DASATINIB TAB 20 MG  | 21531820000320 | Brand   |
| SPRYCEL                    | DASATINIB TAB 50 MG  | 21531820000340 | Brand   |
| SPRYCEL                    | DASATINIB TAB 70 MG  | 21531820000350 | Brand   |
| SPRYCEL                    | DASATINIB TAB 80 MG  | 21531820000354 | Brand   |
| SPRYCEL                    | DASATINIB TAB 100 MG                                       | 21531820000360 | Brand   |
| SPRYCEL                    | DASATINIB TAB 140 MG                                       | 21531820000380 | Brand   |
| XTANDI                     | ENZALUTAMIDE CAP 40 MG                                     | 21402430000120 | Brand   |
| XTANDI                     | ENZALUTAMIDE TAB 40 MG                                     | 21402430000320 | Brand   |
| XTANDI                     | ENZALUTAMIDE TAB 80 MG                                     | 21402430000340 | Brand   |
| TARCEVA                    | ERLOTINIB HCL TAB 25 MG (BASE<br>EQUIVALENT)               | 21360025100320 | Brand   |
| ERLOTINIB<br>HYDROCHLORIDE | ERLOTINIB HCL TAB 25 MG (BASE EQUIVALENT)                  | 21360025100320 | Generic |
| TARCEVA                    | ERLOTINIB HCL TAB 100 MG (BASE EQUIVALENT)                 | 21360025100330 | Brand   |
| ERLOTINIB<br>HYDROCHLORIDE | ERLOTINIB HCL TAB 100 MG (BASE EQUIVALENT)                 | 21360025100330 | Generic |

| TARCEVA                    | ERLOTINIB HCL TAB 150 MG (BASE EQUIVALENT)      | 21360025100360 | Brand   |
|----------------------------|---|----------------|---------|
| ERLOTINIB<br>HYDROCHLORIDE | ERLOTINIB HCL TAB 150 MG (BASE<br>EQUIVALENT)   | 21360025100360 | Generic |
| EVEROLIMUS                 | EVEROLIMUS TAB 2.5 MG                           | 21532530000310 | Generic |
| AFINITOR                   | EVEROLIMUS TAB 2.5 MG                           | 21532530000310 | Brand   |
| EVEROLIMUS                 | EVEROLIMUS TAB 5 MG                             | 21532530000320 | Generic |
| AFINITOR                   | EVEROLIMUS TAB 5 MG                             | 21532530000320 | Brand   |
| EVEROLIMUS                 | EVEROLIMUS TAB 7.5 MG                           | 21532530000325 | Generic |
| AFINITOR                   | EVEROLIMUS TAB 7.5 MG                           | 21532530000325 | Brand   |
| EVEROLIMUS                 | EVEROLIMUS TAB 10 MG                            | 21532530000330 | Generic |
| AFINITOR                   | EVEROLIMUS TAB 10 MG                            | 21532530000330 | Brand   |
| AFINITOR<br>DISPERZ        | EVEROLIMUS TAB FOR ORAL SUSP 2 MG               | 21532530007310 | Brand   |
| EVEROLIMUS                 | EVEROLIMUS TAB FOR ORAL SUSP 2 MG               | 21532530007310 | Generic |
| AFINITOR<br>DISPERZ        | EVEROLIMUS TAB FOR ORAL SUSP 3 MG               | 21532530007320 | Brand   |
| EVEROLIMUS                 | EVEROLIMUS TAB FOR ORAL SUSP 3 MG               | 21532530007320 | Generic |
| AFINITOR<br>DISPERZ        | EVEROLIMUS TAB FOR ORAL SUSP 5 MG               | 21532530007340 | Brand   |
| EVEROLIMUS                 | EVEROLIMUS TAB FOR ORAL SUSP 5 MG               | 21532530007340 | Generic |
| INREBIC                    | FEDRATINIB HCL CAP 100 MG                       | 21537520200120 | Brand   |
| IRESSA                     | GEFITINIB TAB 250 MG                            | 21360030000320 | Brand   |
| GEFITINIB                  | GEFITINIB TAB 250 MG                            | 21360030000320 | Generic |
| TASIGNA                    | NILOTINIB HCL CAP 50 MG (BASE EQUIVALENT)       | 21531860200110 | Brand   |
| TASIGNA                    | NILOTINIB HCL CAP 150 MG (BASE EQUIVALENT)      | 21531860200115 | Brand   |
| TASIGNA                    | NILOTINIB HCL CAP 200 MG (BASE EQUIVALENT)      | 21531860200125 | Brand   |
| ZEJULA                     | NIRAPARIB TOSYLATE CAP 100 MG (BASE EQUIVALENT) | 21535550200120 | Brand   |
| ZEJULA                     | NIRAPARIB TOSYLATE TAB 100 MG (BASE EQUIVALENT) | 21535550200320 | Brand   |
| ZEJULA                     | NIRAPARIB TOSYLATE TAB 200 MG (BASE EQUIVALENT) | 21535550200330 | Brand   |
| ZEJULA                     | NIRAPARIB TOSYLATE TAB 300 MG (BASE EQUIVALENT) | 21535550200340 | Brand   |
| LYNPARZA                   | OLAPARIB TAB 100 MG                             | 21535560000330 | Brand   |

| LYNPARZA              | OLAPARIB TAB 150 MG                               | 21535560000340 | Brand   |
|-----------------------|---|----------------|---------|
| TAGRISSO              | OSIMERTINIB MESYLATE TAB 40 MG (BASE EQUIVALENT)  | 21360068200320 | Brand   |
| TAGRISSO              | OSIMERTINIB MESYLATE TAB 80 MG (BASE EQUIVALENT)  | 21360068200330 | Brand   |
| VOTRIENT              | PAZOPANIB HCL TAB 200 MG (BASE EQUIV)             | 21533042100320 | Brand   |
| RUBRACA               | RUCAPARIB CAMSYLATE TAB 200 MG (BASE EQUIVALENT)  | 21535570200320 | Brand   |
| RUBRACA               | RUCAPARIB CAMSYLATE TAB 250 MG (BASE EQUIVALENT)  | 21535570200325 | Brand   |
| RUBRACA               | RUCAPARIB CAMSYLATE TAB 300 MG (BASE EQUIVALENT)  | 21535570200330 | Brand   |
| JAKAFI                | RUXOLITINIB PHOSPHATE TAB 5 MG (BASE EQUIVALENT)  | 21537560200310 | Brand   |
| JAKAFI                | RUXOLITINIB PHOSPHATE TAB 10 MG (BASE EQUIVALENT) | 21537560200320 | Brand   |
| JAKAFI                | RUXOLITINIB PHOSPHATE TAB 15 MG (BASE EQUIVALENT) | 21537560200325 | Brand   |
| JAKAFI                | RUXOLITINIB PHOSPHATE TAB 20 MG (BASE EQUIVALENT) | 21537560200330 | Brand   |
| JAKAFI                | RUXOLITINIB PHOSPHATE TAB 25 MG (BASE EQUIVALENT) | 21537560200335 | Brand   |
| RETEVMO               | SELPERCATINIB CAP 40 MG                           | 21535779000120 | Brand   |
| RETEVMO               | SELPERCATINIB CAP 80 MG                           | 21535779000140 | Brand   |
| NEXAVAR               | SORAFENIB TOSYLATE TAB 200 MG (BASE EQUIVALENT)   | 21533060400320 | Brand   |
| SORAFENIB             | SORAFENIB TOSYLATE TAB 200 MG (BASE EQUIVALENT)   | 21533060400320 | Generic |
| SORAFENIB<br>TOSYLATE | SORAFENIB TOSYLATE TAB 200 MG (BASE EQUIVALENT)   | 21533060400320 | Generic |
| SUTENT                | SUNITINIB MALATE CAP 12.5 MG (BASE EQUIVALENT)    | 21533070300120 | Brand   |
| SUNITINIB<br>MALATE   | SUNITINIB MALATE CAP 12.5 MG (BASE EQUIVALENT)    | 21533070300120 | Generic |
| SUTENT                | SUNITINIB MALATE CAP 25 MG (BASE EQUIVALENT)      | 21533070300130 | Brand   |
| SUNITINIB<br>MALATE   | SUNITINIB MALATE CAP 25 MG (BASE EQUIVALENT)      | 21533070300130 | Generic |
| SUTENT                | SUNITINIB MALATE CAP 37.5 MG (BASE EQUIVALENT)    | 21533070300135 | Brand   |
| SUNITINIB<br>MALATE   | SUNITINIB MALATE CAP 37.5 MG (BASE EQUIVALENT)    | 21533070300135 | Generic |
| SUTENT                | SUNITINIB MALATE CAP 50 MG (BASE EQUIVALENT)      | 21533070300140 | Brand   |

| SUNITINIB<br>MALATE | SUNITINIB MALATE CAP 50 MG (BASE EQUIVALENT) | 21533070300140 | Generic |
|---------------------|--|----------------|---------|
| TAZVERIK            | TAZEMETOSTAT HBR TAB 200 MG                  | 21533675200320 | Brand   |
| ZELBORAF            | VEMURAFENIB TAB 240 MG                       | 21532080000320 | Brand   |
| BOSULIF             | BOSUTINIB CAP 50 MG                          | 21531812000120 | Brand   |
| BOSULIF             | BOSUTINIB CAP 100 MG                         | 21531812000130 | Brand   |

- 1 One of the following:
- **1.1** The requested drug is being used alone or in a combination regimen that is FDA-labeled for the treatment of the specific condition the member presents with\*

OR

**1.2** The requested drug is being used alone or in a combination regimen that has a class 1 or 2 recommendation for use from the National Comprehensive Cancer Network (NCCN) in the specific condition of the member\*

OR

- **1.3** The requested drug is being used alone or in a combination regimen that is recommended for use in the specific condition of the member in one of the following:\*
  - United States Pharmacopeia Drug Information
  - American Hospital Formulary Service Drug Information
  - One article in a major peer-reviewed medical journal that recognizes the safety and efficacy of the requested drug in the member's specific condition

#### **AND**

- 2 Prescribed by or in consultation with one of the following:
  - oncologist
  - hematologist
  - other specialist in the treatment of malignancy

| Notes | *Includes any relevant genetic testing, mutations, etc. |
|-------|---|
|-------|---|

Product Name: Bosulif, Cabometyx, Generic erlotinib, Generic everolimus, Generic gefitinib, Generic sorafenib, Generic sunitinib, Inlyta, Inrebic, Jakafi, Lynparza, Nubeqa, Piqray, Retevmo, Rubraca, Sprycel, Tagrisso, Tasigna, Tarceva, Tazverik, Votrient, Xalkori, Xtandi, Zejula, Zelboraf, Zykadia

| Approval Length | 12 month(s)                    |
|-----------------|--------------------------------|
| Therapy Stage   | Reauthorization                |
| Guideline Type  | Prior Authorization - MN Plans |

| Product Name               | Generic Name   | GPI            | Brand/Generic |
|----------------------------|--|----------------|---------------|
| PIQRAY 200MG<br>DAILY DOSE | ALPELISIB TAB THERAPY PACK 200 MG DAILY DOSE               | 2153801000B720 | Brand         |
| PIQRAY 250MG<br>DAILY DOSE | ALPELISIB TAB PACK 250 MG DAILY DOSE (200 MG & 50 MG TABS) | 2153801000B725 | Brand         |
| PIQRAY 300MG<br>DAILY DOSE | ALPELISIB TAB PACK 300 MG DAILY DOSE (2X150 MG TAB)        | 2153801000B730 | Brand         |
| INLYTA                     | AXITINIB TAB 1 MG  | 21335013000320 | Brand         |
| INLYTA                     | AXITINIB TAB 5 MG  | 21335013000340 | Brand         |
| BOSULIF                    | BOSUTINIB TAB 100 MG                                       | 21531812000320 | Brand         |
| BOSULIF                    | BOSUTINIB TAB 400 MG                                       | 21531812000327 | Brand         |
| BOSULIF                    | BOSUTINIB TAB 500 MG                                       | 21531812000340 | Brand         |
| CABOMETYX                  | CABOZANTINIB S-MALATE TAB 20 MG (BASE EQUIVALENT)          | 21533010100320 | Brand         |
| CABOMETYX                  | CABOZANTINIB S-MALATE TAB 40 MG (BASE EQUIVALENT)          | 21533010100330 | Brand         |
| CABOMETYX                  | CABOZANTINIB S-MALATE TAB 60 MG (BASE EQUIVALENT)          | 21533010100340 | Brand         |
| ZYKADIA                    | CERITINIB TAB 150 MG                                       | 21530514000330 | Brand         |
| XALKORI                    | CRIZOTINIB CAP 200 MG                                      | 21530517000120 | Brand         |
| XALKORI                    | CRIZOTINIB CAP 250 MG                                      | 21530517000125 | Brand         |
| NUBEQA                     | DAROLUTAMIDE TAB 300 MG                                    | 21402425000320 | Brand         |
| SPRYCEL                    | DASATINIB TAB 20 MG  | 21531820000320 | Brand         |
| SPRYCEL                    | DASATINIB TAB 50 MG  | 21531820000340 | Brand         |
| SPRYCEL                    | DASATINIB TAB 70 MG  | 21531820000350 | Brand         |
| SPRYCEL                    | DASATINIB TAB 80 MG  | 21531820000354 | Brand         |
| SPRYCEL                    | DASATINIB TAB 100 MG                                       | 21531820000360 | Brand         |

| SPRYCEL                    | DASATINIB TAB 140 MG                             | 21531820000380 | Brand   |
|----------------------------|--|----------------|---------|
| XTANDI                     | ENZALUTAMIDE CAP 40 MG                           | 21402430000120 | Brand   |
| XTANDI                     | ENZALUTAMIDE TAB 40 MG                           | 21402430000320 | Brand   |
| XTANDI                     | ENZALUTAMIDE TAB 80 MG                           | 21402430000340 | Brand   |
| ERLOTINIB<br>HYDROCHLORIDE | ERLOTINIB HCL TAB 25 MG (BASE<br>EQUIVALENT)     | 21360025100320 | Generic |
| ERLOTINIB<br>HYDROCHLORIDE | ERLOTINIB HCL TAB 100 MG (BASE EQUIVALENT)       | 21360025100330 | Generic |
| ERLOTINIB<br>HYDROCHLORIDE | ERLOTINIB HCL TAB 150 MG (BASE EQUIVALENT)       | 21360025100360 | Generic |
| EVEROLIMUS                 | EVEROLIMUS TAB 2.5 MG                            | 21532530000310 | Generic |
| EVEROLIMUS                 | EVEROLIMUS TAB 5 MG                              | 21532530000320 | Generic |
| EVEROLIMUS                 | EVEROLIMUS TAB 7.5 MG                            | 21532530000325 | Generic |
| EVEROLIMUS                 | EVEROLIMUS TAB 10 MG                             | 21532530000330 | Generic |
| EVEROLIMUS                 | EVEROLIMUS TAB FOR ORAL SUSP 2 MG                | 21532530007310 | Generic |
| EVEROLIMUS                 | EVEROLIMUS TAB FOR ORAL SUSP 3 MG                | 21532530007320 | Generic |
| EVEROLIMUS                 | EVEROLIMUS TAB FOR ORAL SUSP 5 MG                | 21532530007340 | Generic |
| INREBIC                    | FEDRATINIB HCL CAP 100 MG                        | 21537520200120 | Brand   |
| GEFITINIB                  | GEFITINIB TAB 250 MG                             | 21360030000320 | Generic |
| TASIGNA                    | NILOTINIB HCL CAP 50 MG (BASE EQUIVALENT)        | 21531860200110 | Brand   |
| TASIGNA                    | NILOTINIB HCL CAP 150 MG (BASE EQUIVALENT)       | 21531860200115 | Brand   |
| TASIGNA                    | NILOTINIB HCL CAP 200 MG (BASE EQUIVALENT)       | 21531860200125 | Brand   |
| ZEJULA                     | NIRAPARIB TOSYLATE CAP 100 MG (BASE EQUIVALENT)  | 21535550200120 | Brand   |
| ZEJULA                     | NIRAPARIB TOSYLATE TAB 100 MG (BASE EQUIVALENT)  | 21535550200320 | Brand   |
| ZEJULA                     | NIRAPARIB TOSYLATE TAB 200 MG (BASE EQUIVALENT)  | 21535550200330 | Brand   |
| ZEJULA                     | NIRAPARIB TOSYLATE TAB 300 MG (BASE EQUIVALENT)  | 21535550200340 | Brand   |
| LYNPARZA                   | OLAPARIB TAB 100 MG                              | 21535560000330 | Brand   |
| LYNPARZA                   | OLAPARIB TAB 150 MG                              | 21535560000340 | Brand   |
| TAGRISSO                   | OSIMERTINIB MESYLATE TAB 40 MG (BASE EQUIVALENT) | 21360068200320 | Brand   |
| TAGRISSO                   | OSIMERTINIB MESYLATE TAB 80 MG (BASE EQUIVALENT) | 21360068200330 | Brand   |

| VOTRIENT              | PAZOPANIB HCL TAB 200 MG (BASE EQUIV)             | 21533042100320 | Brand   |
|-----------------------|---|----------------|---------|
| RUBRACA               | RUCAPARIB CAMSYLATE TAB 200 MG (BASE EQUIVALENT)  | 21535570200320 | Brand   |
| RUBRACA               | RUCAPARIB CAMSYLATE TAB 250 MG (BASE EQUIVALENT)  | 21535570200325 | Brand   |
| RUBRACA               | RUCAPARIB CAMSYLATE TAB 300 MG (BASE EQUIVALENT)  | 21535570200330 | Brand   |
| JAKAFI                | RUXOLITINIB PHOSPHATE TAB 5 MG (BASE EQUIVALENT)  | 21537560200310 | Brand   |
| JAKAFI                | RUXOLITINIB PHOSPHATE TAB 10 MG (BASE EQUIVALENT) | 21537560200320 | Brand   |
| JAKAFI                | RUXOLITINIB PHOSPHATE TAB 15 MG (BASE EQUIVALENT) | 21537560200325 | Brand   |
| JAKAFI                | RUXOLITINIB PHOSPHATE TAB 20 MG (BASE EQUIVALENT) | 21537560200330 | Brand   |
| JAKAFI                | RUXOLITINIB PHOSPHATE TAB 25 MG (BASE EQUIVALENT) | 21537560200335 | Brand   |
| RETEVMO               | SELPERCATINIB CAP 40 MG                           | 21535779000120 | Brand   |
| RETEVMO               | SELPERCATINIB CAP 80 MG                           | 21535779000140 | Brand   |
| SORAFENIB             | SORAFENIB TOSYLATE TAB 200 MG (BASE EQUIVALENT)   | 21533060400320 | Generic |
| SORAFENIB<br>TOSYLATE | SORAFENIB TOSYLATE TAB 200 MG (BASE EQUIVALENT)   | 21533060400320 | Generic |
| SUNITINIB<br>MALATE   | SUNITINIB MALATE CAP 12.5 MG (BASE EQUIVALENT)    | 21533070300120 | Generic |
| SUNITINIB<br>MALATE   | SUNITINIB MALATE CAP 25 MG (BASE EQUIVALENT)      | 21533070300130 | Generic |
| SUNITINIB<br>MALATE   | SUNITINIB MALATE CAP 37.5 MG (BASE EQUIVALENT)    | 21533070300135 | Generic |
| SUNITINIB<br>MALATE   | SUNITINIB MALATE CAP 50 MG (BASE EQUIVALENT)      | 21533070300140 | Generic |
| TAZVERIK              | TAZEMETOSTAT HBR TAB 200 MG                       | 21533675200320 | Brand   |
| ZELBORAF              | VEMURAFENIB TAB 240 MG                            | 21532080000320 | Brand   |
| BOSULIF               | BOSUTINIB CAP 50 MG                               | 21531812000120 | Brand   |
| BOSULIF               | BOSUTINIB CAP 100 MG                              | 21531812000130 | Brand   |

- 1 One of the following:
- **1.1** The requested drug is being used alone or in a combination regimen that is FDA-labeled for the treatment of the specific condition the member presents with\*

OR

**1.2** The requested drug is being used alone or in a combination regimen that has a class 1 or 2 recommendation for use from the National Comprehensive Cancer Network (NCCN) in the specific condition of the member\*

OR

- **1.3** The requested drug is being used alone or in a combination regimen that is recommended for use in the specific condition of the member in one of the following:\*
  - United States Pharmacopeia Drug Information
  - American Hospital Formulary Service Drug Information
  - One article in a major peer-reviewed medical journal that recognizes the safety and efficacy of the requested drug in the member's specific condition

#### **AND**

- 2 Prescribed by or in consultation with one of the following:
  - oncologist
  - hematologist
  - other specialist in the treatment of malignancy

| Notes | *Includes any relevant genetic testing, mutations, etc. |
|-------|---|
|-------|---|

# 2. Revision History

| Date      | Notes  |
|-----------|--|
| 2/14/2024 | Update program – Bosulif capsules added criteria |

| R         | Restricted Paroxetine   |  |  |
|-----------|---|--|--|
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|           |   |  |  |

# **Prior Authorization Guideline**

| Guideline ID          | GL-131421             |
|-----------------------|-----------------------|
| <b>Guideline Name</b> | Restricted Paroxetine |
| Formulary             | Quartz                |

# **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

# 1. Criteria

| Product Name: Paroxetine mesylate                       |  |  |
|---|--|--|
| Approval Length 12 month(s)                             |  |  |
| Therapy Stage Initial Authorization                     |  |  |
| Guideline Type Prior Authorization-IL and MN Plans Only |  |  |

| Product<br>Name | Generic Name                                | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| PAROXETINE      | PAROXETINE MESYLATE CAP 7.5 MG (BASE EQUIV) | 62226060300110 | Generic       |

# **Approval Criteria**

1 - Diagnosis of vasomotor symptoms due to menopause

#### **AND**

2 - Failure of a trial of generic paroxetine (Paxil generic) at an equivalent dose

## AND

**3** - The prescriber provides an evidence-based clinical rationale for why the requested formulation would provide different results.

| Product Name: Paroxetine mesylate                       |  |  |
|---|--|--|
| Approval Length 12 month(s)                             |  |  |
| Therapy Stage Reauthorization                           |  |  |
| Guideline Type Prior Authorization-IL and MN Plans Only |  |  |

| Product<br>Name | Generic Name                                | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| PAROXETINE      | PAROXETINE MESYLATE CAP 7.5 MG (BASE EQUIV) | 62226060300110 | Generic       |

## **Approval Criteria**

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug.

| Product Name: Paroxetine mesylate                             |  |  |
|---|--|--|
| Approval Length 12/31/2039                                    |  |  |
| Guideline Type Prior Authorization-All plans except IL and MN |  |  |

| Product<br>Name | Generic Name                                | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| PAROXETINE      | PAROXETINE MESYLATE CAP 7.5 MG (BASE EQUIV) | 62226060300110 | Generic       |

### **Approval Criteria**

1 - Diagnosis of vasomotor symptoms due to menopause

### **AND**

2 - Failure of a trial of generic paroxetine (Paxil generic) at an equivalent dose

### **AND**

**3** - The prescriber provides an evidence-based clinical rationale for why the requested formulation would provide different results.

# 2. Revision History

| Date       | Notes       |
|------------|-------------|
| 10/16/2023 | New program |

| Rest                    | tricted Pl  | nosphate   | Binders |  |
|-------------------------|---|--|---------|--|
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|                         |   |  |         |  |

# **Prior Authorization Guideline**

| Guideline ID   | GL-131422                    |  |
|----------------|------------------------------|--|
| Guideline Name | Restricted Phosphate Binders |  |
| Formulary      | Quartz                       |  |

# **Guideline Note:**

| Effective Date: |
|-----------------|
|-----------------|

# 1. Criteria

| Product Name: Velphoro                                  |  |
|---|--|
| Approval Length 12 month(s)                             |  |
| Therapy Stage Initial Authorization                     |  |
| Guideline Type Prior Authorization-IL and MN Plans Only |  |

| Product<br>Name | Generic Name                             | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| VELPHORO        | SUCROFERRIC OXYHYDROXIDE CHEW TAB 500 MG | 52800080100520 | Brand         |

# **Approval Criteria**

1 - Diagnosis of chronic kidney disease (CKD) requiring dialysis

#### AND

**2** - Trial and failure, contraindication, or intolerance to BOTH a sevelamer product (e.g. Renagel, Renvela) and lanthanum (Fosrenol)

| Product Name: Velphoro                                  |                 |
|---|-----------------|
| Approval Length 12 month(s)                             |                 |
| Therapy Stage   | Reauthorization |
| Guideline Type Prior Authorization-IL and MN Plans Only |                 |

| Product<br>Name | Generic Name                             | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| VELPHORO        | SUCROFERRIC OXYHYDROXIDE CHEW TAB 500 MG | 52800080100520 | Brand         |

### **Approval Criteria**

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug.

| Product Name: Velphoro  |  |
|---|--|
| Approval Length 12/31/2039                                    |  |
| Guideline Type Prior Authorization-All plans except IL and MN |  |

| Product<br>Name | Generic Name                             | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| VELPHORO        | SUCROFERRIC OXYHYDROXIDE CHEW TAB 500 MG | 52800080100520 | Brand         |

### **Approval Criteria**

1 - Diagnosis of chronic kidney disease (CKD) requiring dialysis

#### AND

**2** - Trial and failure, contraindication, or intolerance to BOTH a sevelamer product (e.g. Renagel, Renvela) and lanthanum (Fosrenol)

# 2. Revision History

| Date      | Notes       |
|-----------|-------------|
| 10/9/2023 | New Program |

| Restricted Progesterone                                  |  |  |  |
|--|--|--|--|
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# **Prior Authorization Guideline**

| Guideline ID          | GL-137000               |
|-----------------------|-------------------------|
| <b>Guideline Name</b> | Restricted Progesterone |
| Formulary             | Quartz                  |

# **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

# 1. Criteria

| Product Name: Crinone, Endometrin, progesterone injection |                                     |  |
|---|-------------------------------------|--|
| Diagnosis Pregnancy                                       |                                     |  |
| Approval Length   | 12 month(s)                         |  |
| Therapy Stage   | Therapy Stage Initial Authorization |  |
| Guideline Type Prior Authorization - IL and MN Plans Only |                                     |  |

| Product Name | Generic Name                       | GPI            | Brand/Generic |
|--------------|------------------------------------|----------------|---------------|
| CRINONE      | PROGESTERONE VAGINAL GEL 4%        | 55370060004010 | Brand         |
| CRINONE      | PROGESTERONE VAGINAL GEL 8%        | 55370060004020 | Brand         |
| ENDOMETRIN   | PROGESTERONE VAGINAL INSERT 100 MG | 55370060009910 | Brand         |
| PROGESTERONE | PROGESTERONE IM IN OIL 50 MG/ML    | 26000040001705 | Generic       |

- **1** One of the following:
- **1.1** For members in the 1st trimester of pregnancy, ALL of the following:
  - Submission of medical records (e.g., chart notes) documenting member is pregnant
  - Prescriber determines that progesterone is to maintain pregnancy
  - For Progesterone Injection requests ONLY: The drug is being self-administered

- **1.2** For members in the 2nd trimester of pregnancy, ALL of the following:
  - For Progesterone Injection requests ONLY: The drug is being self-administered
  - Submission of medical records (e.g., chart notes) documenting a singleton pregnancy
  - Submission of medical records (e.g., chart notes) documenting member has a history of preterm birth

| Notes | *Member new to the plan (as evidenced by coverage effective date of I ess than or equal to 90 days) who initiated therapy using a manufactur er-sponsored free drug program, provider samples, and/or vouchers wil I go through initial criteria, otherwise for continuation of therapy for new to plan, reauthorization criteria applies |
|-------|---|
|       | *Continuation of therapy/coverage criteria will not be applied to person s who were not previously approved for coverage whose therapy was i nitiated using a manufacturer-sponsored free drug program, provider s amples, and/or vouchers.   |

| Product Name: Crinone, Endometrin, progesterone injection |                               |  |
|---|-------------------------------|--|
| Diagnosis Pregnancy                                       |                               |  |
| Approval Length   | 12 month(s)                   |  |
| Therapy Stage   | Therapy Stage Reauthorization |  |
| Guideline Type Prior Authorization - IL and MN Plans Only |                               |  |

| Product Name | Generic Name GPI Brand                             |                      | Brand/Generic |
|--------------|--|----------------------|---------------|
| CRINONE      | PROGESTERONE VAGINAL GEL 4%                        | 55370060004010 Brand |               |
| CRINONE      | PROGESTERONE VAGINAL GEL 8%                        | 55370060004020       | Brand         |
| ENDOMETRIN   | PROGESTERONE VAGINAL INSERT 100 MG                 | 55370060009910       | Brand         |
| PROGESTERONE | DGESTERONE IM IN OIL 50 MG/ML 26000040001705 Gener |                      | Generic       |

- **1** One of the following:
- **1.1** For members in the 1st trimester of pregnancy, ALL of the following:
  - Submission of medical records (e.g., chart notes) documenting member is pregnant
  - Prescriber determines that progesterone is to maintain pregnancy
  - For Progesterone Injection requests ONLY: The drug is being self-administered

- **1.2** For members in the 2nd trimester of pregnancy, ALL of the following:
  - For Progesterone Injection requests ONLY: The drug is being self-administered
  - Submission of medical records (e.g., chart notes) documenting a singleton pregnancy
  - Submission of medical records (e.g., chart notes) documenting member has a history of preterm birth

| Notes | *Member new to the plan (as evidenced by coverage effective date of I ess than or equal to 90 days) who initiated therapy using a manufactur er-sponsored free drug program, provider samples, and/or vouchers wil I go through initial criteria, otherwise for continuation of therapy for new to plan, reauthorization criteria applies |
|-------|---|
|       | *Continuation of therapy/coverage criteria will not be applied to person s who were not previously approved for coverage whose therapy was i nitiated using a manufacturer-sponsored free drug program, provider s amples, and/or vouchers.   |

| Product Name: Crinone, Endometrin, progesterone injection       |   |               |  |  |
|---|---|---------------|--|--|
| Diagnosis   | Pregnancy   | Pregnancy     |  |  |
| Approval Length   | Approval Length 1st trimester use = 4 months. 2nd trimester use = 6 months. |               |  |  |
| Therapy Stage Initial Authorization                             |   |               |  |  |
| Guideline Type Prior Authorization - All plans except IL and MN |   |               |  |  |
| Product Name Generic Name GPI Brand/Ge                          |   | Brand/Generic |  |  |

| Product Name | Generic Name                               | Brand/Generic  |       |
|--------------|--|----------------|-------|
| CRINONE      | PROGESTERONE VAGINAL GEL 4%                | 55370060004010 | Brand |
| CRINONE      | PROGESTERONE VAGINAL GEL 8% 55370060004020 |                | Brand |

| ENDOMETRIN   | PROGESTERONE VAGINAL INSERT 100 MG | 55370060009910 | Brand   |
|--------------|------------------------------------|----------------|---------|
| PROGESTERONE | PROGESTERONE IM IN OIL 50 MG/ML    | 26000040001705 | Generic |

- **1** One of the following:
- **1.1** For members in the 1st trimester of pregnancy, ALL of the following:
  - Submission of medical records (e.g., chart notes) documenting member is pregnant
  - Prescriber determines that progesterone is to maintain pregnancy
  - For Progesterone Injection requests ONLY: The drug is being self-administered

- **1.2** For members in the 2nd trimester of pregnancy, ALL of the following:
  - For Progesterone Injection requests ONLY: The drug is being self-administered
  - Submission of medical records (e.g., chart notes) documenting a singleton pregnancy
  - Submission of medical records (e.g., chart notes) documenting member has a history of preterm birth

| Notes | *Member new to the plan (as evidenced by coverage effective date of I ess than or equal to 90 days) who initiated therapy using a manufactur er-sponsored free drug program, provider samples, and/or vouchers wil I go through initial criteria, otherwise for continuation of therapy for new to plan, reauthorization criteria applies |
|-------|---|
|       | *Continuation of therapy/coverage criteria will not be applied to person s who were not previously approved for coverage whose therapy was i nitiated using a manufacturer-sponsored free drug program, provider s amples, and/or vouchers.   |

| Product Name: Crinone, Endometrin, progesterone injection |   |  |               |
|---|---|--|---------------|
| Diagnosis   | Pregnancy   |  |               |
| Approval Length   | 1st trimester use = 4 months. 2nd trimester use = 6 months. |  |               |
| Therapy Stage   | Reauthorization   |  |               |
| Guideline Type  | Prior Authorization - All plans except IL and MN            |  |               |
| Product Name Generic Name GPI Brand/Gener                 |   |  | Brand/Generic |

| CRINONE      | PROGESTERONE VAGINAL GEL 4% 55370060004010 Brand |                | Brand   |
|--------------|--|----------------|---------|
| CRINONE      | PROGESTERONE VAGINAL GEL 8% 55370060004020 Bra   |                | Brand   |
| ENDOMETRIN   | PROGESTERONE VAGINAL INSERT 100 MG               | 55370060009910 | Brand   |
| PROGESTERONE | PROGESTERONE IM IN OIL 50 MG/ML                  | 26000040001705 | Generic |

- **1** One of the following:
- **1.1** For members in the 1st trimester of pregnancy, ALL of the following:
  - For Progesterone Injection requests ONLY: The drug is being self-administered
  - Submission of medical records (e.g., chart notes) documenting member is pregnant
  - Prescriber determines that progesterone is to maintain pregnancy

- **1.2** For members in the 2nd trimester of pregnancy, ALL of the following:
  - For Progesterone Injection requests ONLY: The drug is being self-administered
  - Submission of medical records (e.g., chart notes) documenting a singleton pregnancy
  - Submission of medical records (e.g., chart notes) documenting member has a history of preterm birth

| Notes | *Member new to the plan (as evidenced by coverage effective date of I ess than or equal to 90 days) who initiated therapy using a manufactur er-sponsored free drug program, provider samples, and/or vouchers wil I go through initial criteria, otherwise for continuation of therapy for new to plan, reauthorization criteria applies |
|-------|---|
|       | *Continuation of therapy/coverage criteria will not be applied to person s who were not previously approved for coverage whose therapy was i nitiated using a manufacturer-sponsored free drug program, provider s amples, and/or vouchers.   |

| Product Name: Crinone, Endometrin, progesterone injection |                       |  |
|---|-----------------------|--|
| Diagnosis   | Infertility           |  |
| Approval Length   | 12 month(s)           |  |
| Therapy Stage   | Initial Authorization |  |

| Guideline Type |      | Prior Authorization - IL Plan  |                |               |
|----------------|------|--------------------------------|----------------|---------------|
| Product Name   | Gene | ric Name                       | GPI            | Brand/Generic |
| CRINONE        | PROG | ESTERONE VAGINAL GEL 4%        | 55370060004010 | Brand         |
| CRINONE        | PROG | ESTERONE VAGINAL GEL 8%        | 55370060004020 | Brand         |
| ENDOMETRIN     | PROG | ESTERONE VAGINAL INSERT 100 MG | 55370060009910 | Brand         |
| PROGESTERONE   | PROG | ESTERONE IM IN OIL 50 MG/ML    | 26000040001705 | Generic       |

1 - Quartz plan issued in the state of Illinois

#### AND

 ${\bf 2}$  - Provider attests patient has infertility coverage as outlined in Illinois Insurance Code 215 ILCS 5/356m

| Notes | *Member new to the plan (as evidenced by coverage effective date of I ess than or equal to 90 days) who initiated therapy using a manufactur er-sponsored free drug program, provider samples, and/or vouchers wil I go through initial criteria, otherwise for continuation of therapy for new to plan, reauthorization criteria applies |
|-------|---|
|       | *Continuation of therapy/coverage criteria will not be applied to person s who were not previously approved for coverage whose therapy was i nitiated using a manufacturer-sponsored free drug program, provider s amples, and/or vouchers.   |

| Product Name: Crinone, Endometrin, progesterone injection |                                      |         |  |
|---|--------------------------------------|---------|--|
| Diagnosis   | Infertility                          |         |  |
| Approval Length   | 12 month(s)                          |         |  |
| Therapy Stage   | Reauthorization                      |         |  |
| Guideline Type  | e Type Prior Authorization - IL Plan |         |  |
|   |                                      | D 1/0 : |  |

| Product Name | Generic Name                       | GPI            | Brand/Generic |
|--------------|------------------------------------|----------------|---------------|
| CRINONE      | PROGESTERONE VAGINAL GEL 4%        | 55370060004010 | Brand         |
| CRINONE      | PROGESTERONE VAGINAL GEL 8%        | 55370060004020 | Brand         |
| ENDOMETRIN   | PROGESTERONE VAGINAL INSERT 100 MG | 55370060009910 | Brand         |

| PROGESTERONE PRO   | GESTERONE IM IN OIL 50 MG/ML  | 26000040001705    | Generic          |
|--|---|-------------------|------------------|
| Ammunual Oritania  |   |                   |                  |
| Approval Criteria  |   |                   |                  |
| <b>1</b> - Quartz plan issued  | d in the state of Illinois  |                   |                  |
|  |   |                   |                  |
|  | AND   |                   |                  |
|  |   |                   |                  |
| 2 - Provider attests patient has infertility coverage as outlined in Illinois Insurance Code 215 ILCS 5/356m |   |                   | ce Code 215      |
| Notes  | *Member new to the plan (as evidenced by coverage effective date of I ess than or equal to 90 days) who initiated therapy using a manufactur er-sponsored free drug program, provider samples, and/or vouchers wil I go through initial criteria, otherwise for continuation of therapy for new to plan, reauthorization criteria applies |                   |                  |
|  | *Continuation of therapy/coverage cr<br>s who were not previously approved<br>nitiated using a manufacturer-sponso<br>amples, and/or vouchers.  | for coverage whos | se therapy was i |

# 2. Revision History

| Date       | Notes                                  |
|------------|--|
| 11/28/2023 | Updated provider attestation verbiage. |

| Restricte   | d Tacrolimus Formulations                                   |
|---|---|
| The detail longs served to rightly of The Bit Ray State Seat near | de mand a desse del la cida de provincia de manda de manda. |

# **Prior Authorization Guideline**

| Guideline ID          | GL-129869                          |
|-----------------------|------------------------------------|
| <b>Guideline Name</b> | Restricted Tacrolimus Formulations |
| Formulary             | Quartz                             |

# **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

# 1. Criteria

| Product Name: Prograf granule packets |                                       |
|---------------------------------------|---------------------------------------|
| Approval Length                       | 12 month(s)                           |
| Therapy Stage                         | Initial Authorization                 |
| Guideline Type                        | Prior Authorization - IL and MN Plans |

| Product<br>Name | Generic Name                      | GPI            | Brand/Generic |
|-----------------|-----------------------------------|----------------|---------------|
| PROGRAF         | TACROLIMUS PACKET FOR SUSP 0.2 MG | 99404080003010 | Brand         |
| PROGRAF         | TACROLIMUS PACKET FOR SUSP 1 MG   | 99404080003030 | Brand         |

# **Approval Criteria**

1 - Member has swallowing impairment or other medical condition that prevents use of solid

dose forms

#### **AND**

- 2 One of the following:
- **2.1** Trial and failure, contraindication, or intolerance to an adequate trial of an alternative (e.g. sirolimus, cyclosporine)

OR

**2.2** Submission of medical records (e.g., chart notes) documenting evidence-based rationale for why the alternatives would not be medically appropriate for the member's condition

| Product Name: Astagraf XL, Envarsus XR |                                       |
|--|---------------------------------------|
| Approval Length                        | 12 month(s)                           |
| Therapy Stage                          | Initial Authorization                 |
| Guideline Type                         | Prior Authorization - IL and MN Plans |

| Product<br>Name | Generic Name                   | GPI            | Brand/Generic |
|-----------------|--------------------------------|----------------|---------------|
| ASTAGRAF<br>XL  | TACROLIMUS CAP ER 24HR 0.5 MG  | 99404080007005 | Brand         |
| ASTAGRAF<br>XL  | TACROLIMUS CAP ER 24HR 1 MG    | 99404080007010 | Brand         |
| ASTAGRAF<br>XL  | TACROLIMUS CAP ER 24HR 5 MG    | 99404080007020 | Brand         |
| ENVARSUS<br>XR  | TACROLIMUS TAB ER 24HR 0.75 MG | 99404080007510 | Brand         |
| ENVARSUS<br>XR  | TACROLIMUS TAB ER 24HR 1 MG    | 99404080007515 | Brand         |
| ENVARSUS<br>XR  | TACROLIMUS TAB ER 24HR 4 MG    | 99404080007520 | Brand         |

#### **Approval Criteria**

**1** - Trial and failure (documented inability to achieve goal trough drug levels despite appropriate dose adjustment and teaching/adherence interventions from a pharmacist and other health care providers) or intolerance of immediate release tacrolimus

| Product Name: Prograf granule packets, Astagraf XL, Envarsus XR |                                       |
|---|---------------------------------------|
| Approval Length   | 12 month(s)                           |
| Therapy Stage   | Reauthorization                       |
| Guideline Type  | Prior Authorization - IL and MN Plans |

| Product<br>Name | Generic Name                      | GPI            | Brand/Generic |
|-----------------|-----------------------------------|----------------|---------------|
| PROGRAF         | TACROLIMUS PACKET FOR SUSP 0.2 MG | 99404080003010 | Brand         |
| PROGRAF         | TACROLIMUS PACKET FOR SUSP 1 MG   | 99404080003030 | Brand         |
| ASTAGRAF<br>XL  | TACROLIMUS CAP ER 24HR 0.5 MG     | 99404080007005 | Brand         |
| ASTAGRAF<br>XL  | TACROLIMUS CAP ER 24HR 1 MG       | 99404080007010 | Brand         |
| ASTAGRAF<br>XL  | TACROLIMUS CAP ER 24HR 5 MG       | 99404080007020 | Brand         |
| ENVARSUS<br>XR  | TACROLIMUS TAB ER 24HR 0.75 MG    | 99404080007510 | Brand         |
| ENVARSUS<br>XR  | TACROLIMUS TAB ER 24HR 1 MG       | 99404080007515 | Brand         |
| ENVARSUS<br>XR  | TACROLIMUS TAB ER 24HR 4 MG       | 99404080007520 | Brand         |

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug

| Product Name: Prograf granule packets                                 |  |  |
|---|--|--|
| Approval Length 12/31/2039  |  |  |
| Guideline Type Prior Authorization - All Plans Except IL and MN Plans |  |  |

| Product<br>Name | Generic Name                      | GPI            | Brand/Generic |
|-----------------|-----------------------------------|----------------|---------------|
| PROGRAF         | TACROLIMUS PACKET FOR SUSP 0.2 MG | 99404080003010 | Brand         |
| PROGRAF         | TACROLIMUS PACKET FOR SUSP 1 MG   | 99404080003030 | Brand         |

# **Approval Criteria**

**1** - Member has swallowing impairment or other medical condition that prevents use of solid dose forms

#### **AND**

- **2** One of the following:
- **2.1** Trial and failure, contraindication, or intolerance to an adequate trial of an alternative (e.g. sirolimus, cyclosporine)

#### OR

**2.2** Submission of medical records (e.g., chart notes) documenting evidence-based rationale for why the alternatives would not be medically appropriate for the member's condition

| Product Name: Astagraf XL, Envarsus XR |  |
|--|--|
| Approval Length 12/31/2039             |  |
| Guideline Type                         | Prior Authorization - All Plans Except IL and MN Plans |

| Product<br>Name | Generic Name GPI               |                | Brand/Generic |
|-----------------|--------------------------------|----------------|---------------|
| ASTAGRAF<br>XL  | TACROLIMUS CAP ER 24HR 0.5 MG  | 99404080007005 | Brand         |
| ASTAGRAF<br>XL  | TACROLIMUS CAP ER 24HR 1 MG    | 99404080007010 | Brand         |
| ASTAGRAF<br>XL  | TACROLIMUS CAP ER 24HR 5 MG    | 99404080007020 | Brand         |
| ENVARSUS<br>XR  | TACROLIMUS TAB ER 24HR 0.75 MG | 99404080007510 | Brand         |
| ENVARSUS<br>XR  | TACROLIMUS TAB ER 24HR 1 MG    | 99404080007515 | Brand         |
| ENVARSUS<br>XR  | TACROLIMUS TAB ER 24HR 4 MG    | 99404080007520 | Brand         |

### **Approval Criteria**

**1** - Trial and failure (documented inability to achieve goal trough drug levels despite appropriate dose adjustment and teaching/adherence interventions from a pharmacist and other health care providers) or intolerance of immediate release tacrolimus

# 2. Revision History

| Date       | Notes                   |
|------------|-------------------------|
| 10/12/2023 | 2024 New Implementation |

| Retinoid Products  |  |  |  |
|--|--|--|--|
| (g) The hand they ment to heighter. The has to be been soon, seemed, a state to be had to be published to constitute |  |  |  |

# **Prior Authorization Guideline**

| Guideline ID          | GL-131450         |
|-----------------------|-------------------|
| <b>Guideline Name</b> | Retinoid Products |
| Formulary             | Quartz            |

# **Guideline Note:**

| Effective Date: |
|-----------------|
|-----------------|

# 1. Criteria

| Product Name: Tretinoin, OTC adapalene, Brand Avita |   |  |                |               |
|---|---|--|----------------|---------------|
| Approval Length                                     |   | 12/31/2039   |                |               |
| Guideline Type                                      |   | Prior Authorization - All plans except IL and MN Plans |                |               |
| Product<br>Name                                     | Generic Name                            |  | GPI            | Brand/Generic |
| DIFFERIN  | ADAPALENE GEL 0.1%                      |  | 90050003004010 | Brand         |
| CVS<br>ADAPALENE                                    | ADAPALENE GEL 0.1%                      |  | 90050003004010 | Generic       |
| ADAPALENE   | ADAPALENE GEL 0.1%                      |  | 90050003004010 | Generic       |
| ADAPALENE<br>TREATMENT                              | ADAPALENE GEL 0.1%                      |  | 90050003004010 | Generic       |
| ALTRENO   | TRETINOIN LOTION 0.05%                  |  | 90050030004130 | Brand         |
| TRETINOIN   | TRETINOIN CREAM 0.025% 90050030003703 G |  | Generic        |               |

| TRETINOIN | TRETINOIN CREAM 0.05%  | 90050030003705 | Generic |
|-----------|------------------------|----------------|---------|
| TRETINOIN | TRETINOIN CREAM 0.1%   | 90050030003710 | Generic |
| TRETINOIN | TRETINOIN GEL 0.01%    | 90050030004005 | Generic |
| TRETINOIN | TRETINOIN GEL 0.025%   | 90050030004010 | Generic |
| TRETINOIN | TRETINOIN GEL 0.05%    | 90050030004015 | Generic |
| AVITA     | TRETINOIN CREAM 0.025% | 90050030003703 | Brand   |

1 - Diagnosis of acne or rosacea

| Product Name: Tretinoin, OTC adapalene, Brand Avita |                                       |  |
|---|---------------------------------------|--|
| Approval Length                                     | 12 month(s)                           |  |
| Therapy Stage                                       | Initial Authorization                 |  |
| Guideline Type                                      | Prior Authorization - IL and MN Plans |  |

| Product<br>Name        | Generic Name           | GPI            | Brand/Generic |
|------------------------|------------------------|----------------|---------------|
| DIFFERIN               | ADAPALENE GEL 0.1%     | 90050003004010 | Brand         |
| CVS<br>ADAPALENE       | ADAPALENE GEL 0.1%     | 90050003004010 | Generic       |
| ADAPALENE              | ADAPALENE GEL 0.1%     | 90050003004010 | Generic       |
| ADAPALENE<br>TREATMENT | ADAPALENE GEL 0.1%     | 90050003004010 | Generic       |
| ALTRENO                | TRETINOIN LOTION 0.05% | 90050030004130 | Brand         |
| TRETINOIN              | TRETINOIN CREAM 0.025% | 90050030003703 | Generic       |
| TRETINOIN              | TRETINOIN CREAM 0.05%  | 90050030003705 | Generic       |
| TRETINOIN              | TRETINOIN CREAM 0.1%   | 90050030003710 | Generic       |
| TRETINOIN              | TRETINOIN GEL 0.01%    | 90050030004005 | Generic       |
| TRETINOIN              | TRETINOIN GEL 0.025%   | 90050030004010 | Generic       |
| TRETINOIN              | TRETINOIN GEL 0.05%    | 90050030004015 | Generic       |
| AVITA                  | TRETINOIN CREAM 0.025% | 90050030003703 | Brand         |

# **Approval Criteria**

## 1 - Diagnosis of acne or rosacea

| Product Name: Aklief |  |  |
|----------------------|--|--|
| Approval Length      | 12/31/2039   |  |
| Guideline Type       | Prior Authorization - All plans except IL and MN Plans |  |

| Product<br>Name | Generic Name             | GPI            | Brand/Generic |
|-----------------|--------------------------|----------------|---------------|
| AKLIEF          | TRIFAROTENE CREAM 0.005% | 90050035003720 | Brand         |

## **Approval Criteria**

1 - Diagnosis of acne or rosacea

### AND

- 2 Trial and failure, contraindication, or intolerance to BOTH of the following:
  - preferred tretinoin
  - adapalene agent

| Product Name: Aklief |                                       |  |
|----------------------|---------------------------------------|--|
| Approval Length      | 12 month(s)                           |  |
| Therapy Stage        | Initial Authorization                 |  |
| Guideline Type       | Prior Authorization - IL and MN Plans |  |

| Product<br>Name | Generic Name             | GPI            | Brand/Generic |
|-----------------|--------------------------|----------------|---------------|
| AKLIEF          | TRIFAROTENE CREAM 0.005% | 90050035003720 | Brand         |

## **Approval Criteria**

1 - Diagnosis of acne or rosacea

### AND

- 2 Trial and failure, contraindication, or intolerance to BOTH of the following:
  - preferred tretinoin
  - adapalene agent

| Product Name: Prescription adapalene products |  |  |
|---|--|--|
| Approval Length                               | 12/31/2039   |  |
| Guideline Type                                | Prior Authorization - All plans except IL and MN Plans |  |

| Product<br>Name   | Generic Name         | GPI            | Brand/Generic |
|-------------------|----------------------|----------------|---------------|
| ADAPALENE         | ADAPALENE SOLN 0.1%  | 90050003002010 | Brand         |
| ADAPALENE         | ADAPALENE CREAM 0.1% | 90050003003710 | Generic       |
| ADAPALENE         | ADAPALENE GEL 0.3%   | 90050003004030 | Generic       |
| ADAPALENE<br>PUMP | ADAPALENE GEL 0.3%   | 90050003004030 | Generic       |
| ADAPALENE         | ADAPALENE PADS 0.1%  | 90050003004310 | Brand         |

## **Approval Criteria**

1 - Diagnosis of acne or rosacea

#### **AND**

2 - Trial and failure, contraindication, or intolerance to adapalene 0.1% gel

| Product Name: Prescription adapalene products |      |                                       |               |  |
|---|------|---------------------------------------|---------------|--|
| Approval Le                                   | ngth | 12 month(s)                           |               |  |
| Therapy Stage                                 |      | Initial Authorization                 |               |  |
| Guideline Type                                |      | Prior Authorization - IL and MN Plans |               |  |
| Product Generic Name                          |      | GPI                                   | Brand/Generic |  |

| ADAPALENE         | ADAPALENE SOLN 0.1%  | 90050003002010 | Brand   |
|-------------------|----------------------|----------------|---------|
| ADAPALENE         | ADAPALENE CREAM 0.1% | 90050003003710 | Generic |
| ADAPALENE         | ADAPALENE GEL 0.3%   | 90050003004030 | Generic |
| ADAPALENE<br>PUMP | ADAPALENE GEL 0.3%   | 90050003004030 | Generic |
| ADAPALENE         | ADAPALENE PADS 0.1%  | 90050003004310 | Brand   |

1 - Diagnosis of acne or rosacea

## AND

2 - Trial and failure, contraindication, or intolerance to adapalene 0.1% gel

| Product Name: Tazarotene products                                     |  |  |
|---|--|--|
| Approval Length 12/31/2039  |  |  |
| Guideline Type Prior Authorization - All plans except IL and MN Plans |  |  |

| Product<br>Name | Generic Name                | GPI            | Brand/Generic |
|-----------------|-----------------------------|----------------|---------------|
| TAZAROTENE      | TAZAROTENE (ACNE) FOAM 0.1% | 90050027003930 | Brand         |
| FABIOR          | TAZAROTENE (ACNE) FOAM 0.1% | 90050027003930 | Brand         |
| TAZAROTENE      | TAZAROTENE CREAM 0.1%       | 90250070003730 | Generic       |
| TAZAROTENE      | TAZAROTENE GEL 0.05%        | 90250070004020 | Generic       |
| TAZAROTENE      | TAZAROTENE GEL 0.1%         | 90250070004030 | Generic       |
| TAZORAC         | TAZAROTENE CREAM 0.05%      | 90250070003720 | Brand         |

# **Approval Criteria**

1 - Diagnosis of psoriasis

OR

- 2 Both of the following:
- 2.1 Diagnosis of acne or rosacea

- **2.2** Trial and failure, contraindication, or intolerance to BOTH of the following:
  - preferred tretinoin
  - adapalene agent

| Product Name: Tazarotene products                    |  |  |  |
|--|--|--|--|
| Approval Length 12 month(s)                          |  |  |  |
| Therapy Stage Initial Authorization                  |  |  |  |
| Guideline Type Prior Authorization - IL and MN Plans |  |  |  |

| Product<br>Name | Generic Name                | GPI            | Brand/Generic |
|-----------------|-----------------------------|----------------|---------------|
| TAZAROTENE      | TAZAROTENE (ACNE) FOAM 0.1% | 90050027003930 | Brand         |
| FABIOR          | TAZAROTENE (ACNE) FOAM 0.1% | 90050027003930 | Brand         |
| TAZAROTENE      | TAZAROTENE CREAM 0.1%       | 90250070003730 | Generic       |
| TAZAROTENE      | TAZAROTENE GEL 0.05%        | 90250070004020 | Generic       |
| TAZAROTENE      | TAZAROTENE GEL 0.1%         | 90250070004030 | Generic       |
| TAZORAC         | TAZAROTENE CREAM 0.05%      | 90250070003720 | Brand         |

## **Approval Criteria**

1 - Diagnosis of psoriasis

OR

- **2** Both of the following:
- 2.1 Diagnosis of acne or rosacea

- 2.2 Trial and failure, contraindication, or intolerance to BOTH of the following:
  - preferred tretinoin
  - adapalene agent

| Product Name: Duobrii   |  |  |
|---|--|--|
| Approval Length 12/31/2039  |  |  |
| Guideline Type Prior Authorization - All plans except IL and MN Plans |  |  |

| Product<br>Name | Generic Name   | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| DUOBRII         | HALOBETASOL PROPIONATE-TAZAROTENE LOTION 0.01-0.045% | 90559902484120 | Brand         |

# **Approval Criteria**

1 - Diagnosis of psoriasis

## AND

**2** - Trial and failure, contraindication, or intolerance to one preferred high or super-high potency topical corticosteroid

| Product Name: Duobrii                                |                       |  |  |
|--|-----------------------|--|--|
| Approval Length 12 month(s)                          |                       |  |  |
| Therapy Stage  | Initial Authorization |  |  |
| Guideline Type Prior Authorization - IL and MN Plans |                       |  |  |

| Product<br>Name | Generic Name   | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| DUOBRII         | HALOBETASOL PROPIONATE-TAZAROTENE LOTION 0.01-0.045% | 90559902484120 | Brand         |
|                 |  | _              |               |

1 - Diagnosis of psoriasis

## **AND**

**2** - Trial and failure, contraindication, or intolerance to one preferred high or super-high potency topical corticosteroid

| Product Name: Clindamycin/tretinoin products                          |   |                |         |  |
|---|---|----------------|---------|--|
| Approval Length   | 12/31/2039  |                |         |  |
| Guideline Type Prior Authorization - All plans except IL and MN Plans |   |                |         |  |
| Product Name  | roduct Name Generic Name GPI Brand/Generi         |                |         |  |
| CLINDAMYCIN<br>PHOSPHATE/TRETINOIN                                    | CLINDAMYCIN PHOSPHATE-TRETINOIN<br>GEL 1.2-0.025% | 90059902654020 | Generic |  |

## **Approval Criteria**

1 - Diagnosis of acne or rosacea

## **AND**

**2** - Trial and failure of concurrent use of the individual products (topical clindamycin and preferred tretinoin)

| Product Name: Clindamycin/tretinoin products  |  |  |  |  |
|---|--|--|--|--|
| Approval Length   | 12 month(s)  |  |  |  |
| Therapy Stage   | Initial Authorization                                |  |  |  |
| Guideline Type  | Guideline Type Prior Authorization - IL and MN Plans |  |  |  |
| Product Name  | roduct Name Generic Name GPI Brand/Generic           |  |  |  |
| CLINDAMYCIN CLINDAMYCIN PHOSPHATE-TRETINOIN 90059902654020 Generic PHOSPHATE/TRETINOIN GEL 1.2-0.025% |  |  |  |  |
|   |  |  |  |  |

1 - Diagnosis of acne or rosacea

## AND

**2** - Trial and failure of concurrent use of the individual products (topical clindamycin and preferred tretinoin)

| Product Name: All Pr   | Product Name: All Products Listed Above |                 |               |  |
|------------------------|---|-----------------|---------------|--|
| Approval Length        | 12 month(s)                             |                 |               |  |
| Therapy Stage          | Reauthorization                         | Reauthorization |               |  |
| Guideline Type         | Prior Authorization - IL and MN Pla     | ans             |               |  |
| Product Name           | Generic Name                            | GPI             | Brand/Generic |  |
| ADAPALENE              | ADAPALENE SOLN 0.1%                     | 90050003002010  | Brand         |  |
| ADAPALENE              | ADAPALENE CREAM 0.1%                    | 90050003003710  | Generic       |  |
| DIFFERIN               | ADAPALENE GEL 0.1%                      | 90050003004010  | Brand         |  |
| CVS ADAPALENE          | ADAPALENE GEL 0.1%                      | 90050003004010  | Generic       |  |
| ADAPALENE              | ADAPALENE GEL 0.1%                      | 90050003004010  | Generic       |  |
| ADAPALENE<br>TREATMENT | ADAPALENE GEL 0.1%                      | 90050003004010  | Generic       |  |
| ADAPALENE              | ADAPALENE GEL 0.3%                      | 90050003004030  | Generic       |  |
| ADAPALENE PUMP         | ADAPALENE GEL 0.3%                      | 90050003004030  | Generic       |  |
| TAZAROTENE             | TAZAROTENE (ACNE) FOAM 0.1%             | 90050027003930  | Brand         |  |
| FABIOR                 | TAZAROTENE (ACNE) FOAM 0.1%             | 90050027003930  | Brand         |  |
| TAZAROTENE             | TAZAROTENE CREAM 0.1%                   | 90250070003730  | Generic       |  |
| TAZAROTENE             | TAZAROTENE GEL 0.05%                    | 90250070004020  | Generic       |  |
| TAZAROTENE             | TAZAROTENE GEL 0.1%                     | 90250070004030  | Generic       |  |
| ALTRENO                | TRETINOIN LOTION 0.05%                  | 90050030004130  | Brand         |  |
| TRETINOIN              | TRETINOIN CREAM 0.025%                  | 90050030003703  | Generic       |  |
| TRETINOIN              | TRETINOIN CREAM 0.05%                   | 90050030003705  | Generic       |  |
| TRETINOIN              | TRETINOIN CREAM 0.1%                    | 90050030003710  | Generic       |  |

| TRETINOIN                          | TRETINOIN GEL 0.01%                                      | 90050030004005 | Generic |
|------------------------------------|--|----------------|---------|
| TRETINOIN                          | TRETINOIN GEL 0.025%                                     | 90050030004010 | Generic |
| TRETINOIN                          | TRETINOIN GEL 0.05%                                      | 90050030004015 | Generic |
| AKLIEF                             | TRIFAROTENE CREAM 0.005%                                 | 90050035003720 | Brand   |
| CLINDAMYCIN<br>PHOSPHATE/TRETINOIN | CLINDAMYCIN PHOSPHATE-TRETINOIN<br>GEL 1.2-0.025%        | 90059902654020 | Generic |
| DUOBRII                            | HALOBETASOL PROPIONATE-<br>TAZAROTENE LOTION 0.01-0.045% | 90559902484120 | Brand   |
| AVITA                              | TRETINOIN CREAM 0.025%                                   | 90050030003703 | Brand   |
| TAZORAC                            | TAZAROTENE CREAM 0.05%                                   | 90250070003720 | Brand   |
| ADAPALENE                          | ADAPALENE PAD 0.1% SWAB                                  | 90050003004310 | Brand   |

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug

# 2. Revision History

| Date       | Notes                   |
|------------|-------------------------|
| 10/31/2023 | 2024 New Implementation |

| R | Revcovi (elapegademase)  |  |  |  |  |
|---|--|--|--|--|--|
| = | The Standard process to England. The force has been count, or admits to the Standard in process the concentral and models. |  |  |  |  |
|   |  |  |  |  |  |

# **Prior Authorization Guideline**

| Guideline ID          | GL-129217               |
|-----------------------|-------------------------|
| <b>Guideline Name</b> | Revcovi (elapegademase) |
| Formulary             | Quartz                  |

# **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

# 1. Criteria

| Product Name: Revcovi              |                                     |  |
|------------------------------------|-------------------------------------|--|
| Approval Length 12 month(s)        |                                     |  |
| Therapy Stage                      | Therapy Stage Initial Authorization |  |
| Guideline Type Prior Authorization |                                     |  |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| REVCOVI         | ELAPEGADEMASE-LVLR IM SOLN 2.4 MG/1.5ML (1.6 MG/ML) | 30902030202020 | Brand         |

# **Approval Criteria**

**1** - Both of the following:

**1.1** Diagnosis of adenosine deaminase severe combined immune deficiency (ADA-SCID)

## **AND**

1.2 Prescribed by, or in consultation with, an expert in the treatment of immune deficiencies

| Product Name: Revcovi |                     |
|-----------------------|---------------------|
| Approval Length       | 12 month(s)         |
| Therapy Stage         | Reauthorization     |
| Guideline Type        | Prior Authorization |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| REVCOVI         | ELAPEGADEMASE-LVLR IM SOLN 2.4 MG/1.5ML (1.6 MG/ML) | 30902030202020 | Brand         |

## **Approval Criteria**

**1** - The prescriber provides recent clinical documentation from the past 6 months of a trough plasma ADA activity ≥ 30 mmol/hr/L and a trough erythrocyte dAXP level below 0.02 mmol/L

# 2. Revision History

| Date     | Notes       |
|----------|-------------|
| 8/9/2023 | New program |

| Rezurock (belumosudil mesylate)  |  |  |  |
|--|--|--|--|
| The before the state of the state and send send send of the bit special and the state of the better state. |  |  |  |

# **Prior Authorization Guideline**

| Guideline ID          | GL-128187                       |
|-----------------------|---------------------------------|
| <b>Guideline Name</b> | Rezurock (belumosudil mesylate) |
| Formulary             | Quartz                          |

# **Guideline Note:**

| Effective Date: |
|-----------------|
|-----------------|

# 1. Criteria

| Product Name: Rezurock*     |                       |  |
|-----------------------------|-----------------------|--|
| Approval Length 12 month(s) |                       |  |
| Therapy Stage               | Initial Authorization |  |
| Guideline Type              | Prior Authorization   |  |

| Product Generic Name |                                 | GPI Brand/Gen  |       |
|----------------------|---------------------------------|----------------|-------|
| REZUROCK             | BELUMOSUDIL MESYLATE TAB 200 MG | 99398510500320 | Brand |

# **Approval Criteria**

1 - Diagnosis of chronic graft-versus-host disease (chronic GVHD)

**2** - Prescribed by or in consultation by a specialist with experience in the treatment of GVHD (e.g.hematologist, oncologist, immunologist, etc.)

## AND

**3** - The requested is being used alone or in a combination regimen that has a class 1 or 2 recommendation for use from the National Comprehensive Cancer Network (NCCN) for the treatment of chronic GVHD

|  | *Member new to the plan (as evidenced by coverage effective date of I ess than or equal to 90 days) and were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers will go through reauthorization criteria |
|--|--|
|--|--|

| Product Name: Rezurock* |                     |
|-------------------------|---------------------|
| Approval Length         | 12 month(s)         |
| Therapy Stage           | Reauthorization     |
| Guideline Type          | Prior Authorization |

| Product Generic Name<br>Name |                                 | GPI            | Brand/Generic |
|------------------------------|---------------------------------|----------------|---------------|
| REZUROCK                     | BELUMOSUDIL MESYLATE TAB 200 MG | 99398510500320 | Brand         |

## **Approval Criteria**

1 - Diagnosis of chronic graft-versus-host disease (chronic GVHD)

## AND

**2** - Prescribed by or in consultation by a specialist with experience in the treatment of GVHD (e.g.hematologist, oncologist, immunologist, etc.)

## **AND**

**3** - The requested is being used alone or in a combination regimen that has a class 1 or 2 recommendation for use from the National Comprehensive Cancer Network (NCCN) for the treatment of chronic GVHD

## AND

**4** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug

| Notes | *Member new to the plan (as evidenced by coverage effective date of I ess than or equal to 90 days) and were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers will go through rea |
|-------|---|
|       | uthorization criteria   |

# 2. Revision History

| Date     | Notes       |
|----------|-------------|
| 9/7/2023 | New Program |

| Rinvoq   | (upada  | citinib                                | ) |  |
|--|---|--|---|--|
| The letter image current to displayed. The lie may | have been recool, unweed, or distinct. We'lly that the la | is politically exceptific and treatme. |   |  |
|  |   |  |   |  |

# **Prior Authorization Guideline**

| Guideline ID          | GL-135400             |  |
|-----------------------|-----------------------|--|
| <b>Guideline Name</b> | Rinvoq (upadacitinib) |  |
| Formulary             | Quartz                |  |

## **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

## Note:

Member new to the plan (as evidenced by coverage effective date of less than or equal to 90 days) who initiated therapy using a manufacturer-sponsored free drug program, provider samples, and/or vouchers will go through initial criteria, otherwise for continuation of therapy for new to plan, reauthorization criteria applies.

## 1. Criteria

| Product Name: Rinvoq |            |  |                |               |
|----------------------|------------|--|----------------|---------------|
| Diagnosis            |            | Psoriatic Arthritis (PsA)                              |                |               |
| Approval Length      |            | 12/31/2039   |                |               |
| Guideline Type       |            | Prior Authorization - All Plans except IL and MN Plans |                |               |
| Product<br>Name      | Generic Na | Generic Name   |                | Brand/Generic |
| RINVOQ               | UPADACITIN | IB TAB ER 24HR 15 MG                                   | 66603072007520 | Brand         |
| RINVOQ               | UPADACITIN | IB TAB ER 24HR 30 MG                                   | 66603072007530 | Brand         |

| RINVOQ | UPADACITINIB TAB ER 24HR 45 MG | 66603072007540 | Brand |
|--------|--------------------------------|----------------|-------|
|--------|--------------------------------|----------------|-------|

1 - Diagnosis of moderate to severely active psoriatic arthritis (PsA)

## **AND**

2 - Prescribed by or in consultation with a dermatologist or rheumatologist

#### **AND**

- **3** Submission of medical records (e.g., chart notes) documenting at least ONE of the following:
  - actively inflamed joints
  - axial disease
  - · active skin, nail, or scalp psoriasis involvement
  - dactylitis
  - enthesitis

## **AND**

**4** - Trial and failure, contraindication, or intolerance to at least one TNF agent (e.g. adalimumab, etanercept, etc.) as per package label

## **AND**

**5** - Not used in combination with other biologic DMARDs (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

| Product Name: Rinvoq |                           |  |
|----------------------|---------------------------|--|
| Diagnosis            | Psoriatic Arthritis (PsA) |  |
| Approval Length      | 12 month(s)               |  |
| Therapy Stage        | Initial Authorization     |  |

| Guideline Type  |              | Prior Authorization - IL and MN Plans | 3              |               |
|-----------------|--------------|---------------------------------------|----------------|---------------|
| Product<br>Name | Generic Name |                                       | GPI            | Brand/Generic |
| RINVOQ          | UPADACITIN   | IB TAB ER 24HR 15 MG                  | 66603072007520 | Brand         |
| RINVOQ          | UPADACITIN   | IB TAB ER 24HR 30 MG                  | 66603072007530 | Brand         |
| RINVOQ          | UPADACITIN   | IB TAB ER 24HR 45 MG                  | 66603072007540 | Brand         |

1 - Diagnosis of moderate to severely active psoriatic arthritis (PsA)

#### **AND**

2 - Prescribed by or in consultation with a dermatologist or rheumatologist

## **AND**

- **3** Submission of medical records (e.g., chart notes) documenting at least ONE of the following:
  - actively inflamed joints
  - axial disease
  - active skin, nail, or scalp psoriasis involvement
  - dactylitis
  - enthesitis

#### **AND**

**4** - Trial and failure, contraindication, or intolerance to at least one TNF agent (e.g. adalimumab, etanercept, etc.) as per package label

#### **AND**

**5** - Not used in combination with other biologic DMARDs (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

| Product Name: Rinvoq |  |  |
|----------------------|--|--|
| Diagnosis            | Moderate to Severely Active Rheumatoid Arthritis (RA)  |  |
| Approval Length      | 12/31/2039   |  |
| Guideline Type       | Prior Authorization - All Plans except IL and MN Plans |  |

| Product<br>Name | Generic Name                   | GPI            | Brand/Generic |
|-----------------|--------------------------------|----------------|---------------|
| RINVOQ          | UPADACITINIB TAB ER 24HR 15 MG | 66603072007520 | Brand         |
| RINVOQ          | UPADACITINIB TAB ER 24HR 30 MG | 66603072007530 | Brand         |
| RINVOQ          | UPADACITINIB TAB ER 24HR 45 MG | 66603072007540 | Brand         |

1 - Diagnosis of moderate to severely active rheumatoid arthritis (RA)

## AND

- **2** Submission of medical records (e.g., chart notes) documenting a minimum duration of a 3-month trial and failure, intolerance, or contraindication to ONE of the following:
  - methotrexate (MTX)\*
  - leflunomide
  - hydroxychloroquine
  - sulfasalazine

## AND

**3** - Prescribed by or in consultation with a rheumatologist

## AND

**4** - Therapy must not be used in combination with other biologic disease modifying antirheumatic drug (DMARD) (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

## AND

| <b>5</b> - Trial and failure, contraindication, or intolerance to at least one TNF agent (e.g. adalimumab, etanercept, etc.) as per package label |   |  |
|---|---|--|
| Notes   | * Absolute contraindications to methotrexate are pregnancy, nursing, al coholism, alcoholic liver disease or other chronic liver disease, immuno deficiency syndromes, bone marrow hyperplasia, leukopenia, thromboc ytopenia or significant anemia, or hypersensitivity to methotrexate. |  |

| Product Name: Rinvoq |   |  |
|----------------------|---|--|
| Diagnosis            | Moderate to Severely Active Rheumatoid Arthritis (RA) |  |
| Approval Length      | 12 month(s)   |  |
| Therapy Stage        | Initial Authorization                                 |  |
| Guideline Type       | Prior Authorization - IL and MN Plans                 |  |

| Product<br>Name | Generic Name                   | GPI            | Brand/Generic |
|-----------------|--------------------------------|----------------|---------------|
| RINVOQ          | UPADACITINIB TAB ER 24HR 15 MG | 66603072007520 | Brand         |
| RINVOQ          | UPADACITINIB TAB ER 24HR 30 MG | 66603072007530 | Brand         |
| RINVOQ          | UPADACITINIB TAB ER 24HR 45 MG | 66603072007540 | Brand         |

1 - Diagnosis of moderate to severely active rheumatoid arthritis (RA)

## **AND**

- **3** Submission of medical records (e.g., chart notes) documenting a minimum duration of a 3-month trial and failure, contraindication, or intolerance to ONE of the following:
  - methotrexate (MTX)
  - leflunomide
  - hydroxychloroquine
  - sulfasalazine

## **AND**

2 - Prescribed by or in consultation with a rheumatologist

**5** - Therapy must not be used in combination with other biologic disease modifying antirheumatic drug (DMARD) (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

## **AND**

**4** - Trial and failure, contraindication, or intolerance to at least one TNF agent (e.g. adalimumab, etanercept, etc.) as per package label

| Notes | * Absolute contraindications to methotrexate are pregnancy, nursing, al  |
|-------|--|
|       | coholism, alcoholic liver disease or other chronic liver disease, immuno |
|       | deficiency syndromes, bone marrow hyperplasia, leukopenia, thromboc      |
|       | ytopenia or significant anemia, or hypersensitivity to methotrexate.     |

| Product Name: Rinvoq |  |  |
|----------------------|--|--|
| Diagnosis            | Ankylosing Spondylitis (AS), Non-radiographic axial spondyloarthritis (nr-axSpA) |  |
| Approval Length      | 12/31/2039   |  |
| Guideline Type       | Prior Authorization - All Plans except IL and MN Plans                           |  |

| Product<br>Name | Generic Name                   | GPI            | Brand/Generic |
|-----------------|--------------------------------|----------------|---------------|
| RINVOQ          | UPADACITINIB TAB ER 24HR 15 MG | 66603072007520 | Brand         |
| RINVOQ          | UPADACITINIB TAB ER 24HR 30 MG | 66603072007530 | Brand         |
| RINVOQ          | UPADACITINIB TAB ER 24HR 45 MG | 66603072007540 | Brand         |

## **Approval Criteria**

- 1 Diagnosis of one of the following:
  - Ankylosing spondylitis (AS)
  - Active non-radiographic axial spondyloarthritis (nr-axSpA)

## AND

**2** - For diagnoses of Non-radiographic axial spondyloarthritis (nr-axSpA): Objective signs of inflammation are present (i.e. lab C-reactive protein elevated, imaging scans indicate inflammation) NOTE: Applies to nr-axSpA diagnosis ONLY

## **AND**

**3** - Prescribed by or in consultation with a rheumatologist

#### AND

**4** - Minimum duration of a 1-month trial and failure, contraindication, or intolerance of scheduled prescription doses of TWO different NSAIDs (e.g., naproxen, nabumetone, diclofenac)

## **AND**

**5** - Trial and failure, contraindication, or intolerance to at least one TNF agent (e.g. adalimumab, etanercept, etc.) as per package label

#### **AND**

**6** - Not used in combination with other biologic DMARDs (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

| Product Name: Rinvoq |  |  |
|----------------------|--|--|
| Diagnosis            | Ankylosing Spondylitis (AS), Non-radiographic axial spondyloarthritis (nr-axSpA) |  |
| Approval Length      | 12 month(s)  |  |
| Therapy Stage        | Initial Authorization  |  |
| Guideline Type       | Prior Authorization - IL and MN Plans  |  |

| Product<br>Name | Generic Name                   | GPI            | Brand/Generic |
|-----------------|--------------------------------|----------------|---------------|
| RINVOQ          | UPADACITINIB TAB ER 24HR 15 MG | 66603072007520 | Brand         |
| RINVOQ          | UPADACITINIB TAB ER 24HR 30 MG | 66603072007530 | Brand         |
| RINVOQ          | UPADACITINIB TAB ER 24HR 45 MG | 66603072007540 | Brand         |

- 1 Diagnosis of one of the following:
  - Ankylosing spondylitis (AS)
  - Active non-radiographic axial spondyloarthritis (nr-axSpA)

#### **AND**

**2** - For diagnoses of Non-radiographic axial spondyloarthritis (nr-axSpA): Objective signs of inflammation are present (i.e. lab C-reactive protein elevated, imaging scans indicate inflammation) NOTE: Applies to nr-axSpA diagnosis ONLY

#### **AND**

3 - Prescribed by or in consultation with a rheumatologist

#### **AND**

**4** - Minimum duration of a 1-month trial and failure, contraindication, or intolerance of scheduled prescription doses of TWO different NSAIDs (e.g., naproxen, nabumetone, diclofenac)

#### AND

**5** - Trial and failure, contraindication, or intolerance to at least one TNF agent (e.g. adalimumab, etanercept, etc.) as per package label

## **AND**

**6** - Not used in combination with other biologic DMARDs (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

| Product Name: Rinvoq |   |  |
|----------------------|---|--|
| Diagnosis            | Moderate to Severely Active Ulcerative Colitis (UC) |  |

| Approval Length | 12/31/2039   |
|-----------------|--|
| Guideline Type  | Prior Authorization - All Plans except IL and MN Plans |

| Product<br>Name | Generic Name                   | GPI            | Brand/Generic |
|-----------------|--------------------------------|----------------|---------------|
| RINVOQ          | UPADACITINIB TAB ER 24HR 15 MG | 66603072007520 | Brand         |
| RINVOQ          | UPADACITINIB TAB ER 24HR 30 MG | 66603072007530 | Brand         |
| RINVOQ          | UPADACITINIB TAB ER 24HR 45 MG | 66603072007540 | Brand         |

1 - Diagnosis of moderate to severely active ulcerative colitis (UC)

## **AND**

2 - Prescribed by or in consultation with a gastroenterologist

## **AND**

- **3** Member is considered high-risk based on ONE of the following characteristics:
  - Extensive colitis
  - Deep ulcers
  - Age less than 40 years
  - High CRP and ESR
  - Steroid-requiring disease
  - History of hospitalization
  - C. difficile infection
  - CMV infection

## AND

**4** - Trial and failure, contraindication, or intolerance to a short course (2 to 4 weeks) of oral corticosteroids

## **AND**

**5** - Trial and failure, contraindication, or intolerance to at least one TNF agent (e.g. adalimumab, etanercept, etc.) as per package label

## AND

**6** - Not used in combination with other biologic DMARDs (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

| Product Name: Rinvoq  |  |  |
|---|--|--|
| Diagnosis Moderate to Severely Active Ulcerative Colitis (UC) |  |  |
| Approval Length 12 month(s)                                   |  |  |
| Therapy Stage Initial Authorization                           |  |  |
| Guideline Type Prior Authorization - IL and MN Plans          |  |  |

| Product<br>Name | Generic Name                   | GPI            | Brand/Generic |
|-----------------|--------------------------------|----------------|---------------|
| RINVOQ          | UPADACITINIB TAB ER 24HR 15 MG | 66603072007520 | Brand         |
| RINVOQ          | UPADACITINIB TAB ER 24HR 30 MG | 66603072007530 | Brand         |
| RINVOQ          | UPADACITINIB TAB ER 24HR 45 MG | 66603072007540 | Brand         |

## **Approval Criteria**

**1** - Diagnosis of moderate to severely active ulcerative colitis (UC)

#### **AND**

**2** - Prescribed by or in consultation with a gastroenterologist

## AND

- **3** Member is considered high-risk based on ONE of the following characteristics:
  - Extensive colitis
  - Deep ulcers
  - Age less than 40 years
  - High CRP and ESR

- Steroid-requiring disease
- History of hospitalization
- C. difficile infection
- CMV infection

**4** - Trial and failure, contraindication, or intolerance to a short course (2 to 4 weeks) of oral corticosteroids

#### AND

**5** - Trial and failure, contraindication, or intolerance to at least one TNF agent (e.g. adalimumab, etanercept, etc.) as per package label

## **AND**

**6** - Not used in combination with other biologic DMARDs (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

| Product Name: Rinvoq |  |  |
|----------------------|--|--|
| Diagnosis            | Atopic Dermatitis (AD)                                 |  |
| Approval Length      | 12/31/2039   |  |
| Guideline Type       | Prior Authorization - All Plans except IL and MN Plans |  |

| Product<br>Name | Generic Name                   | GPI            | Brand/Generic |
|-----------------|--------------------------------|----------------|---------------|
| RINVOQ          | UPADACITINIB TAB ER 24HR 15 MG | 66603072007520 | Brand         |
| RINVOQ          | UPADACITINIB TAB ER 24HR 30 MG | 66603072007530 | Brand         |
| RINVOQ          | UPADACITINIB TAB ER 24HR 45 MG | 66603072007540 | Brand         |

## **Approval Criteria**

**1** - Diagnosis of moderate to severe atopic dermatitis (AD) based on body surface area (greater than 10%), extent of disability, extent of pruritus, or impact on sleep, quality of life, current use of systemic immunomodulators)

2 - Prescribed by or in consultation with a dermatologist, allergist, or immunologist

## AND

- **3** Trial and failure, contraindication, or intolerance to ONE of the following:
  - Biologics used in AD (e.g., dupilumab, tralokinumab, abrocitinib)
  - Other systemic agents (e.g. methotrexate, cyclosporine, azathioprine, etc.)

## **AND**

**4** - Not used in combination with other biologic DMARDs (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

| Product Name: Rinvoq |                                       |  |
|----------------------|---------------------------------------|--|
| Diagnosis            | Atopic Dermatitis (AD)                |  |
| Approval Length      | 12 month(s)                           |  |
| Therapy Stage        | Initial Authorization                 |  |
| Guideline Type       | Prior Authorization - IL and MN Plans |  |

| Product<br>Name | Generic Name                   | GPI            | Brand/Generic |
|-----------------|--------------------------------|----------------|---------------|
| RINVOQ          | UPADACITINIB TAB ER 24HR 15 MG | 66603072007520 | Brand         |
| RINVOQ          | UPADACITINIB TAB ER 24HR 30 MG | 66603072007530 | Brand         |
| RINVOQ          | UPADACITINIB TAB ER 24HR 45 MG | 66603072007540 | Brand         |

## **Approval Criteria**

**1** - Diagnosis of moderate to severe atopic dermatitis (AD) based on body surface area (greater than 10%), extent of disability, extent of pruritus, or impact on sleep, quality of life, current use of systemic immunomodulators)

2 - Prescribed by or in consultation with a dermatologist, allergist, or immunologist

## **AND**

- 3 Trial and failure, contraindication, or intolerance to ONE of the following:
  - Biologics used in AD (e.g., dupilumab, tralokinumab, abrocitinib)
  - Other systemic agents (e.g. methotrexate, cyclosporine, azathioprine, etc.)

## **AND**

**4** - Not used in combination with other biologic DMARDs (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

| Product Name: Rinvoq |  |  |
|----------------------|--|--|
| Diagnosis            | Moderate to Severely Active Crohn's Disease (CD)       |  |
| Approval Length      | 12/31/2039   |  |
| Guideline Type       | Prior Authorization - All Plans except IL and MN Plans |  |

| Product<br>Name | Generic Name                   | GPI            | Brand/Generic |
|-----------------|--------------------------------|----------------|---------------|
| RINVOQ          | UPADACITINIB TAB ER 24HR 15 MG | 66603072007520 | Brand         |
| RINVOQ          | UPADACITINIB TAB ER 24HR 30 MG | 66603072007530 | Brand         |
| RINVOQ          | UPADACITINIB TAB ER 24HR 45 MG | 66603072007540 | Brand         |

## **Approval Criteria**

1 - Diagnosis of moderate to severely active Crohn's disease (CD)

## **AND**

2 - Prescribed by or in consultation with a gastroenterologist

- 3 One of the following:
- **3.1** Member is considered high-risk based on ONE of the following characteristics:
  - Age less than 30 years at diagnosis
  - Extensive anatomic involvement
  - Perianal and/or severe rectal disease
  - Deep ulcers
  - Prior surgical resection
  - Stricturing and/or penetrating behavior
  - Fistulizing disease
  - Extraintestinal manifestations of inflammation (e.g., uveitis, erythema nodosum, pyoderma gangrenosum, spondyloarthropathy)

OR

- **3.2** Both of the following:
- **3.2.1** Member is considered low-risk

## **AND**

## **3.2.2** One of the following:

- Trial and failure, contraindication, or intolerance to one conventional therapy (e.g., azathioprine, balsalazide, corticosteroids, mesalamine, mercaptopurine, methotrexate, sulfasalazine)
- Inadequate disease control or inability to achieve remission after an adequate trial of 3 months with one conventional therapy
- Demonstrated steroid dependence
- Conventional therapy clinically inappropriate based on location of disease

#### AND

4 - Member is 18 years of age or older

**5** - Trial and failure, contraindication, or intolerance to at least one TNF agent (e.g. adalimumab, etanercept, etc.) as per package label

## **AND**

**6** - Not used in combination with other biologic DMARDs (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

| Product Name: Rinvoq         Diagnosis       Moderate to Severely Active Crohn's Disease (CD)         Approval Length       12 month(s)         Therapy Stage       Initial Authorization         Guideline Type       Prior Authorization - IL and MN Plans |  |
|--|--|
|--|--|

| Product<br>Name | Generic Name                   | GPI            | Brand/Generic |
|-----------------|--------------------------------|----------------|---------------|
| RINVOQ          | UPADACITINIB TAB ER 24HR 15 MG | 66603072007520 | Brand         |
| RINVOQ          | UPADACITINIB TAB ER 24HR 30 MG | 66603072007530 | Brand         |
| RINVOQ          | UPADACITINIB TAB ER 24HR 45 MG | 66603072007540 | Brand         |

## **Approval Criteria**

1 - Diagnosis of moderate to severely active Crohn's disease (CD)

#### **AND**

2 - Prescribed by or in consultation with a gastroenterologist

## **AND**

- 3 One of the following:
- **3.1** Member is considered high-risk based on ONE of the following characteristics:

- Age less than 30 years at diagnosis
- Extensive anatomic involvement
- Perianal and/or severe rectal disease
- Deep ulcers
- Prior surgical resection
- Stricturing and/or penetrating behavior
- Fistulizing disease
- Extraintestinal manifestations of inflammation (e.g., uveitis, erythema nodosum, pyoderma gangrenosum, spondyloarthropathy)

OR

- **3.2** Both of the following:
- **3.2.1** Member is considered low-risk

**AND** 

## **3.2.2** One of the following:

- Trial and failure, contraindication, or intolerance to one conventional therapy (e.g., azathioprine, balsalazide, corticosteroids, mesalamine, mercaptopurine, methotrexate, sulfasalazine)
- Inadequate disease control or inability to achieve remission after an adequate trial of 3 months with one conventional therapy
- Demonstrated steroid dependence
- Conventional therapy clinically inappropriate based on location of disease

**AND** 

4 - Member is 18 years of age or older

AND

**5** - Trial and failure, contraindication, or intolerance to at least one TNF agent (e.g. adalimumab, etanercept, etc.) as per package label

**AND** 

**6** - Not used in combination with other biologic DMARDs (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

| Product Name: Rinvoq                                 |                 |
|--|-----------------|
| Diagnosis All Indications                            |                 |
| Approval Length                                      | 12 month(s)     |
| Therapy Stage  | Reauthorization |
| Guideline Type Prior Authorization - IL and MN Plans |                 |

| Product<br>Name | Generic Name                   | GPI            | Brand/Generic |
|-----------------|--------------------------------|----------------|---------------|
| RINVOQ          | UPADACITINIB TAB ER 24HR 15 MG | 66603072007520 | Brand         |
| RINVOQ          | UPADACITINIB TAB ER 24HR 30 MG | 66603072007530 | Brand         |
| RINVOQ          | UPADACITINIB TAB ER 24HR 45 MG | 66603072007540 | Brand         |

## **Approval Criteria**

**1** - Prescriber provides clinical documentation from the previous 12 months of the member's response to therapy including individual improvements in functional status related to therapeutic response

| Product Name: Rinvoq |                |
|----------------------|----------------|
| Approval Length      | 12 month(s)    |
| Guideline Type       | Quantity Limit |

| Product<br>Name | Generic Name                          | GPI            | Brand/Generic |
|-----------------|---------------------------------------|----------------|---------------|
| RINVOQ          | UPADACITINIB TAB ER 24HR 15 MG        | 66603072007520 | Brand         |
| RINVOQ          | RINVOQ UPADACITINIB TAB ER 24HR 30 MG |                | Brand         |
| RINVOQ          | UPADACITINIB TAB ER 24HR 45 MG        | 66603072007540 | Brand         |

## **Approval Criteria**

- **1** One of the following:
- **1.1** For members with diagnoses of Ulcerative Colitis, ALL of the following:

**1.1.1** Failure of a two-month trial of every other week therapy after completion of induction dosing regimen

#### **AND**

**1.1.2** Based on subtherapeutic drug concentrations and absence (or low levels) of drug antibodies

#### **AND**

**1.1.3** Provision of published literature supporting efficacy and safety of dosing regimen beyond induction of 8 weeks

#### OR

- **1.2** Members requesting early dose escalation (sooner use of higher doses to avoid untoward outcomes related to uncontrolled inflammation), BOTH of the following:
- **1.2.1** Submission of medical records (e.g., chart notes) documenting clinical details with description of the regimen (SHORT TERM APPROVAL- 3-month approval)

#### AND

**1.2.2** Member has difficult to control inflammation (e.g. biologic experiences with 2 or 3 previous biologic agents, member with perianal disease needing higher trough drug levels, etc.)

# 2. Revision History

| Date      | Notes                   |
|-----------|-------------------------|
| 12/5/2023 | 2024 New Implementation |

|   | Rytary (Carbidopa/Levodopa)   |  |  |  |  |
|---|---|--|--|--|--|
| [ | The thirty permitting part follows, british and quant, a that wife first to permit an excellent rate. |  |  |  |  |
|   |   |  |  |  |  |

# **Prior Authorization Guideline**

| Guideline ID          | GL-128987                   |  |
|-----------------------|-----------------------------|--|
| <b>Guideline Name</b> | Rytary (Carbidopa/Levodopa) |  |
| Formulary             | Quartz                      |  |

# **Guideline Note:**

| Effective Date: |
|-----------------|
|-----------------|

# 1. Criteria

| Product Name: Rytary                                 |                       |
|--|-----------------------|
| Approval Length 12 month(s)                          |                       |
| Therapy Stage  | Initial Authorization |
| Guideline Type Prior Authorization - IL and MN Plans |                       |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| RYTARY          | RYTARY CARBIDOPA & LEVODOPA CAP ER 23.75-95 MG 7320 |                | Brand         |
| RYTARY          | RYTARY CARBIDOPA & LEVODOPA CAP ER 36.25-145 MG     |                | Brand         |
| RYTARY          | RYTARY CARBIDOPA & LEVODOPA CAP ER 48.75-195 MG 7:  |                | Brand         |
| RYTARY          | CARBIDOPA & LEVODOPA CAP ER 61.25-245 MG            | 73209902100250 | Brand         |

**1** - Have a diagnosis of Parkinson's disease, post-encephalitic parkinsonism, or parkinsonism following intoxication from carbon monoxide or manganese

## **AND**

2 - Prescribed by, or in consultation with, a Neurologist

#### AND

**3** - Have experienced breakthrough symptoms despite titrated treatment with CONCURRENT immediate-release and extended-release carbidopa/levodopa generics

| Product Name: Rytary |                                       |  |
|----------------------|---------------------------------------|--|
| Approval Length      | 12 month(s)                           |  |
| Therapy Stage        | Reauthorization                       |  |
| Guideline Type       | Prior Authorization - IL and MN Plans |  |

| Product<br>Name | Generic Name                             | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| RYTARY          | CARBIDOPA & LEVODOPA CAP ER 23.75-95 MG  | 73209902100220 | Brand         |
| RYTARY          | CARBIDOPA & LEVODOPA CAP ER 36.25-145 MG | 73209902100230 | Brand         |
| RYTARY          | CARBIDOPA & LEVODOPA CAP ER 48.75-195 MG | 73209902100240 | Brand         |
| RYTARY          | CARBIDOPA & LEVODOPA CAP ER 61.25-245 MG | 73209902100250 | Brand         |

## **Approval Criteria**

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug.

| Product Name: Rytary               |   |               |  |  |
|------------------------------------|---|---------------|--|--|
| Approval Length 12/31/2039         |   |               |  |  |
| Guideline T                        | Guideline Type Prior Authorization - All Plans except IL and MN Plans |               |  |  |
| Product Generic Name GPI Brand/Gen |   | Brand/Generic |  |  |

| Name   |  |                |       |
|--------|--|----------------|-------|
| RYTARY | CARBIDOPA & LEVODOPA CAP ER 23.75-95 MG  | 73209902100220 | Brand |
| RYTARY | CARBIDOPA & LEVODOPA CAP ER 36.25-145 MG | 73209902100230 | Brand |
| RYTARY | CARBIDOPA & LEVODOPA CAP ER 48.75-195 MG | 73209902100240 | Brand |
| RYTARY | CARBIDOPA & LEVODOPA CAP ER 61.25-245 MG | 73209902100250 | Brand |

- 1 All of the following:
- **1.1** Have a diagnosis of Parkinson's disease, post-encephalitic parkinsonism, or parkinsonism following intoxication from carbon monoxide or manganese

## **AND**

**1.2** Prescribed by, or in consultation with, a Neurologist

#### **AND**

**1.3** Have experienced breakthrough symptoms despite titrated treatment with CONCURRENT immediate-release and extended-release carbidopa/levodopa generics

## OR

**2** - Person is new to the plan (within the past 90 days) and submission of medical notes (e.g., chart notes) from the past 12 months that the person is continuing therapy with the requested medication

# 2. Revision History

| Date      | Notes       |
|-----------|-------------|
| 9/20/2023 | New Program |

| Sam                       | isca (To  | olvapta   | ın)               |  |
|---------------------------|---|---|-------------------|--|
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|                           |   |   |                   |  |

# **Prior Authorization Guideline**

| Guideline ID   | GL-131950          |
|----------------|--------------------|
| Guideline Name | Samsca (Tolvaptan) |
| Formulary      | Quartz             |

# **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

# 1. Criteria

| Product Name: Generic: Tolvaptan |   |  |  |
|----------------------------------|---|--|--|
| Approval Length                  | 12 month(s)   |  |  |
| Therapy Stage                    | Initial Authorization                                   |  |  |
| Guideline Type                   | Guideline Type Prior Authorization-IL and MN Plans Only |  |  |

| Product<br>Name | Generic Name        | GPI            | Brand/Generic |
|-----------------|---------------------|----------------|---------------|
| TOLVAPTAN       | TOLVAPTAN TAB 15 MG | 30454060000320 | Generic       |
| TOLVAPTAN       | TOLVAPTAN TAB 30 MG | 30454060000330 | Generic       |

# **Approval Criteria**

1 - Diagnosis of severe hypervolemic or euvolemic hyponatremia (sodium level < 125 mEq/L)

OR symptomatic less severe hyponatremia (sodium level 125 mEq/L -134 mEq/L)

## **AND**

2 - Current hospitalization for hyponatremia

#### **AND**

**3** - Symptoms or low serum sodium levels persist despite supervised fluid restriction and appropriate sodium supplementation

| Product Name: Generic: Tolvaptan   |   |  |               |  |
|------------------------------------|---|--|---------------|--|
| Approval Length 12 month(s)        |   |  |               |  |
| Therapy Sta                        | Therapy Stage Reauthorization                           |  |               |  |
| Guideline Ty                       | Guideline Type Prior Authorization-IL and MN Plans Only |  |               |  |
| Product Congris Name CPI Brand/Cor |   |  | Brand/Conorio |  |

| Product<br>Name | Generic Name        | GPI            | Brand/Generic |
|-----------------|---------------------|----------------|---------------|
| TOLVAPTAN       | TOLVAPTAN TAB 15 MG | 30454060000320 | Generic       |
| TOLVAPTAN       | TOLVAPTAN TAB 30 MG | 30454060000330 | Generic       |

## **Approval Criteria**

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug.

| Product Name: Generic: Tolvaptan                              |            |  |
|---|------------|--|
| Approval Length   | 12/31/2039 |  |
| Guideline Type Prior Authorization-All plans except IL and MN |            |  |

| Product<br>Name | Generic Name        | GPI            | Brand/Generic |
|-----------------|---------------------|----------------|---------------|
| TOLVAPTAN       | TOLVAPTAN TAB 15 MG | 30454060000320 | Generic       |
| TOLVAPTAN       | TOLVAPTAN TAB 30 MG | 30454060000330 | Generic       |
|                 |                     |                |               |

**1** - Diagnosis of severe hypervolemic or euvolemic hyponatremia (sodium level < 125 mEq/L) OR symptomatic less severe hyponatremia (sodium level 125 mEq/L -134 mEq/L)

**AND** 

2 - Current hospitalization for hyponatremia

AND

**3** - Symptoms or low serum sodium levels persist despite supervised fluid restriction and appropriate sodium supplementation

# 2. Revision History

| Date       | Notes       |
|------------|-------------|
| 10/31/2023 | New program |

| Sarafem (Fluoxetine 10 mg Tablet)   |  |  |  |
|---|--|--|--|
| (3) Technologue and indepent Technologue and content and content into the forth its parts for averable artistics. |  |  |  |
|   |  |  |  |

# **Prior Authorization Guideline**

| Guideline ID          | uideline ID GL-137190             |  |
|-----------------------|-----------------------------------|--|
| <b>Guideline Name</b> | Sarafem (Fluoxetine 10 mg Tablet) |  |
| Formulary             | Quartz                            |  |

# **Guideline Note:**

| Effective Date: |
|-----------------|
|-----------------|

# 1. Criteria

| Product Name: Fluoxetine 10 mg Tablet |                                       |
|---------------------------------------|---------------------------------------|
| Approval Length                       | 12 month(s)                           |
| Therapy Stage                         | Initial Authorization                 |
| Guideline Type                        | Prior Authorization - IL and MN Plans |

| Product Name                | Generic Name                    | GPI            | Brand/Generic |
|-----------------------------|---------------------------------|----------------|---------------|
| FLUOXETINE<br>HYDROCHLORIDE | FLUOXETINE HCL TAB 10 MG        | 58160040000310 | Generic       |
| FLUOXETINE<br>HYDROCHLORIDE | FLUOXETINE HCL (PMDD) TAB 10 MG | 62206040000310 | Generic       |

## **Approval Criteria**

1 - Person requires a dose that cannot be met using the preferred fluoxetine capsule

formulations (5 or 15 mg per day

#### **AND**

**2** - An adequate trial of daily dosing at 10 mg and 20 mg capsule did not control symptoms or caused intolerable side effects

| Product Name: Fluoxetine 10 mg Tablet                |  |
|--|--|
| Approval Length 12 month(s)                          |  |
| Therapy Stage Reauthorization                        |  |
| Guideline Type Prior Authorization - IL and MN Plans |  |

| Product Name                | Generic Name                    | GPI            | Brand/Generic |
|-----------------------------|---------------------------------|----------------|---------------|
| FLUOXETINE<br>HYDROCHLORIDE | FLUOXETINE HCL TAB 10 MG        | 58160040000310 | Generic       |
| FLUOXETINE<br>HYDROCHLORIDE | FLUOXETINE HCL (PMDD) TAB 10 MG | 62206040000310 | Generic       |

## **Approval Criteria**

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug.

| Product Name: Fluoxetine 10 mg Tablet                           |  |
|---|--|
| Approval Length 12/31/2039                                      |  |
| Guideline Type Prior Authorization - All plans except IL and MN |  |

| Product Name                | Generic Name                    | GPI            | Brand/Generic |
|-----------------------------|---------------------------------|----------------|---------------|
| FLUOXETINE<br>HYDROCHLORIDE | FLUOXETINE HCL TAB 10 MG        | 58160040000310 | Generic       |
| FLUOXETINE<br>HYDROCHLORIDE | FLUOXETINE HCL (PMDD) TAB 10 MG | 62206040000310 | Generic       |

## **Approval Criteria**

**1** - Person requires a dose that cannot be met using the preferred fluoxetine capsule formulations (5 or 15 mg per day

#### AND

**2** - An adequate trial of daily dosing at 10 mg and 20 mg capsule did not control symptoms or caused intolerable side effects

| Product Name: Fluoxetine 10 mg Tablet         |      |                      |                |               |
|---|------|----------------------|----------------|---------------|
| Guideline Type                                |      | Quantity limit       |                |               |
| Product Name                                  | Gene | eric Name            | GPI            | Brand/Generic |
| FLUOXETINE<br>HYDROCHLORIDE                   | FLUO | XETINE HCL TAB 10 MG | 58160040000310 | Generic       |
| FLUOXETINE HCL (PMDD) TAB 10 MG HYDROCHLORIDE |      | 62206040000310       | Generic        |               |

# **Approval Criteria**

**1** - Doses greater than 15mg (1.5 tablets) per day should be denied. Doses greater than 15mg (1.5 tablets) per day require use of the preferred fluoxetine capsule (ie. fluoxetine 10mg capsule, fluoxetine 20mg capsule, fluoxetine 40mg capsule).

# 2. Revision History

| Date       | Notes          |
|------------|----------------|
| 11/30/2023 | Update Program |

| Savella (milnacipran)  |  |  |  |  |
|--|--|--|--|--|
| [4] The litted large connet be diployed. The fire any has been record, created, or debat large find to late points to the connection and installs. |  |  |  |  |
|  |  |  |  |  |
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# **Prior Authorization Guideline**

| Guideline ID          | GL-129647             |  |
|-----------------------|-----------------------|--|
| <b>Guideline Name</b> | Savella (milnacipran) |  |
| Formulary             | Quartz                |  |

# **Guideline Note:**

| Effective Date: |
|-----------------|
|-----------------|

# 1. Criteria

| Product Name: Savella                                |  |
|--|--|
| Approval Length 12 month(s)                          |  |
| Therapy Stage Initial Authorization                  |  |
| Guideline Type Prior Authorization - IL and MN Plans |  |

| Product<br>Name              | Generic Name   | GPI            | Brand/Generic |
|------------------------------|--|----------------|---------------|
| SAVELLA                      | MILNACIPRAN HCL TAB 12.5 MG                                  | 62504050100320 | Brand         |
| SAVELLA                      | MILNACIPRAN HCL TAB 25 MG                                    | 62504050100330 | Brand         |
| SAVELLA                      | MILNACIPRAN HCL TAB 50 MG                                    | 62504050100340 | Brand         |
| SAVELLA                      | MILNACIPRAN HCL TAB 100 MG                                   | 62504050100350 | Brand         |
| SAVELLA<br>TITRATION<br>PACK | MILNACIPRAN HCL TAB 12.5 MG (5) & 25 MG (8) & 50 MG (42) PAK | 62504050106320 | Brand         |

**1** - Trial of at least 2 preferred treatment options for fibromyalgia: amitriptyline, cyclobenzaprine, venlafaxine, duloxetine, gabapentin, pregabalin

| Product Name: Savella                                |                 |
|--|-----------------|
| Approval Length                                      | 12 month(s)     |
| Therapy Stage  | Reauthorization |
| Guideline Type Prior Authorization - IL and MN Plans |                 |

| Product<br>Name              | Generic Name   | GPI            | Brand/Generic |
|------------------------------|--|----------------|---------------|
| SAVELLA                      | MILNACIPRAN HCL TAB 12.5 MG                                  | 62504050100320 | Brand         |
| SAVELLA                      | MILNACIPRAN HCL TAB 25 MG                                    | 62504050100330 | Brand         |
| SAVELLA                      | MILNACIPRAN HCL TAB 50 MG                                    | 62504050100340 | Brand         |
| SAVELLA                      | MILNACIPRAN HCL TAB 100 MG                                   | 62504050100350 | Brand         |
| SAVELLA<br>TITRATION<br>PACK | MILNACIPRAN HCL TAB 12.5 MG (5) & 25 MG (8) & 50 MG (42) PAK | 62504050106320 | Brand         |

## **Approval Criteria**

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug.

| Product Name: Savella |  |  |
|-----------------------|--|--|
| Approval Length       | 12/31/2039                                       |  |
| Guideline Type        | Prior Authorization - All plans except IL and MN |  |

| Product<br>Name | Generic Name                | GPI            | Brand/Generic |
|-----------------|-----------------------------|----------------|---------------|
| SAVELLA         | MILNACIPRAN HCL TAB 12.5 MG | 62504050100320 | Brand         |
| SAVELLA         | MILNACIPRAN HCL TAB 25 MG   | 62504050100330 | Brand         |
| SAVELLA         | MILNACIPRAN HCL TAB 50 MG   | 62504050100340 | Brand         |
| SAVELLA         | MILNACIPRAN HCL TAB 100 MG  | 62504050100350 | Brand         |

|  | MILNACIPRAN HCL TAB 12.5 MG (5) & 25 MG (8) & 50 MG (42) PAK | 62504050106320 | Brand |
|--|--|----------------|-------|
|--|--|----------------|-------|

**1** - Trial of at least 2 preferred treatment options for fibromyalgia: amitriptyline, cyclobenzaprine, venlafaxine, duloxetine, gabapentin, pregabalin

# 2. Revision History

| Date      | Notes       |
|-----------|-------------|
| 10/6/2023 | New Program |

| Secuado (asei  | napine patches)  |  |
|--|--|--|
| [2] The Solid Programmer to Refuge. The time fact that manual, wasted, a shifted tool, Solid | the state of the s |  |

# **Prior Authorization Guideline**

| Guideline ID          | GL-128186                   |
|-----------------------|-----------------------------|
| <b>Guideline Name</b> | Secuado (asenapine patches) |
| Formulary             | Quartz                      |

# **Guideline Note:**

| Effective Date: |
|-----------------|
|-----------------|

# 1. Criteria

| Product Name: Secuado |                                       |  |
|-----------------------|---------------------------------------|--|
| Approval Length       | 12 month(s)                           |  |
| Therapy Stage         | Initial Authorization                 |  |
| Guideline Type        | Prior Authorization - IL and MN Plans |  |

| Product<br>Name | Generic Name                         | GPI            | Brand/Generic |
|-----------------|--------------------------------------|----------------|---------------|
| SECUADO         | ASENAPINE TD PATCH 24 HR 3.8 MG/24HR | 59155015008520 | Brand         |
| SECUADO         | ASENAPINE TD PATCH 24 HR 5.7 MG/24HR | 59155015008530 | Brand         |
| SECUADO         | ASENAPINE TD PATCH 24 HR 7.6 MG/24HR | 59155015008540 | Brand         |

# **Approval Criteria**

- **1** One of the following:
- **1.1** Trial and failure or intolerance to the sublingual tablet formulation at an equivalent dose

OR

**1.2** Person with swallowing impairment or other medical condition that prevents use of solid dose forms

OR

- 2 For Minnesota Plans One of the following:
- **2.1** When prescribed for emotional disturbance or mental illness, approve if prescriber provides submission of medial records (e.g. chart notes) that all equivalent drugs in the formulary were considered and it has been determined that the drug prescribed will best treat the member's condition

OR

- **2.2** Both of the following for continuation of care: (i.e. formulary changes or new member [as evidenced by coverage effective date of less than or equal to 90 days]):
  - **2.2.1** Member has been treated with the drug for 90 days prior to the change

#### **AND**

**2.2.2** Prescriber provides submission of medical records (e.g., chart notes) that the drug prescribed will best treat the member's condition

| Product Name: Secuado        |                              |                                       |               |  |
|------------------------------|------------------------------|---------------------------------------|---------------|--|
| Approval Len                 | ngth                         | 12 month(s)                           |               |  |
| Therapy Stag                 | nerapy Stage Reauthorization |                                       |               |  |
| Guideline Type               |                              | Prior Authorization - IL and MN Plans |               |  |
| Product Generic Name<br>Name |                              | GPI                                   | Brand/Generic |  |

| SECUADO | ASENAPINE TD PATCH 24 HR 3.8 MG/24HR | 59155015008520 | Brand |
|---------|--------------------------------------|----------------|-------|
| SECUADO | ASENAPINE TD PATCH 24 HR 5.7 MG/24HR | 59155015008530 | Brand |
| SECUADO | ASENAPINE TD PATCH 24 HR 7.6 MG/24HR | 59155015008540 | Brand |

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug

| Product Name: Secuado   |  |
|---|--|
| Approval Length 12/31/2039                                      |  |
| Guideline Type Prior Authorization - All plans except IL and MN |  |

| Product<br>Name | Generic Name                         | GPI            | Brand/Generic |
|-----------------|--------------------------------------|----------------|---------------|
| SECUADO         | ASENAPINE TD PATCH 24 HR 3.8 MG/24HR | 59155015008520 | Brand         |
| SECUADO         | ASENAPINE TD PATCH 24 HR 5.7 MG/24HR | 59155015008530 | Brand         |
| SECUADO         | ASENAPINE TD PATCH 24 HR 7.6 MG/24HR | 59155015008540 | Brand         |

## **Approval Criteria**

1 - Trial and failure or intolerance to the sublingual tablet formulation at an equivalent dose

OR

**2** - Person with swallowing impairment or other medical condition that prevents use of solid dose forms

# 2. Revision History

| Date     | Notes       |
|----------|-------------|
| 9/7/2023 | New Program |

| Serotonin Modulating Antidepress  |   |  |  |  | ants |  |
|-----------------------------------|---|--|--|--|------|--|
| The let at Inage cannot be displa | yest. The fire may have have recent, we assess, or defend, budy t | that the field grains in the account the and it makes. |  |  |      |  |

# **Prior Authorization Guideline**

| Guideline ID          | GL-127881                            |  |
|-----------------------|--------------------------------------|--|
| <b>Guideline Name</b> | Serotonin Modulating Antidepressants |  |
| Formulary             | Quartz                               |  |

# **Guideline Note:**

| Effective Date: |
|-----------------|
|-----------------|

# 1. Criteria

| Product Name: Trintellix |                                |
|--------------------------|--------------------------------|
| Approval Length          | 12 month(s)                    |
| Therapy Stage            | Initial Authorization          |
| Guideline Type           | Step Therapy - IL and MN Plans |

| Product<br>Name | Generic Name                            | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| TRINTELLIX      | VORTIOXETINE HBR TAB 5 MG (BASE EQUIV)  | 58120093100310 | Brand         |
| TRINTELLIX      | VORTIOXETINE HBR TAB 10 MG (BASE EQUIV) | 58120093100320 | Brand         |
| TRINTELLIX      | VORTIOXETINE HBR TAB 20 MG (BASE EQUIV) | 58120093100340 | Brand         |

# **Approval Criteria**

- **1** Trial and failure, contraindication, or intolerance of at least two preferred antidepressants within the Selective Serotonin Reuptake inhibitor (SSRI) or Serotonin Norepinephrine Reuptake inhibitor (SNRI) drug classes
  - citalopram
  - escitalopram
  - sertraline
  - paroxetine
  - fluoxetine
  - venlafaxine
  - duloxetine

| Product Name: Trintellix |                                |  |
|--------------------------|--------------------------------|--|
| Approval Length          | 12 month(s)                    |  |
| Therapy Stage            | Reauthorization                |  |
| Guideline Type           | Step Therapy - IL and MN Plans |  |

| Product<br>Name | Generic Name                            | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| TRINTELLIX      | VORTIOXETINE HBR TAB 5 MG (BASE EQUIV)  | 58120093100310 | Brand         |
| TRINTELLIX      | VORTIOXETINE HBR TAB 10 MG (BASE EQUIV) | 58120093100320 | Brand         |
| TRINTELLIX      | VORTIOXETINE HBR TAB 20 MG (BASE EQUIV) | 58120093100340 | Brand         |

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug

| Product Name: Trintellix |   |  |
|--------------------------|---|--|
| Approval Length          | 12/31/2039                                      |  |
| Guideline Type           | Step Therapy - All plans except IL and MN Plans |  |

| Product<br>Name | Generic Name                            | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| TRINTELLIX      | VORTIOXETINE HBR TAB 5 MG (BASE EQUIV)  | 58120093100310 | Brand         |
| TRINTELLIX      | VORTIOXETINE HBR TAB 10 MG (BASE EQUIV) | 58120093100320 | Brand         |
| TRINTELLIX      | VORTIOXETINE HBR TAB 20 MG (BASE EQUIV) | 58120093100340 | Brand         |

- **1** Trial and failure, contraindication, or intolerance of at least two preferred antidepressants within the Selective Serotonin Reuptake inhibitor (SSRI) or Serotonin Norepinephrine Reuptake inhibitor (SNRI) drug classes
  - citalopram
  - escitalopram
  - sertraline
  - paroxetine
  - fluoxetine
  - venlafaxine
  - duloxetine

# 2. Revision History

| Date      | Notes       |
|-----------|-------------|
| 8/21/2023 | New Program |

| Signifor (Pasireotide Diasparte)  |  |
|---|--|
| (3) had been required indigated. The first indicated associated a control of the first price for control and control. |  |

# **Prior Authorization Guideline**

| Guideline ID          | GL-131411                        |
|-----------------------|----------------------------------|
| <b>Guideline Name</b> | Signifor (Pasireotide Diasparte) |
| Formulary             | Quartz                           |

# **Guideline Note:**

| Effective Date: |
|-----------------|
|-----------------|

# 1. Criteria

| Product Name: Signifor |  |
|------------------------|--|
| Approval Length        | 12 month(s)                              |
| Therapy Stage          | Initial Authorization                    |
| Guideline Type         | Prior Authorization-IL and MN Plans Only |

| Product<br>Name | Generic Name                                       | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| SIGNIFOR        | PASIREOTIDE DIASPARTATE INJ 0.3 MG/ML (BASE EQUIV) | 30170075202020 | Brand         |
| SIGNIFOR        | PASIREOTIDE DIASPARTATE INJ 0.6 MG/ML (BASE EQUIV) | 30170075202030 | Brand         |
| SIGNIFOR        | PASIREOTIDE DIASPARTATE INJ 0.9 MG/ML (BASE EQUIV) | 30170075202040 | Brand         |

- 1 Diagnosis of Cushing disease
- 1.1 Ongoing symptoms despite pituitary surgery or nonsurgical candidate

**AND** 

2 - Age greater than or equal to 18 years

**AND** 

3 - Trial and failure, contraindication, or intolerance to octreotide

OR

4 - Other FDA labeled indications

| Product Name: Signifor |  |
|------------------------|--|
| Approval Length        | 12 month(s)                              |
| Therapy Stage          | Reauthorization                          |
| Guideline Type         | Prior Authorization-IL and MN Plans Only |

| Product<br>Name | Generic Name                                       | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| SIGNIFOR        | PASIREOTIDE DIASPARTATE INJ 0.3 MG/ML (BASE EQUIV) | 30170075202020 | Brand         |
| SIGNIFOR        | PASIREOTIDE DIASPARTATE INJ 0.6 MG/ML (BASE EQUIV) | 30170075202030 | Brand         |
| SIGNIFOR        | PASIREOTIDE DIASPARTATE INJ 0.9 MG/ML (BASE EQUIV) | 30170075202040 | Brand         |

### **Approval Criteria**

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug.

| Product Name: Signifor |  |
|------------------------|--|
| Approval Length        | 12/31/2039                                     |
| Guideline Type         | Prior Authorization-All plans except IL and MN |

| Product<br>Name | Generic Name                                       | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| SIGNIFOR        | PASIREOTIDE DIASPARTATE INJ 0.3 MG/ML (BASE EQUIV) | 30170075202020 | Brand         |
| SIGNIFOR        | PASIREOTIDE DIASPARTATE INJ 0.6 MG/ML (BASE EQUIV) | 30170075202030 | Brand         |
| SIGNIFOR        | PASIREOTIDE DIASPARTATE INJ 0.9 MG/ML (BASE EQUIV) | 30170075202040 | Brand         |

- 1 Diagnosis of Cushing disease
- 1.1 Ongoing symptoms despite pituitary surgery or nonsurgical candidate

**AND** 

2 - Age greater than or equal to 18 years

**AND** 

3 - Trial and failure, contraindication, or intolerance to octreotide

OR

4 - Other FDA labeled indications

# 2. Revision History

| Date       | Notes       |
|------------|-------------|
| 10/24/2023 | New program |

| Simponi (golimumab)  |  |  |
|--|--|--|
| The Management of States and Control and C |  |  |
|  |  |  |

# **Prior Authorization Guideline**

| Guideline ID   | GL-137422           |
|----------------|---------------------|
| Guideline Name | Simponi (golimumab) |
| Formulary      | Quartz              |

# **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

## Note:

Member new to the plan (as evidenced by coverage effective date of less than or equal to 90 days) who initiated therapy using a manufacturer-sponsored free drug program, provider samples, and/or vouchers will go through initial criteria, otherwise for continuation of therapy for new to plan, reauthorization criteria applies.

## 1. Criteria

| Product Name: Simponi               |   |  |                |               |
|-------------------------------------|---|--|----------------|---------------|
| Diagnosis Psoriatic Arthritis (PsA) |   |  |                |               |
| Approval Le                         | oval Length 12/31/2039                                    |  |                |               |
| Guideline Type                      |   | Prior Authorization - All plans except IL and MN Plans |                |               |
| Product<br>Name                     | Generic Name  |  | GPI            | Brand/Generic |
| SIMPONI                             | GOLIMUMAB SUBCUTANEOUS SOLN AUTO-<br>INJECTOR 50 MG/0.5ML |  | 6627004000D520 | Brand         |

| SIMPONI | GOLIMUMAB SUBCUTANEOUS SOLN AUTO-<br>INJECTOR 100 MG/ML    | 6627004000D540 | Brand |
|---------|--|----------------|-------|
| SIMPONI | GOLIMUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 50 MG/0.5ML  | 6627004000E520 | Brand |
| SIMPONI | GOLIMUMAB SUBCUTANEOUS SOLN PREFILLED<br>SYRINGE 100 MG/ML | 6627004000E540 | Brand |

1 - Diagnosis of moderate to severely active psoriatic arthritis (PsA)

#### **AND**

- **2** Submission of medical records (e.g., chart notes) documenting at least ONE of the following:
  - · actively inflamed joints
  - axial disease
  - · active skin, nail, or scalp psoriasis involvement
  - dactylitis
  - enthesitis

#### **AND**

3 - Prescribed by or in consultation with a Dermatologist or Rheumatologist

### AND

**4** - Not used in combination with other biologic DMARDs (e.g., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

#### **AND**

5 - Medication will be self-administered

| Product Name: Simponi |                           |
|-----------------------|---------------------------|
| Diagnosis             | Psoriatic Arthritis (PsA) |

| Approval Length | 12 month(s)                           |
|-----------------|---------------------------------------|
| Therapy Stage   | Initial Authorization                 |
| Guideline Type  | Prior Authorization - IL and MN Plans |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| SIMPONI         | GOLIMUMAB SUBCUTANEOUS SOLN AUTO-<br>INJECTOR 50 MG/0.5ML | 6627004000D520 | Brand         |
| SIMPONI         | GOLIMUMAB SUBCUTANEOUS SOLN AUTO-<br>INJECTOR 100 MG/ML   | 6627004000D540 | Brand         |
| SIMPONI         | GOLIMUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 50 MG/0.5ML | 6627004000E520 | Brand         |
| SIMPONI         | GOLIMUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 100 MG/ML   | 6627004000E540 | Brand         |

1 - Diagnosis of moderate to severely active psoriatic arthritis (PsA)

#### AND

2 - Prescribed by or in consultation with a Dermatologist or Rheumatologist

#### **AND**

- **3** Submission of medical records (e.g., chart notes) documenting at least ONE of the following:
  - actively inflamed joints
  - axial disease
  - active skin/nail/scalp psoriasis involvement
  - dactylitis
  - enthesitis

#### **AND**

**4** - Not used in combination with other biologic DMARDs (e.g., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

#### **AND**

**5** - Medication will be self-administered

| Product Name: Simponi   |  |  |
|---|--|--|
| Diagnosis   | Moderate to Severely Active Rheumatoid Arthritis |  |
| Approval Length 12/31/2039  |  |  |
| Guideline Type Prior Authorization - All plans except IL and MN Plans |  |  |

| Product<br>Name | Generic Name   | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| SIMPONI         | GOLIMUMAB SUBCUTANEOUS SOLN AUTO-<br>INJECTOR 50 MG/0.5ML    | 6627004000D520 | Brand         |
| SIMPONI         | GOLIMUMAB SUBCUTANEOUS SOLN AUTO-<br>INJECTOR 100 MG/ML      | 6627004000D540 | Brand         |
| SIMPONI         | GOLIMUMAB SUBCUTANEOUS SOLN PREFILLED<br>SYRINGE 50 MG/0.5ML | 6627004000E520 | Brand         |
| SIMPONI         | GOLIMUMAB SUBCUTANEOUS SOLN PREFILLED<br>SYRINGE 100 MG/ML   | 6627004000E540 | Brand         |

## **Approval Criteria**

1 - Diagnosis of moderate to severely active Rheumatoid arthritis (RA)

#### **AND**

2 - Prescribed by or in consultation with a Rheumatologist

#### AND

- **3** Submission of medical records (e.g., chart notes) documenting a 3-month trial and failure, intolerance, or contraindication to ONE of the following:
  - Methotrexate (MTX)\*
  - Leflunomide
  - Hydroxychloroquine

Sulfasalazine

#### **AND**

**4** - Therapy must not be used in combination with other biologic disease modifying anti-rheumatic drug (DMARD) (e.g., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

#### **AND**

5 - Medication will be self-administered

| *Absolute contraindications to methotrexate are pregnancy, nursing, al   |
|--|
| coholism, alcoholic liver disease or other chronic liver disease, immuno deficiency syndromes, bone marrow hyperplasia, leukopenia, thromboc |
| ytopenia or significant anemia, or hypersensitivity to methotrexate.   |

| Product Name: Simponi |  |  |
|-----------------------|--|--|
| Diagnosis             | Moderate to Severely Active Rheumatoid Arthritis |  |
| Approval Length       | 12 month(s)                                      |  |
| Therapy Stage         | Initial Authorization                            |  |
| Guideline Type        | Prior Authorization - IL and MN Plans            |  |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| SIMPONI         | GOLIMUMAB SUBCUTANEOUS SOLN AUTO-<br>INJECTOR 50 MG/0.5ML | 6627004000D520 | Brand         |
| SIMPONI         | GOLIMUMAB SUBCUTANEOUS SOLN AUTO-<br>INJECTOR 100 MG/ML   | 6627004000D540 | Brand         |
| SIMPONI         | GOLIMUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 50 MG/0.5ML | 6627004000E520 | Brand         |
| SIMPONI         | GOLIMUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 100 MG/ML   | 6627004000E540 | Brand         |

## **Approval Criteria**

1 - Diagnosis of moderate to severely active Rheumatoid arthritis (RA)

#### AND

2 - Prescribed by or in consultation with a Rheumatologist

#### **AND**

- **3** Submission of medical records (e.g., chart notes) documenting a 3-month trial and failure, intolerance, or contraindication to ONE of the following:
  - Methotrexate (MTX)\*
  - Leflunomide
  - Hydroxychloroquine
  - Sulfasalazine

#### AND

**4** - Therapy must not be used in combination with other biologic disease modifying antirheumatic drug (DMARD) (e.g., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

#### **AND**

5 - Medication will be self-administered

| Notes | *Absolute contraindications to methotrexate are pregnancy, nursing, al   |
|-------|--|
|       | coholism, alcoholic liver disease or other chronic liver disease, immuno |
|       | deficiency syndromes, bone marrow hyperplasia, leukopenia, thromboc      |
|       | ytopenia or significant anemia, or hypersensitivity to methotrexate.     |

| Product Name: Simponi   |                             |
|---|-----------------------------|
| Diagnosis   | Ankylosing spondylitis (AS) |
| Approval Length   | 12/31/2039                  |
| Guideline Type Prior Authorization - All plans except IL and MN Plans |                             |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| SIMPONI         | GOLIMUMAB SUBCUTANEOUS SOLN AUTO-<br>INJECTOR 50 MG/0.5ML | 6627004000D520 | Brand         |
| SIMPONI         | GOLIMUMAB SUBCUTANEOUS SOLN AUTO-                         | 6627004000D540 | Brand         |

|         | INJECTOR 100 MG/ML  |                |       |
|---------|---|----------------|-------|
| SIMPONI | GOLIMUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 50 MG/0.5ML | 6627004000E520 | Brand |
| SIMPONI | GOLIMUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 100 MG/ML   | 6627004000E540 | Brand |

1 - Diagnosis of Ankylosing spondylitis (AS)

#### **AND**

2 - Prescribed by or in consultation with a Rheumatologist

#### **AND**

**3** - Trial and failure to a 1-month trial of scheduled prescription doses of two different NSAIDs (e.g., naproxen, nabumetone, diclofenac, etc.)

#### **AND**

**4** - Medication will not be used in combination with other biologic disease modifying antirheumatic drug (DMARD) (e.g., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc)

#### **AND**

5 - Medication will be self-administered (not in clinic/provider office)

| Product Name: Simponi                 |                                       |
|---------------------------------------|---------------------------------------|
| Diagnosis Ankylosing spondylitis (AS) |                                       |
| Approval Length                       | 12 month(s)                           |
| Therapy Stage                         | Initial Authorization                 |
| Guideline Type                        | Prior Authorization - IL and MN Plans |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| SIMPONI         | GOLIMUMAB SUBCUTANEOUS SOLN AUTO-<br>INJECTOR 50 MG/0.5ML | 6627004000D520 | Brand         |
| SIMPONI         | GOLIMUMAB SUBCUTANEOUS SOLN AUTO-<br>INJECTOR 100 MG/ML   | 6627004000D540 | Brand         |
| SIMPONI         | GOLIMUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 50 MG/0.5ML | 6627004000E520 | Brand         |
| SIMPONI         | GOLIMUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 100 MG/ML   | 6627004000E540 | Brand         |

1 - Diagnosis of Ankylosing spondylitis (AS)

#### **AND**

2 - Prescribed by or in consultation with a Rheumatologist

#### **AND**

**3** - Trial and failure to a 1-month trial of scheduled prescription doses of two different NSAIDs (e.g., naproxen, nabumetone, diclofenac, etc.)

#### **AND**

**4** - Medication will not be used in combination with other biologic disease modifying antirheumatic drug (DMARD) (e.g., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc)

#### **AND**

5 - Medication will be self-administered (not in clinic/provider office)

| Product Name: Simponi |                         |
|-----------------------|-------------------------|
| Diagnosis             | Ulcerative Colitis (UC) |

| Approval Length | 12/31/2039   |
|-----------------|--|
| Guideline Type  | Prior Authorization - All plans except IL and MN Plans |

| Product<br>Name | Generic Name   | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| SIMPONI         | GOLIMUMAB SUBCUTANEOUS SOLN AUTO-<br>INJECTOR 50 MG/0.5ML  | 6627004000D520 | Brand         |
| SIMPONI         | GOLIMUMAB SUBCUTANEOUS SOLN AUTO-<br>INJECTOR 100 MG/ML    | 6627004000D540 | Brand         |
| SIMPONI         | GOLIMUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 50 MG/0.5ML  | 6627004000E520 | Brand         |
| SIMPONI         | GOLIMUMAB SUBCUTANEOUS SOLN PREFILLED<br>SYRINGE 100 MG/ML | 6627004000E540 | Brand         |

**1** - Diagnosis of moderate to severely active ulcerative colitis (UC)

#### AND

**2** - Prescribed by or in consultation with a Gastroenterologist

#### AND

**3** - Trial and failure or contraindication to at least a short course (2-4 weeks) of oral corticosteroids

#### **AND**

- **4** High-risk individual as evidence by ONE of the following:
  - Extensive colitis
  - Deep ulcers
  - Age less than 40 years
  - High C-reactive protein (CRP) and erythrocyte sedimentation rate (ESR)
  - Steroid-requiring disease
  - History of hospitalization
  - C. difficile infection
  - CMV infection

#### **AND**

**5** - Medication will not be used in combination with other biologic disease modifying antirheumatic drug (DMARD) (e.g., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc)

#### **AND**

6 - Medication will be self-administered (not in clinic/provider office)

| Product Name: Simponi |                                       |
|-----------------------|---------------------------------------|
| Diagnosis             | Ulcerative Colitis (UC)               |
| Approval Length       | 12 month(s)                           |
| Therapy Stage         | Initial Authorization                 |
| Guideline Type        | Prior Authorization - IL and MN Plans |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| SIMPONI         | GOLIMUMAB SUBCUTANEOUS SOLN AUTO-<br>INJECTOR 50 MG/0.5ML | 6627004000D520 | Brand         |
| SIMPONI         | GOLIMUMAB SUBCUTANEOUS SOLN AUTO-<br>INJECTOR 100 MG/ML   | 6627004000D540 | Brand         |
| SIMPONI         | GOLIMUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 50 MG/0.5ML | 6627004000E520 | Brand         |
| SIMPONI         | GOLIMUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 100 MG/ML   | 6627004000E540 | Brand         |

# **Approval Criteria**

1 - Diagnosis of moderate to severely active ulcerative colitis (UC)

#### **AND**

2 - Prescribed by or in consultation with a Gastroenterologist

#### AND

**3** - Trial and failure or contraindication to at least a short course (2-4 weeks) of oral corticosteroids

#### **AND**

- 4 High-risk individual as evidence by ONE of the following:
  - Extensive colitis
  - Deep ulcers
  - Age less than 40 years
  - High C-reactive protein (CRP) and erythrocyte sedimentation rate (ESR)
  - Steroid-requiring disease
  - History of hospitalization
  - C. difficile infection
  - CMV infection

#### **AND**

**5** - Medication will not be used in combination with other biologic disease modifying antirheumatic drug (DMARD) (e.g., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc)

#### **AND**

6 - Medication will be self-administered (not in clinic/provider office)

| Product Name: Simponi |                                       |
|-----------------------|---------------------------------------|
| Diagnosis             | All Indications Above                 |
| Approval Length       | 12 month(s)                           |
| Therapy Stage         | Reauthorization                       |
| Guideline Type        | Prior Authorization - IL and MN Plans |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
|                 | GOLIMUMAB SUBCUTANEOUS SOLN AUTO-<br>INJECTOR 50 MG/0.5ML | 6627004000D520 | Brand         |

| SIMPONI | GOLIMUMAB SUBCUTANEOUS SOLN AUTO-<br>INJECTOR 100 MG/ML    | 6627004000D540 | Brand |
|---------|--|----------------|-------|
| SIMPONI | GOLIMUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 50 MG/0.5ML  | 6627004000E520 | Brand |
| SIMPONI | GOLIMUMAB SUBCUTANEOUS SOLN PREFILLED<br>SYRINGE 100 MG/ML | 6627004000E540 | Brand |

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member demonstrates positive clinical response to therapy

| Product Name: Simponi |  |
|-----------------------|--|
| Diagnosis             | Ankylosing spondylitis (AS), Moderate to Severely Active Rheumatoid Arthritis, Psoriatic arthritis (PsA) |
| Approval Length       | 12/31/2039   |
| Guideline Type        | Quantity Exception - All plans except IL and MN Plans  |

| Product<br>Name | Generic Name   | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| SIMPONI         | GOLIMUMAB SUBCUTANEOUS SOLN AUTO-<br>INJECTOR 50 MG/0.5ML  | 6627004000D520 | Brand         |
| SIMPONI         | GOLIMUMAB SUBCUTANEOUS SOLN AUTO-<br>INJECTOR 100 MG/ML    | 6627004000D540 | Brand         |
| SIMPONI         | GOLIMUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 50 MG/0.5ML  | 6627004000E520 | Brand         |
| SIMPONI         | GOLIMUMAB SUBCUTANEOUS SOLN PREFILLED<br>SYRINGE 100 MG/ML | 6627004000E540 | Brand         |

## **Approval Criteria**

**1** - Failure of an adherent 3-month trial of standard maintenance dosing with concomitant methotrexate (unless contraindicated or not appropriate for indication being requested)

| Product Name: Simponi |  |
|-----------------------|--|
| Diagnosis             | Ankylosing spondylitis (AS), Moderate to Severely Active Rheumatoid Arthritis, Psoriatic arthritis (PsA) |
| Approval Length       | 12 month(s)  |
| Guideline Type        | Quantity Exception - IL and MN Plans   |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| SIMPONI         | GOLIMUMAB SUBCUTANEOUS SOLN AUTO-<br>INJECTOR 50 MG/0.5ML | 6627004000D520 | Brand         |
| SIMPONI         | GOLIMUMAB SUBCUTANEOUS SOLN AUTO-<br>INJECTOR 100 MG/ML   | 6627004000D540 | Brand         |
| SIMPONI         | GOLIMUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 50 MG/0.5ML | 6627004000E520 | Brand         |
| SIMPONI         | GOLIMUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 100 MG/ML   | 6627004000E540 | Brand         |

**1** - Failure of an adherent 3-month trial of standard maintenance dosing with concomitant methotrexate (unless contraindicated or not appropriate for indication being requested)

| Product Name: Simponi |   |
|-----------------------|---|
| Diagnosis             | Ulcerative Colitis (UC)                               |
| Approval Length       | 12/31/2039  |
| Guideline Type        | Quantity Exception - All plans except IL and MN Plans |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| SIMPONI         | GOLIMUMAB SUBCUTANEOUS SOLN AUTO-<br>INJECTOR 50 MG/0.5ML | 6627004000D520 | Brand         |
| SIMPONI         | GOLIMUMAB SUBCUTANEOUS SOLN AUTO-<br>INJECTOR 100 MG/ML   | 6627004000D540 | Brand         |
| SIMPONI         | GOLIMUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 50 MG/0.5ML | 6627004000E520 | Brand         |
| SIMPONI         | GOLIMUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 100 MG/ML   | 6627004000E540 | Brand         |

### **Approval Criteria**

1 - Failure of a two-month trial of monthly therapy after completion of induction dosing regimen

### **AND**

2 - Based on subtherapeutic drug concentrations and absence (or low levels) of drug antibodies

| Product Name: Simponi |                                      |
|-----------------------|--------------------------------------|
| Diagnosis             | Ulcerative Colitis (UC)              |
| Approval Length       | 12 month(s)                          |
| Guideline Type        | Quantity Exception - IL and MN Plans |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| SIMPONI         | GOLIMUMAB SUBCUTANEOUS SOLN AUTO-<br>INJECTOR 50 MG/0.5ML | 6627004000D520 | Brand         |
| SIMPONI         | GOLIMUMAB SUBCUTANEOUS SOLN AUTO-<br>INJECTOR 100 MG/ML   | 6627004000D540 | Brand         |
| SIMPONI         | GOLIMUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 50 MG/0.5ML | 6627004000E520 | Brand         |
| SIMPONI         | GOLIMUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 100 MG/ML   | 6627004000E540 | Brand         |

1 - Failure of a two-month trial of monthly therapy after completion of induction dosing regimen

### **AND**

2 - Based on subtherapeutic drug concentrations and absence (or low levels) of drug antibodies

# 2. Revision History

| Date      | Notes                   |
|-----------|-------------------------|
| 12/6/2023 | 2024 New Implementation |

| Skyrizi (risankizumab)   |
|--|
| The State Progress of the State Stat |
|  |

# **Prior Authorization Guideline**

| Guideline ID          | GL-134612              |
|-----------------------|------------------------|
| <b>Guideline Name</b> | Skyrizi (risankizumab) |
| Formulary             | Quartz                 |

# **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

## Note:

Member new to the plan (as evidenced by coverage effective date of less than or equal to 90 days) who initiated therapy using a manufacturer-sponsored free drug program, provider samples, and/or vouchers will go through initial criteria, otherwise for continuation of therapy for new to plan, reauthorization criteria applies.

## 1. Criteria

| Product Name: Skyrizi   |   |                |                |               |
|---|---|----------------|----------------|---------------|
| Diagnosis   | osis Plaque Psoriasis   |                |                |               |
| Approval L  | ength   | gth 12/31/2039 |                |               |
| Guideline Type Prior Authorization - All plans except IL and MN Plans |   |                |                |               |
| Product<br>Name   | Generic Name  |                | GPI            | Brand/Generic |
| SKYRIZI   | RISANKIZUMAB-RZAA SUBCUTANEOUS SOLN<br>CARTRIDGE 180 MG/1.2ML |                | 5250406070E210 | Brand         |

| SKYRIZI        | RISANKIZUMAB-RZAA SUBCUTANEOUS SOLN<br>CARTRIDGE 360 MG/2.4ML | 5250406070E220 | Brand |
|----------------|---|----------------|-------|
| SKYRIZI<br>PEN | RISANKIZUMAB-RZAA SOLN AUTO-INJECTOR 150<br>MG/ML             | 9025057070D520 | Brand |
| SKYRIZI        | RISANKIZUMAB-RZAA SOLN PREFILLED SYRINGE 150<br>MG/ML         | 9025057070E540 | Brand |

1 - Diagnosis of moderate to severe plaque psoriasis

#### **AND**

- **2** ONE of the following:
  - Significant functional disability
  - Body surface area (BSA) involvement of greater than or equal to 3%
  - Debilitating palmer/plantar psoriasis or other vulnerable areas that are difficult to treat (e.g., nails, scalp, genitals, or intertriginous areas

#### **AND**

**3** - Trial and failure, contraindication or intolerance to topical treatment (e.g., topical corticosteroids, calcipotriene, retinoids, calcineurin inhibitors, tazarotene)

#### AND

**4** - Therapy must not be used in combination with other biologic disease modifying antirheumatic drug (DMARD) (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

#### **AND**

5 - Medication will be self-administered

#### **AND**

### **6** - Prescribed by or in consultation with a dermatologist

| Product Name: Skyrizi |                                       |
|-----------------------|---------------------------------------|
| Diagnosis             | Plaque Psoriasis                      |
| Approval Length       | 12 month(s)                           |
| Therapy Stage         | Initial Authorization                 |
| Guideline Type        | Prior Authorization - IL and MN Plans |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| SKYRIZI         | RISANKIZUMAB-RZAA SUBCUTANEOUS SOLN<br>CARTRIDGE 180 MG/1.2ML | 5250406070E210 | Brand         |
| SKYRIZI         | RISANKIZUMAB-RZAA SUBCUTANEOUS SOLN<br>CARTRIDGE 360 MG/2.4ML | 5250406070E220 | Brand         |
| SKYRIZI<br>PEN  | RISANKIZUMAB-RZAA SOLN AUTO-INJECTOR 150<br>MG/ML             | 9025057070D520 | Brand         |
| SKYRIZI         | RISANKIZUMAB-RZAA SOLN PREFILLED SYRINGE 150<br>MG/ML         | 9025057070E540 | Brand         |

# **Approval Criteria**

1 - Diagnosis of moderate to severe plaque psoriasis

#### **AND**

- **2** ONE of the following:
  - Significant functional disability
  - Body surface area (BSA) involvement of greater than or equal to 3%
  - Debilitating palmer/plantar psoriasis or other vulnerable areas that are difficult to treat (e.g., nails, scalp, genitals, or intertriginous areas

#### **AND**

**3** - Trial and failure, contraindication or intolerance to topical treatment (e.g., topical corticosteroids, calcipotriene, retinoids, calcineurin inhibitors, tazarotene)

| -                |    | _ |
|------------------|----|---|
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| $\boldsymbol{H}$ | ıv | ப |

**4** - Therapy must not be used in combination with other biologic disease modifying anti-rheumatic drug (DMARD) (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

#### **AND**

5 - Medication will be self-administered

#### **AND**

6 - Prescribed by or in consultation with a dermatologist

| Product Name: Skyrizi |  |
|-----------------------|--|
| Diagnosis             | Psoriatic Arthritis (PsA)                              |
| Approval Length       | 12/31/2039   |
| Guideline Type        | Prior Authorization - All plans except IL and MN Plans |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| SKYRIZI         | RISANKIZUMAB-RZAA SUBCUTANEOUS SOLN<br>CARTRIDGE 180 MG/1.2ML | 5250406070E210 | Brand         |
| SKYRIZI         | RISANKIZUMAB-RZAA SUBCUTANEOUS SOLN<br>CARTRIDGE 360 MG/2.4ML | 5250406070E220 | Brand         |
| SKYRIZI<br>PEN  | RISANKIZUMAB-RZAA SOLN AUTO-INJECTOR 150<br>MG/ML             | 9025057070D520 | Brand         |
| SKYRIZI         | RISANKIZUMAB-RZAA SOLN PREFILLED SYRINGE 150<br>MG/ML         | 9025057070E540 | Brand         |

## **Approval Criteria**

2 - Diagnosis of moderate to severely active psoriatic arthritis

#### **AND**

- **1** Submission of medical records (e.g., chart notes) documenting at least ONE of the following:
  - Actively inflamed joints
  - Axial disease
  - Active skin, nail, or scalp psoriasis involvement
  - Dactylitis
  - Enthesitis

#### **AND**

**2** - Not used in combination with other biologic DMARDs (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

#### **AND**

3 - Medication will be self-administered

#### **AND**

**5** - Prescribed by or in consultation with a Dermatologist or Rheumatologist

| Product Name: Skyrizi |                                       |
|-----------------------|---------------------------------------|
| Diagnosis             | Psoriatic Arthritis (PsA)             |
| Approval Length       | 12 month(s)                           |
| Therapy Stage         | Initial Authorization                 |
| Guideline Type        | Prior Authorization - IL and MN Plans |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| SKYRIZI         | RISANKIZUMAB-RZAA SUBCUTANEOUS SOLN<br>CARTRIDGE 180 MG/1.2ML | 5250406070E210 | Brand         |
| SKYRIZI         | RISANKIZUMAB-RZAA SUBCUTANEOUS SOLN<br>CARTRIDGE 360 MG/2.4ML | 5250406070E220 | Brand         |
| SKYRIZI<br>PEN  | RISANKIZUMAB-RZAA SOLN AUTO-INJECTOR 150<br>MG/ML             | 9025057070D520 | Brand         |
| SKYRIZI         | RISANKIZUMAB-RZAA SOLN PREFILLED SYRINGE 150<br>MG/ML         | 9025057070E540 | Brand         |

2 - Diagnosis of moderate to severely active psoriatic arthritis

#### AND

- **1** Submission of medical records (e.g., chart notes) documenting at least ONE of the following:
  - Actively inflamed joints
  - Axial disease
  - · Active skin, nail, or scalp psoriasis involvement
  - Dactylitis
  - Enthesitis

#### **AND**

**2** - Not used in combination with other biologic DMARDs (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

### **AND**

3 - Medication will be self-administered

#### **AND**

**5** - Prescribed by or in consultation with a Dermatologist or Rheumatologist

| Product Name: Skyrizi   |                 |
|---|-----------------|
| Diagnosis   | Crohn's Disease |
| Approval Length   | 12/31/2039      |
| Guideline Type Prior Authorization - All plans except IL and MN Plans |                 |
|   |                 |

| Product<br>Name | Generic Name                        | GPI            | Brand/Generic |
|-----------------|-------------------------------------|----------------|---------------|
| SKYRIZI         | RISANKIZUMAB-RZAA SUBCUTANEOUS SOLN | 5250406070E210 | Brand         |

|                | CARTRIDGE 180 MG/1.2ML  |                |       |
|----------------|---|----------------|-------|
| SKYRIZI        | RISANKIZUMAB-RZAA SUBCUTANEOUS SOLN<br>CARTRIDGE 360 MG/2.4ML | 5250406070E220 | Brand |
| SKYRIZI<br>PEN | RISANKIZUMAB-RZAA SOLN AUTO-INJECTOR 150<br>MG/ML             | 9025057070D520 | Brand |
| SKYRIZI        | RISANKIZUMAB-RZAA SOLN PREFILLED SYRINGE 150<br>MG/ML         | 9025057070E540 | Brand |

1 - Diagnosis of moderate to severely active Crohn's disease

AND

2 - Member is greater than 18 years of age

**AND** 

- **3** ONE of the following:
- **3.1** Member is a High-risk individual with ONE of the following traits:
  - Age less than 30 at diagnosis
  - Extensive anatomic involvement
  - Perianal and/or severe rectal disease
  - Deep ulcers
  - Prior surgical resection
  - Stricturing and/or penetrating behavior
  - Fistulizing disease
  - Extraintestinal manifestations of inflammation (i.e. uveitis, erythema nodosum, pyoderma gangrenosum, spondyloarthropathy, etc.)]

OR

- **3.2** BOTH of the following
- **3.2.1** Member is a Low-risk individual

AND

### **3.2.2** ONE of the following:

- Intolerance or contraindication to 1 conventional therapy (e.g., azathioprine, balsalazide, corticosteroids, mesalamine, mercaptopurine, methotrexate, sulfasalazine)
- Inadequate disease control or inability to achieve remission after an adequate trial of 3 months with 1 conventional therapy
- Demonstrated steroid dependence
- Conventional therapy is clinically inappropriate based on location of disease

#### **AND**

**4** - Therapy must not be used in combination with other biologic disease modifying antirheumatic drug (DMARD) (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

#### AND

5 - Medication will be self-administered

#### **AND**

6 - Prescribed by or in consultation with a Gastroenterologist

#### **AND**

**7** - Prescriber attests patient has been established on therapy with Risankizumab for Crohn's disease through the medical benefit

| Product Name: Skyrizi |  |                                       |               |  |  |
|-----------------------|--|---------------------------------------|---------------|--|--|
| Diagnosis             |  | Crohn's Disease                       |               |  |  |
| Approval Length       |  | 12 month(s)                           |               |  |  |
| Guideline Type        |  | Prior Authorization - IL and MN Plans |               |  |  |
| Product Generic Name  |  | GPI                                   | Brand/Generic |  |  |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| SKYRIZI         | RISANKIZUMAB-RZAA SUBCUTANEOUS SOLN<br>CARTRIDGE 180 MG/1.2ML | 5250406070E210 | Brand         |

| SKYRIZI        | RISANKIZUMAB-RZAA SUBCUTANEOUS SOLN<br>CARTRIDGE 360 MG/2.4ML | 5250406070E220 | Brand |
|----------------|---|----------------|-------|
| SKYRIZI<br>PEN | RISANKIZUMAB-RZAA SOLN AUTO-INJECTOR 150<br>MG/ML             | 9025057070D520 | Brand |
| SKYRIZI        | RISANKIZUMAB-RZAA SOLN PREFILLED SYRINGE 150<br>MG/ML         | 9025057070E540 | Brand |

1 - Diagnosis of moderate to severely active Crohn's disease

**AND** 

2 - Member is greater than 18 years of age

**AND** 

- **3** ONE of the following:
- **3.1** Member is a High-risk individual with ONE of the following traits:
  - Age less than 30 at diagnosis
  - Extensive anatomic involvement
  - Perianal and/or severe rectal disease
  - Deep ulcers
  - Prior surgical resection
  - Stricturing and/or penetrating behavior
  - Fistulizing disease
  - Extraintestinal manifestations of inflammation (i.e. uveitis, erythema nodosum, pyoderma gangrenosum, spondyloarthropathy, etc.)]

OR

- **3.2** BOTH of the following
- **3.2.1** Member is a Low-risk individual

AND

### **3.2.2** ONE of the following:

- Intolerance or contraindication to 1 conventional therapy (e.g., azathioprine, balsalazide, corticosteroids, mesalamine, mercaptopurine, methotrexate, sulfasalazine)
- Inadequate disease control or inability to achieve remission after an adequate trial of 3 months with 1 conventional therapy
- Demonstrated steroid dependence
- Conventional therapy is clinically inappropriate based on location of disease

#### AND

**4** - Therapy must not be used in combination with other biologic disease modifying antirheumatic drug (DMARD) (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

#### **AND**

5 - Medication will be self-administered

#### **AND**

**6** - Prescribed by or in consultation with a Gastroenterologist

### **AND**

**7** - Prescriber attests patient has been established on therapy with Risankizumab for Crohn's disease through the medical benefit

| Product Name: Skyrizi |                                       |
|-----------------------|---------------------------------------|
| Diagnosis             | All Indications Listed Above          |
| Approval Length       | 12 month(s)                           |
| Therapy Stage         | Reauthorization                       |
| Guideline Type        | Prior Authorization - IL and MN Plans |

| Product<br>Name | Generic Name                        | GPI            | Brand/Generic |
|-----------------|-------------------------------------|----------------|---------------|
| SKYRIZI         | RISANKIZUMAB-RZAA SUBCUTANEOUS SOLN | 5250406070E210 | Brand         |

|                | CARTRIDGE 180 MG/1.2ML  |                |       |
|----------------|---|----------------|-------|
| SKYRIZI        | RISANKIZUMAB-RZAA SUBCUTANEOUS SOLN<br>CARTRIDGE 360 MG/2.4ML | 5250406070E220 | Brand |
| SKYRIZI<br>PEN | RISANKIZUMAB-RZAA SOLN AUTO-INJECTOR 150<br>MG/ML             | 9025057070D520 | Brand |
| SKYRIZI        | RISANKIZUMAB-RZAA SOLN PREFILLED SYRINGE 150<br>MG/ML         | 9025057070E540 | Brand |

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months member demonstrates a positive clinical response to therapy as evidenced by improvements in functional status related to therapeutic response

| Product Name: Skyrizi |                            |
|-----------------------|----------------------------|
| Diagnosis             | Crohn's Disease            |
| Approval Length       | 12 month(s)                |
| Guideline Type        | Quantity Limit - All Plans |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| SKYRIZI         | RISANKIZUMAB-RZAA SUBCUTANEOUS SOLN<br>CARTRIDGE 180 MG/1.2ML | 5250406070E210 | Brand         |
| SKYRIZI         | RISANKIZUMAB-RZAA SUBCUTANEOUS SOLN<br>CARTRIDGE 360 MG/2.4ML | 5250406070E220 | Brand         |
| SKYRIZI<br>PEN  | RISANKIZUMAB-RZAA SOLN AUTO-INJECTOR 150<br>MG/ML             | 9025057070D520 | Brand         |
| SKYRIZI         | RISANKIZUMAB-RZAA SOLN PREFILLED SYRINGE 150 MG/ML            | 9025057070E540 | Brand         |

### **Approval Criteria**

**1** - Trial and failure of a two-month trial of every 12 week therapy after completion of 3 doses of IV infusion for the induction dosing regimen

#### **AND**

2 - Provision of published literature supporting efficacy and safety of dosing regimen

**3** - Based on subtherapeutic drug concentrations and absence (or low levels) of drug antibodies (when clinical lab available).

| Product Name: Skyrizi |   |
|-----------------------|---|
| Diagnosis             | Plaque Psoriasis, Psoriatic Arthritis (PsA) |
| Approval Length       | 12 month(s)                                 |
| Guideline Type        | Quantity Limit - All Plans                  |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| SKYRIZI         | RISANKIZUMAB-RZAA SUBCUTANEOUS SOLN<br>CARTRIDGE 180 MG/1.2ML | 5250406070E210 | Brand         |
| SKYRIZI         | RISANKIZUMAB-RZAA SUBCUTANEOUS SOLN<br>CARTRIDGE 360 MG/2.4ML | 5250406070E220 | Brand         |
| SKYRIZI<br>PEN  | RISANKIZUMAB-RZAA SOLN AUTO-INJECTOR 150<br>MG/ML             | 9025057070D520 | Brand         |
| SKYRIZI         | RISANKIZUMAB-RZAA SOLN PREFILLED SYRINGE 150 MG/ML            | 9025057070E540 | Brand         |

### **Approval Criteria**

**1** - Trial and failure of an adherent 3-month trial of standard maintenance dosing (every 12 weeks) with concomitant methotrexate (unless contraindicated or not appropriate for indication being requested)

| Date       | Notes                   |
|------------|-------------------------|
| 11/30/2023 | 2024 New Implementation |

| Soliqua (  | Insulin Glargine/Lixisenatide)                       |
|--|--|
| The bill of long-reason leadinghood. The fire may hear her | mark come; a think high high problem could not also. |

## **Prior Authorization Guideline**

| Guideline ID          | GL-129739                               |
|-----------------------|---|
| <b>Guideline Name</b> | Soliqua (Insulin Glargine/Lixisenatide) |
| Formulary             | Quartz                                  |

## **Guideline Note:**

| Effective Date: |
|-----------------|
|-----------------|

## 1. Criteria

| Product Name: Soliqua       |                                       |
|-----------------------------|---------------------------------------|
| Approval Length 12 month(s) |                                       |
| Therapy Stage               | Initial Authorization                 |
| Guideline Type              | Prior Authorization - IL and MN Plans |

| Product<br>Name   | Generic Name   | GPI            | Brand/Generic |
|-------------------|--|----------------|---------------|
| SOLIQUA<br>100/33 | INSULIN GLARGINE-LIXISENATIDE SOL PEN-INJ 100-<br>33 UNIT-MCG/ML | 2799100235D220 | Brand         |

## **Approval Criteria**

**1** - Diagnosis of insulin dependent type 2 diabetes mellitus with a total basal insulin dose of less than 60 units/day

2 - Prescribed by, or in consultation with, an Endocrinologist or Certified Diabetic Educator

#### **AND**

**3** - Trial and failure after an adequate trial, intolerance, or contraindication to use of ALL formulary basal insulins (e.g., Semglee-yfgn, insulin degludec) and ALL formulary glucagon-like peptide (GLP) 1 agonists (e.g., Trulicity) in combination

#### AND

**4** - Prescriber supplies published literature to support the requested combination product will produce different clinical results than using the formulary basal insulins and GLP-1 agonists as separate products

| Product Name: Soliqua       |                                       |
|-----------------------------|---------------------------------------|
| Approval Length 12 month(s) |                                       |
| Therapy Stage               | Reauthorization                       |
| Guideline Type              | Prior Authorization - IL and MN Plans |

| Product<br>Name   | Generic Name   | GPI            | Brand/Generic |
|-------------------|--|----------------|---------------|
| SOLIQUA<br>100/33 | INSULIN GLARGINE-LIXISENATIDE SOL PEN-INJ 100-<br>33 UNIT-MCG/ML | 2799100235D220 | Brand         |

### **Approval Criteria**

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug

| Product Name: Soliqua   |  |  |
|---|--|--|
| Approval Length 12/31/2039                                      |  |  |
| Guideline Type Prior Authorization - All plans except IL and MN |  |  |

| Product<br>Name   | Generic Name   | GPI            | Brand/Generic |
|-------------------|--|----------------|---------------|
| SOLIQUA<br>100/33 | INSULIN GLARGINE-LIXISENATIDE SOL PEN-INJ 100-<br>33 UNIT-MCG/ML | 2799100235D220 | Brand         |

**1** - Diagnosis of insulin dependent type 2 diabetes mellitus with a total basal insulin dose of less than 60 units/day

#### **AND**

2 - Prescribed by, or in consultation with, an Endocrinologist or Certified Diabetic Educator

#### **AND**

**3** - Trial and failure after an adequate trial, intolerance, or contraindication to use of ALL formulary basal insulins (e.g., Semglee-yfgn, insulin degludec) and ALL formulary glucagon-like peptide (GLP) 1 agonists (e.g., Trulicity) in combination

### **AND**

**4** - Prescriber supplies published literature to support the requested combination product will produce different clinical results than using the formulary basal insulins and GLP-1 agonists as separate products

| Date       | Notes       |
|------------|-------------|
| 10/25/2023 | New Program |

| • | Solosec (secnidazole) |  |  |  |  |
|---|-----------------------|--|--|--|--|
|   |                       |  |  |  |  |
|   |                       |  |  |  |  |

# **Prior Authorization Guideline**

| Guideline ID   | GL-132774             |  |
|----------------|-----------------------|--|
| Guideline Name | Solosec (secnidazole) |  |
| Formulary      | Quartz                |  |

## **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

## 1. Criteria

| Product Name: Solosec                                |                                    |
|--|------------------------------------|
| Diagnosis Bacterial vaginosis                        |                                    |
| Approval Length                                      | 12 month (s) with a fill count = 1 |
| Guideline Type Prior Authorization - IL and MN Plans |                                    |

| Product<br>Name | Generic Name                     | GPI            | Brand/Generic |
|-----------------|----------------------------------|----------------|---------------|
| SOLOSEC         | SECNIDAZOLE GRANULES PACKET 2 GM | 14000080003020 | Brand         |

## **Approval Criteria**

1 - Diagnosis of bacterial vaginosis

**2** - Trial and failure, contraindication, or intolerance to metronidazole (oral or vaginal gel) and clindamycin

| Product Name: Solosec         |  |
|-------------------------------|--|
| Diagnosis Bacterial vaginosis |  |
| Approval Length               | One time fill                                    |
| Guideline Type                | Prior Authorization - All plans except IL and MN |

| Product<br>Name | Generic Name                     | GPI            | Brand/Generic |
|-----------------|----------------------------------|----------------|---------------|
| SOLOSEC         | SECNIDAZOLE GRANULES PACKET 2 GM | 14000080003020 | Brand         |

## **Approval Criteria**

1 - Diagnosis of bacterial vaginosis

### **AND**

**2** - Trial and failure, contraindication, or intolerance to metronidazole (oral or vaginal gel) and clindamycin

| Product Name: Solosec                                |                                    |
|--|------------------------------------|
| Diagnosis  | trichomoniasis                     |
| Approval Length                                      | 12 month (s) with a fill count = 1 |
| Guideline Type Prior Authorization - IL and MN Plans |                                    |

| Product<br>Name | Generic Name                     | GPI            | Brand/Generic |
|-----------------|----------------------------------|----------------|---------------|
| SOLOSEC         | SECNIDAZOLE GRANULES PACKET 2 GM | 14000080003020 | Brand         |

## **Approval Criteria**

1 - Diagnosis of trichomoniasis

- **2** Trial and failure, contraindication, or intolerance to a seven day course of one of the following:
  - oral metronidazole
  - tinidazole

| Product Name: Solosec  |  |
|--|--|
| Diagnosis trichomoniasis   |  |
| Approval Length One time fill  Guideline Type Prior Authorization - All plans except IL and MN |  |

| Product<br>Name | Generic Name                     | GPI            | Brand/Generic |
|-----------------|----------------------------------|----------------|---------------|
| SOLOSEC         | SECNIDAZOLE GRANULES PACKET 2 GM | 14000080003020 | Brand         |

## **Approval Criteria**

1 - Diagnosis of trichomoniasis

### **AND**

- **2** Trial and failure, contraindication, or intolerance to a seven day course of one of the following:
  - oral metronidazole
  - tinidazole

| Date       | Notes       |
|------------|-------------|
| 10/31/2023 | New Program |

| Somatropin  |
|---|
| The histories growth histories has been been been as and, county a state the histories has enterthe and auto- |
|   |

# **Prior Authorization Guideline**

| Guideline ID          | GL-130503  |  |
|-----------------------|------------|--|
| <b>Guideline Name</b> | Somatropin |  |
| Formulary             | Quartz     |  |

## **Guideline Note:**

| Effective Date: |
|-----------------|
|-----------------|

## 1. Criteria

| Product Name: Omnitrope   |  |  |
|---|--|--|
| Diagnosis Pediatric [less than 18 years of age])                      |  |  |
| Approval Length until age 18  |  |  |
| Guideline Type Prior Authorization - ALL Plans Except IL and MN Plans |  |  |

| Product<br>Name | Generic Name                              | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| OMNITROPE       | SOMATROPIN SOLUTION CARTRIDGE 5 MG/1.5ML  | 3010002000E210 | Brand         |
| OMNITROPE       | SOMATROPIN SOLUTION CARTRIDGE 10 MG/1.5ML | 3010002000E213 | Brand         |
| OMNITROPE       | SOMATROPIN FOR INJ 5.8 MG                 | 30100020002123 | Brand         |

## **Approval Criteria**

| 1 - One of the following:  |
|--|
| 1.1 ALL of the following:  |
| <b>1.1.1</b> Submission of medical records (e.g., chart notes) documenting radiological evidence of open epiphyses with date completed   |
| AND  |
| <b>1.1.2</b> Submission of medical records (e.g., chart notes) documenting that the child's growth velocity value is subnormal (age specific growth rate less than the 25th percentile)                                      |
| AND  |
| <b>1.1.3</b> Submission of medical records (e.g., chart notes) documenting that the child has delayed bone age (e.g., provide date of completion and the value of bone age)  |
| AND  |
| <b>1.1.4</b> Submission of medical records (e.g., chart notes) documenting (e.g., provide date and value of test) that the child has subnormal GH response to at least one provocative stimulation test (less than 10 ng/mL) |
| AND  |
| 1.1.5 Member is less than 18 years of age  |
| OR   |
| 1.2 Both of the following:   |
| 1.2.1 Member is less than 18 years of age  |
| AND  |
| 1.2.2 Diagnosis of Turner syndrome   |

2 - Prescribed by or in consultation with an endocrinologist

| Product Name: Omnitrope |  |  |
|-------------------------|--|--|
| Diagnosis               | Pediatric [less than 18 years of age]) |  |
| Approval Length         | 12 month(s)                            |  |
| Therapy Stage           | Initial Authorization                  |  |
| Guideline Type          | Prior Authorization - IL and MN Plans  |  |

| Product<br>Name | Generic Name                              | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| OMNITROPE       | SOMATROPIN SOLUTION CARTRIDGE 5 MG/1.5ML  | 3010002000E210 | Brand         |
| OMNITROPE       | SOMATROPIN SOLUTION CARTRIDGE 10 MG/1.5ML | 3010002000E213 | Brand         |
| OMNITROPE       | SOMATROPIN FOR INJ 5.8 MG                 | 30100020002123 | Brand         |

### **Approval Criteria**

- 1 One of the following:
- 1.1 ALL of the following:
- **1.1.1** Submission of medical records (e.g., chart notes) documenting radiological evidence of open epiphyses with date completed

#### **AND**

**1.1.2** Submission of medical records (e.g., chart notes) documenting that the child's growth velocity value is subnormal (age specific growth rate less than the 25th percentile)

#### **AND**

**1.1.3** Submission of medical records (e.g., chart notes) documenting that the child has delayed bone age (e.g., provide date of completion and the value of bone age)

**1.1.4** Submission of medical records (e.g., chart notes) documenting (e.g., provide date and value of test) that the Child has subnormal GH response to at least one provocative stimulation test (less than 10 ng/mL)

### **AND**

1.1.5 Member is less than 18 years of age

OR

- **1.2** Both of the following:
- **1.2.1** Member is less than 18 years of age

**AND** 

1.2.2 Diagnosis of Turner syndrome

#### **AND**

2 - Prescribed by or in consultation with an endocrinologist

| Product Name: Omnitrope |  |  |
|-------------------------|--|--|
| Diagnosis               | Pediatric [less than 18 years of age]) |  |
| Approval Length         | 12 month(s)                            |  |
| Therapy Stage           | Reauthorization                        |  |
| Guideline Type          | Prior Authorization - IL and MN Plans  |  |
|                         |  |  |

| ı | Product<br>Name | Generic Name                             | GPI            | Brand/Generic |
|---|-----------------|--|----------------|---------------|
|   | OMNITROPE       | SOMATROPIN SOLUTION CARTRIDGE 5 MG/1.5ML | 3010002000E210 | Brand         |

| OMNITROPE | SOMATROPIN SOLUTION CARTRIDGE 10 MG/1.5ML | 3010002000E213 | Brand |
|-----------|---|----------------|-------|
| OMNITROPE | SOMATROPIN FOR INJ 5.8 MG                 | 30100020002123 | Brand |

| 1 - One of the following | 1 | - One | of the | following |
|--------------------------|---|-------|--------|-----------|
|--------------------------|---|-------|--------|-----------|

- 1.1 ALL of the following:
- **1.1.1** Submission of medical records (e.g., chart notes) documenting radiological evidence of open epiphyses with date completed

#### **AND**

**1.1.2** Submission of medical records (e.g., chart notes) documenting that the child's growth velocity value is subnormal (age specific growth rate less than the 25th percentile)

#### **AND**

**1.1.3** Submission of medical records (e.g., chart notes) documenting that the child has delayed bone age (e.g., provide date of completion and the value of bone age)

#### AND

**1.1.4** Submission of medical records (e.g., chart notes) documenting (e.g., provide date and value of test) that the Child has subnormal GH response to at least one provocative stimulation test (less than 10 ng/mL)

#### **AND**

1.1.5 Member is less than 18 years of age

OR

**1.2** Both of the following:

1.2.1 Member is less than 18 years of age

**AND** 

1.2.2 Diagnosis of Turner syndrome

#### **AND**

2 - Prescribed by or in consultation with an endocrinologist

| Product Name: Omnitrope |                                   |
|-------------------------|-----------------------------------|
| Diagnosis               | Adult [18 years of age or older]) |
| Approval Length         | 12 month(s)                       |
| Therapy Stage           | Initial Authorization             |
| Guideline Type          | Prior Authorization - ALL Plans   |

| Product<br>Name | Generic Name                              | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| OMNITROPE       | SOMATROPIN SOLUTION CARTRIDGE 5 MG/1.5ML  | 3010002000E210 | Brand         |
| OMNITROPE       | SOMATROPIN SOLUTION CARTRIDGE 10 MG/1.5ML | 3010002000E213 | Brand         |
| OMNITROPE       | SOMATROPIN FOR INJ 5.8 MG                 | 30100020002123 | Brand         |

## **Approval Criteria**

- 1 One of the following:
- **1.1** ALL of the following:
- 1.1.1 Member has growth hormone deficiency as a child

### **AND**

1.1.2 Continued low IGF-1 levels or evidence of GH deficiency as noted by stimulation testing

| AND   |
|---|
| 1.1.3 Member is 18 years of age or older  |
| OR  |
| 1.2 ALL of the following:   |
| 1.2.1 Member is 18 years of age or older  |
| AND   |
| <b>1.2.2</b> Abnormal structure of the hypothalamus or pituitary gland on MRI as a result of injury, tumor, infection or inflammation |
| AND   |
| <b>1.2.3</b> Evidence of GH deficiency as noted by stimulation testing or when the diagnosis is panhypopituitarism                    |
| AND   |

| Notes                     | *Member new to the plan (as evidenced b |
|---------------------------|---|
| 2 - Prescribed by or in a | consultation with an endocrinologist    |

\*Member new to the plan (as evidenced by coverage effective date of I ess than or equal to 90 days) who initiated therapy using a manufactur er-sponsored free drug program, provider samples, and/or vouchers wil I go through initial criteria, otherwise for continuation of therapy for new to plan, reauthorization criteria applies

| Product Name: Omnitrope            |  |                                 |               |  |
|------------------------------------|--|---------------------------------|---------------|--|
| Diagnosis Adult [18 years of age]) |  |                                 |               |  |
| Approval Length 12 month(s)        |  |                                 |               |  |
| Therapy Stage                      |  | Reauthorization                 |               |  |
| Guideline Type Prior A             |  | Prior Authorization - ALL Plans |               |  |
| Product Generic Name               |  | GPI                             | Brand/Generic |  |

| Name      |   |                |       |
|-----------|---|----------------|-------|
| OMNITROPE | SOMATROPIN SOLUTION CARTRIDGE 5 MG/1.5ML  | 3010002000E210 | Brand |
| OMNITROPE | SOMATROPIN SOLUTION CARTRIDGE 10 MG/1.5ML | 3010002000E213 | Brand |
| OMNITROPE | SOMATROPIN FOR INJ 5.8 MG                 | 30100020002123 | Brand |

| OWNTROFE            | SOMATROFIN SOLUTION CARTRIDGE 3 MG/1.5ML            | 3010002000E210     | Dianu             |
|---------------------|---|--------------------|-------------------|
| OMNITROPE           | SOMATROPIN SOLUTION CARTRIDGE 10 MG/1.5ML           | 3010002000E213     | Brand             |
| OMNITROPE           | SOMATROPIN FOR INJ 5.8 MG                           | 30100020002123     | Brand             |
|                     |   |                    |                   |
| Approval Cı         | riteria   |                    |                   |
|                     |   |                    |                   |
| 1 - One of th       | -   |                    |                   |
| <b>1.1</b> ALL of t | the following:                                      |                    |                   |
| <b>1.1.1</b> Mem    | ber has growth hormone deficiency as a child        |                    |                   |
|                     |   |                    |                   |
|                     | AND   |                    |                   |
| 1.1.2 Cont          | inued low IGF-1 levels or evidence of GH deficie    | ncy as noted by st | imulation testing |
| 2 00.11             |   |                    | g                 |
|                     | AND   |                    |                   |
|                     |   |                    |                   |
| <b>1.1.3</b> Mem    | ber is 18 years of age                              |                    |                   |
|                     |   |                    |                   |
|                     | OR  |                    |                   |
| <b>1.2</b> ALL of t | the following:                                      |                    |                   |
|                     | ber is 18 years of age                              |                    |                   |
| 1.2.1 IVICITI       | ber is to years or age                              |                    |                   |
|                     | AND   |                    |                   |
|                     |   |                    |                   |
|                     | ormal structure of the hypothalamus or pituitary gl | land on MRI as a r | esult of injury,  |
| iumor, intect       | ion or inflammation                                 |                    |                   |
|                     | AND   |                    |                   |
|                     |   |                    |                   |

**1.2.3** Evidence of GH deficiency as noted by stimulation testing or when the diagnosis is

panhypopituitarism

#### AND

2 - Prescribed by or in consultation with an endocrinologist

| Product Name: Omnitrope |                                    |  |
|-------------------------|------------------------------------|--|
| Diagnosis               | Adult [older than 18 years of age] |  |
| Approval Length         | 12 month(s)                        |  |
| Therapy Stage           | Reauthorization                    |  |
| Guideline Type          | Prior Authorization - ALL Plans    |  |

| Product<br>Name | Generic Name                              | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| OMNITROPE       | SOMATROPIN SOLUTION CARTRIDGE 5 MG/1.5ML  | 3010002000E210 | Brand         |
| OMNITROPE       | SOMATROPIN SOLUTION CARTRIDGE 10 MG/1.5ML | 3010002000E213 | Brand         |
| OMNITROPE       | SOMATROPIN FOR INJ 5.8 MG                 | 30100020002123 | Brand         |

### **Approval Criteria**

1 - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is benefitting from drug treatment (i.e., decreased fatigue, increased exercise endurance, age normalized IGF-1 levels, improvements in cholesterol panel, BMD, or body composition) including dates/values if applicable

| Product Name: Serostim  |                       |  |
|---|-----------------------|--|
| Approval Length 1 month(s)  |                       |  |
| Therapy Stage   | Initial Authorization |  |
| Guideline Type Prior Authorization - ALL Plans Except IL and MN Plans |                       |  |

| Product<br>Name | Generic Name   | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| SEROSTIM        | SOMATROPIN (NON-REFRIGERATED) FOR<br>SUBCUTANEOUS INJ 4 MG | 30100020102118 | Brand         |
| SEROSTIM        | SOMATROPIN (NON-REFRIGERATED) FOR<br>SUBCUTANEOUS INJ 5 MG | 30100020102121 | Brand         |

| SEROSTIM SOMATROPIN (NON-REFRIGERATED) FOR SUBCUTANEOUS INJ 6 MG | 30100020102125 | Brand |
|--|----------------|-------|
|--|----------------|-------|

1 - Diagnosis of AIDS wasting or cachexia

### **AND**

**2** - Member continues on antiviral therapy

| *Member new to the plan (as evidenced by coverage effective date of I ess than or equal to 90 days) who initiated therapy using a manufactur er-sponsored free drug program, provider samples, and/or vouchers wil I go through initial criteria, otherwise for continuation of therapy for new |
|---|
| to plan, reauthorization criteria applies   |

| Product Name: Serostim |                                       |  |
|------------------------|---------------------------------------|--|
| Approval Length        | 12 month(s)                           |  |
| Therapy Stage          | Initial Authorization                 |  |
| Guideline Type         | Prior Authorization - IL and MN Plans |  |

| Product<br>Name | Generic Name   | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| SEROSTIM        | SOMATROPIN (NON-REFRIGERATED) FOR<br>SUBCUTANEOUS INJ 4 MG | 30100020102118 | Brand         |
| SEROSTIM        | SOMATROPIN (NON-REFRIGERATED) FOR<br>SUBCUTANEOUS INJ 5 MG | 30100020102121 | Brand         |
| SEROSTIM        | SOMATROPIN (NON-REFRIGERATED) FOR<br>SUBCUTANEOUS INJ 6 MG | 30100020102125 | Brand         |

## **Approval Criteria**

1 - Diagnosis of AIDS wasting or cachexia

### **AND**

2 - Member continues on antiviral therapy

|  | *Member new to the plan (as evidenced by coverage effective date of I ess than or equal to 90 days) who initiated therapy using a manufactur er-sponsored free drug program, provider samples, and/or vouchers wil I go through initial criteria, otherwise for continuation of therapy for new to plan, reauthorization criteria applies |
|--|---|
|--|---|

| Product Name: Serostim |                                 |  |
|------------------------|---------------------------------|--|
| Approval Length        | 12 month(s)                     |  |
| Therapy Stage          | Reauthorization                 |  |
| Guideline Type         | Prior Authorization - ALL Plans |  |

| Product<br>Name | Generic Name   | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| SEROSTIM        | SOMATROPIN (NON-REFRIGERATED) FOR<br>SUBCUTANEOUS INJ 4 MG | 30100020102118 | Brand         |
| SEROSTIM        | SOMATROPIN (NON-REFRIGERATED) FOR<br>SUBCUTANEOUS INJ 5 MG | 30100020102121 | Brand         |
| SEROSTIM        | SOMATROPIN (NON-REFRIGERATED) FOR<br>SUBCUTANEOUS INJ 6 MG | 30100020102125 | Brand         |

**1** - Submission of medical records (e.g., chart notes) documenting that member is benefitting from therapy (i.e., weight gain, increased muscle mass)

| Notes | *Member new to the plan (as evidenced by coverage effective date of I ess than or equal to 90 days) who initiated therapy using a manufactur er-sponsored free drug program, provider samples, and/or vouchers wil I go through initial criteria, otherwise for continuation of therapy for new to plan, reauthorization criteria applies |
|-------|---|
|-------|---|

| Product Name: Zorbtive | е                               |
|------------------------|---------------------------------|
| Approval Length        | 12 month(s)                     |
| Therapy Stage          | Initial Authorization           |
| Guideline Type         | Prior Authorization - ALL Plans |

| Product<br>Name | Generic Name   | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| ZORBTIVE        | SOMATROPIN (NON-REFRIGERATED) FOR<br>SUBCUTANEOUS INJ 8.8 MG | 30100020102132 | Brand         |

1 - Diagnosis of Short Bowel Syndrome

#### AND

2 - Member is on a special diet

| *Member new to the plan (as evidenced by coverage effective date of I ess than or equal to 90 days) who initiated therapy using a manufactur er-sponsored free drug program, provider samples, and/or vouchers wil I go through initial criteria, otherwise for continuation of therapy for new |
|---|
| to plan, reauthorization criteria applies   |

| Product Name: Zorbtive |                                 |
|------------------------|---------------------------------|
| Approval Length        | 12 month(s)                     |
| Therapy Stage          | Reauthorization                 |
| Guideline Type         | Prior Authorization - ALL Plans |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
|                 | SOMATROPIN (NON-REFRIGERATED) FOR SUBCUTANEOUS INJ 8.8 MG | 30100020102132 | Brand         |

### **Approval Criteria**

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months that the member is benefitting from therapy (i.e., improvements in necessary intravenous feeding requirements such as calories required, or volumes infused) including dates/values

| Notes | *Member new to the plan (as evidenced by coverage effective date of I   |
|-------|---|
|       | ess than or equal to 90 days) who initiated therapy using a manufactur  |
|       | er-sponsored free drug program, provider samples, and/or vouchers will go through initial criteria, otherwise for continuation of therapy for new to plan, reauthorization criteria applies |

| Date       | Notes                   |
|------------|-------------------------|
| 10/24/2023 | 2024 New Implementation |

| •   | Somaver   | t (Pegv   | /isomar                     | nt) |  |
|-----|---|---|-----------------------------|-----|--|
| 100 | The Selection of Selection Control of Selection Control Selection | mount, museum, or deleted shortly that the bits point | n för annerlik att lisaken. |     |  |

## **Prior Authorization Guideline**

| Guideline ID          | GL-131414              |
|-----------------------|------------------------|
| <b>Guideline Name</b> | Somavert (Pegvisomant) |
| Formulary             | Quartz                 |

## **Guideline Note:**

| Effective Date: |
|-----------------|
|-----------------|

### Note:

Member new to the plan or who are established on therapy will have coverage under their drug benefit for the remainder of the current treatment course. Restrictions to specific network pharmacies and participation in medication management programs may apply.

## 1. Criteria

| Product Name: Somavert  |  |  |                |               |
|-------------------------|--|--|----------------|---------------|
| Approval Length         |  | 12 month(s)                              |                |               |
| Therapy Stage           |  | Initial Authorization                    |                |               |
| Guideline Type          |  | Prior Authorization-IL and MN Plans Only |                |               |
| Product<br>Name         | Generic Na                             | Generic Name                             |                | Brand/Generic |
| SOMAVERT                | PEGVISOMANT FOR INJ 10 MG (AS PROTEIN) |  | 30180060002120 | Brand         |
| SOMAVERT PEGVISOMANT FO |  | NT FOR INJ 15 MG (AS PROTEIN)            | 30180060002130 | Brand         |

| SOMAVERT | PEGVISOMANT FOR INJ 20 MG (AS PROTEIN) | 30180060002140 | Brand |
|----------|--|----------------|-------|
| SOMAVERT | PEGVISOMANT FOR INJ 25 MG (AS PROTEIN) | 30180060002150 | Brand |
| SOMAVERT | PEGVISOMANT FOR INJ 30 MG (AS PROTEIN) | 30180060002160 | Brand |

1 - Person or family member self-administering medication

**AND** 

2 - Diagnosis of acromegaly

**AND** 

**3** - Prescribed by, or in consultation with, an Endocrinologist

**AND** 

4 - Inadequate response to, or not a candidate for, surgical correction

### AND

5 - Trial and failure, contraindication, or intolerance to somatostatin therapy

| Product Name: Somavert |  |  |
|------------------------|--|--|
| Approval Length        | 12 month(s)                              |  |
| Therapy Stage          | Reauthorization                          |  |
| Guideline Type         | Prior Authorization-IL and MN Plans Only |  |

| Product<br>Name | Generic Name                           | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| SOMAVERT        | PEGVISOMANT FOR INJ 10 MG (AS PROTEIN) | 30180060002120 | Brand         |
| SOMAVERT        | PEGVISOMANT FOR INJ 15 MG (AS PROTEIN) | 30180060002130 | Brand         |

| SOMAVERT | PEGVISOMANT FOR INJ 20 MG (AS PROTEIN) | 30180060002140 | Brand |
|----------|--|----------------|-------|
| SOMAVERT | PEGVISOMANT FOR INJ 25 MG (AS PROTEIN) | 30180060002150 | Brand |
| SOMAVERT | PEGVISOMANT FOR INJ 30 MG (AS PROTEIN) | 30180060002160 | Brand |

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug.

| Product Name: Somavert |  |  |
|------------------------|--|--|
| Approval Length        | 12/31/2039                                     |  |
| Guideline Type         | Prior Authorization-All plans except IL and MN |  |

| Product<br>Name | Generic Name                           | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| SOMAVERT        | PEGVISOMANT FOR INJ 10 MG (AS PROTEIN) | 30180060002120 | Brand         |
| SOMAVERT        | PEGVISOMANT FOR INJ 15 MG (AS PROTEIN) | 30180060002130 | Brand         |
| SOMAVERT        | PEGVISOMANT FOR INJ 20 MG (AS PROTEIN) | 30180060002140 | Brand         |
| SOMAVERT        | PEGVISOMANT FOR INJ 25 MG (AS PROTEIN) | 30180060002150 | Brand         |
| SOMAVERT        | PEGVISOMANT FOR INJ 30 MG (AS PROTEIN) | 30180060002160 | Brand         |

## **Approval Criteria**

1 - Person or family member self-administering medication

AND

2 - Diagnosis of acromegaly

AND

3 - Prescribed by, or in consultation with, an Endocrinologist

4 - Inadequate response to, or not a candidate for, surgical correction

### AND

5 - Trial and failure, contraindication, or intolerance to somatostatin therapy

| Date       | Notes       |
|------------|-------------|
| 10/10/2023 | New program |

| Standalone Personal Continuous Gluco  | se Monitors (CGM) |
|---|-------------------|
| 3 things your religion. With the bester seed, create, class will be the state of provide account. |                   |

## **Prior Authorization Guideline**

| Guideline ID          | GL-143341   |
|-----------------------|---|
| <b>Guideline Name</b> | Standalone Personal Continuous Glucose Monitors (CGM) |
| Formulary             | Quartz  |

### **Guideline Note:**

| Effective Date: | 2/23/2024 |
|-----------------|-----------|
|-----------------|-----------|

### Note:

Member new to the plan (as evidenced by coverage effective date of less than or equal to 90 days) who initiated therapy using a manufacturer-sponsored free drug program, provider samples, and/or vouchers will go through initial criteria, otherwise for continuation of therapy for new to plan, reauthorization criteria applies.

### 1. Criteria

| Product Name: Freestyle Libre 2, Freestyle Libre 3 |  |   |                 |               |
|--|--|---|-----------------|---------------|
| Approval Length                                    |  | 12/31/2039                                  |                 |               |
| Guideline Type                                     |  | Prior Authorization - All Plans except      | IL and MN Plans |               |
| FREESTYLE LIBRE *CC                                |  | eneric Name                                 | GPI             | Brand/Generic |
|  |  | ONTINUOUS BLOOD GLUCOSE SYSTEM<br>CEIVER*** | 97202012026200  | Brand         |

| FREESTYLE LIBRE<br>2/SENSOR/FLASH<br>GLUCOSE<br>MONITORING<br>SYSTEM | *CONTINUOUS BLOOD GLUCOSE SYSTEM<br>SENSOR*** | 97202012046300 | Brand |
|--|---|----------------|-------|
| FREESTYLE LIBRE<br>3/SENSOR/GLUCOSE<br>MONITORING<br>SYSTEM          | *CONTINUOUS BLOOD GLUCOSE SYSTEM SENSOR***    | 97202012046300 | Brand |

**1** - Trial and failure or intolerance to a Dexcom product

| Notes | *If patent meets criteria approve all CGM components at NDC list "CG MABBOTT"  |
|-------|--|
|       | Persons with insurance coverage of a formulary CGM may upgrade to the newer formulary model upon request (e.g. authorization for Freestyle Libre 2 and requesting Freestyle Libre 3) |

| Product Name: Freestyle Libre 2, Freestyle Libre 3   |                       |
|--|-----------------------|
| Approval Length                                      | 12 month(s)           |
| Therapy Stage  | Initial Authorization |
| Guideline Type Prior Authorization - IL and MN Plans |                       |

| Product Name   | Generic Name                                    | GPI            | Brand/Generic |
|--|---|----------------|---------------|
| FREESTYLE LIBRE<br>2/READER/FLASH<br>GLUCOSE<br>MONITORING<br>SYSTEM | *CONTINUOUS BLOOD GLUCOSE SYSTEM<br>RECEIVER*** | 97202012026200 | Brand         |
| FREESTYLE LIBRE<br>2/SENSOR/FLASH<br>GLUCOSE<br>MONITORING<br>SYSTEM | *CONTINUOUS BLOOD GLUCOSE SYSTEM SENSOR***      | 97202012046300 | Brand         |
| FREESTYLE LIBRE<br>3/SENSOR/GLUCOSE<br>MONITORING<br>SYSTEM          | *CONTINUOUS BLOOD GLUCOSE SYSTEM<br>SENSOR***   | 97202012046300 | Brand         |

## **Approval Criteria**

**1** - Trial and failure or intolerance to a Dexcom product

| Notes | *If patent meets criteria please approve all CGM components at NDC li st "CGMABBOTT"   |
|-------|--|
|       | Persons with insurance coverage of a formulary CGM may upgrade to the newer formulary model upon request (e.g. authorization for Freestyle Libre 2 and requesting Freestyle Libre 3) |

| Product Name: Freestyle Libre 2, Freestyle Libre 3 |                                       |
|--|---------------------------------------|
| Approval Length                                    | 12 month(s)                           |
| Therapy Stage                                      | Reauthorization                       |
| Guideline Type                                     | Prior Authorization - IL and MN Plans |

| Product Name   | Generic Name                                    | GPI            | Brand/Generic |
|--|---|----------------|---------------|
| FREESTYLE LIBRE<br>2/READER/FLASH<br>GLUCOSE<br>MONITORING<br>SYSTEM | *CONTINUOUS BLOOD GLUCOSE SYSTEM<br>RECEIVER*** | 97202012026200 | Brand         |
| FREESTYLE LIBRE<br>2/SENSOR/FLASH<br>GLUCOSE<br>MONITORING<br>SYSTEM | *CONTINUOUS BLOOD GLUCOSE SYSTEM<br>SENSOR***   | 97202012046300 | Brand         |
| FREESTYLE LIBRE<br>3/SENSOR/GLUCOSE<br>MONITORING<br>SYSTEM          | *CONTINUOUS BLOOD GLUCOSE SYSTEM<br>SENSOR***   | 97202012046300 | Brand         |

**1** - Submission of medical records (e.g., chart notes) documenting regular use of the device (average of at least 5 days per week)

| Notes | *If patent meets criteria please approve all CGM components at NDC li<br>st "CGMABBOTT"<br>Persons with insurance coverage of a formulary CGM may upgrade to t |
|-------|--|
|       | he newer formulary model upon request (e.g. authorization for Freestyl e Libre 2 and requesting Freestyle Libre 3)   |

| Date      | Notes   |
|-----------|---|
| 2/23/2024 | Remove Dexcom from criteria, removal of most requirements for Frees |

| tyle libre |
|------------|

| State Mandate Reference Document   |  |  |  |
|--|--|--|--|
| 3 Nationary was strated. Nation in terms and arms of the fact is provided and artists. |  |  |  |
|  |  |  |  |

# **Prior Authorization Guideline**

| Guideline ID          | GL-137462                        |  |
|-----------------------|----------------------------------|--|
| <b>Guideline Name</b> | State Mandate Reference Document |  |
| Formulary             | Quartz                           |  |

# **Guideline Note:**

| Effective Date:   1/1/2024 | Effective Date: |  |
|----------------------------|-----------------|--|
|----------------------------|-----------------|--|

## 1. Criteria

| Guideline Type Administrative |       |         |  |  |     |               |
|-------------------------------|-------|---------|--|--|-----|---------------|
| Product Name                  | Gener | ic Name |  |  | GPI | Brand/Generic |
| Arkansas                      |       |         |  |  |     |               |
| California                    |       |         |  |  |     |               |
| Connecticut                   |       |         |  |  |     |               |
| Georgia                       |       |         |  |  |     |               |
| Indiana                       |       |         |  |  |     |               |
| Kentucky                      |       |         |  |  |     |               |
| Maryland                      |       |         |  |  |     |               |
| New York                      |       |         |  |  |     |               |
| West Virginia                 |       |         |  |  |     |               |

| State         |  |  |
|---------------|--|--|
| Mandate       |  |  |
| Colorado      |  |  |
| Delaware      |  |  |
| lowa          |  |  |
| Illinois      |  |  |
| Louisiana     |  |  |
| Maine         |  |  |
| Minnesota     |  |  |
| New Mexico    |  |  |
| North Dakota  |  |  |
| Oklahoma      |  |  |
| Pennsylvania  |  |  |
| South Dakota  |  |  |
| Texas         |  |  |
| Virginia      |  |  |
| Wisconsin     |  |  |
| Florida       |  |  |
| Massachusetts |  |  |

- **1** The following mandates apply to Illinois:
- **1.1** Effective 1/1/2018, step therapy requirements are deemed met if the provider submits medical records confirming the patient is currently stabilized on the requested medication for the medical condition under consideration.

OR

**1.2** Effective 1/1/2019, any clinical criteria component involving a trial/failure requirement are deemed met if the prescription drug is used to treat the patient's stage four advanced metastatic cancer and treatment is consistent with the U.S. Food and Drug Administration-approved indication or the National Comprehensive Cancer Network Drugs & Biologics Compendium indication for the treatment of stage four advanced metastatic cancer.

OR

**1.3** Effective 6/9/2023, all clinical criteria are deemed met for intravenous immunoglobulin (IVIg) therapy when the medication is being used for a diagnosis of pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections (PANDAS) or pediatric acute onset neuropsychiatric syndrome (PANS).

OR

2 - For lowa, (effective 1/1/2018), when the provider confirms a patient has previously received either a documented step one prescription drug or submits medical records documenting another prescription drug was received that has the same mechanism of action as the documented step one prescription drug, and the prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event, the patient will not be required to try any other alternatives with the same mechanism of action. Where documented step one prescription drugs are deemed met due to this process, all documented step one prescription drugs with the same mechanism of action will count towards the number of alternatives to be tried/failed. If step through other prescription drugs with a different mechanism of action is still required, the patient must meet the additional criteria. Step therapy requirements are also deemed met if the provider submits medical records confirming that the patient is currently stabilized on the requested medication for the medical condition under consideration. Note: Samples and drugs obtained through coupon cards may not count as sufficient experience with the prescribed medication to be considered stable on the medication.

OR

**3** - For Minnesota, (effective 1/1/2020), any clinical criteria component involving a trial/failure requirement are deemed met if the prescription drug is used to treat the patient's stage four advanced metastatic cancer, or an associated condition, and treatment is consistent with the U.S. Food and Drug Administration-approved indication or the National Comprehensive Cancer Network Drugs & Biologics Compendium indication for the treatment of stage four advanced metastatic cancer.

OR

**4** - For Wisconsin, (effective 11/1/2019), any clinical criteria component involving a trial/failure requirement are deemed met when the provider confirms a patient has previously received either a documented step one prescription drug or submits medical records documenting another prescription drug was received that has the same mechanism of action as the documented step one prescription drug, and the prescription drug was discontinued due to lack

of efficacy or effectiveness, diminished effect, or an adverse event, the patient will not be required to try any other alternatives within the same pharmacological class or with the same mechanism of action. Where documented step one prescription drugs are deemed met due to this process, all documented step one prescription drugs with the same mechanism of action will count towards the number of alternatives to be tried/failed. If step through other prescription drugs with a different mechanism of action is still required, the patient must meet the additional criteria. Any clinical criteria component involving a trial/failure requirement are also deemed met if the provider submits medical records confirming that the patient is currently stabilized on the requested medication for the medical condition under consideration, or if submitted justification and clinical documentation support that the required step one prescription drug is expected to be ineffective.

## 2. Background

#### Benefit/Coverage/Program Information

### **Background:**

This document serves as a reference for changes requested to pharmacy utilization management programs based on state mandates. This includes but is not limited to step therapy, prior authorization regulations, supply limits, first line trial duration limitations, and pain therapy/end of life regulations.

#### **Additional Clinical Rules:**

Applicable clinical programs will apply.

| Date      | Notes   |
|-----------|---|
| 12/7/2023 | Updated to only include applicable states: MN, IL, IA, WI |

| Stelara (Ustekinumab)   |  |
|---|--|
| (g) handayaran dagan halka sadar sadasada sada sada sada sada sad |  |

| Guideline ID          | GL-135407             |  |
|-----------------------|-----------------------|--|
| <b>Guideline Name</b> | Stelara (Ustekinumab) |  |
| Formulary             | Quartz                |  |

## **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

## Note:

Member new to the plan (as evidenced by coverage effective date of less than or equal to 90 days) who initiated therapy using a manufacturer-sponsored free drug program, provider samples, and/or vouchers will go through initial criteria, otherwise for continuation of therapy for new to plan, reauthorization criteria applies.

## 1. Criteria

| Product Name: Stelara SC |                        |  |                |               |
|--------------------------|------------------------|--|----------------|---------------|
| Diagnosis                |                        | Plaque Psoriasis                                       |                |               |
| Approval Lo              | ength                  | 12/31/2039   |                |               |
| Guideline T              | уре                    | Prior Authorization - All Plans except IL and MN Plans |                |               |
| Product<br>Name          | ct Generic Name        |  | GPI            | Brand/Generic |
| STELARA                  | USTEKINUM/<br>MG/0.5ML | AB SOLN PREFILLED SYRINGE 45                           | 9025058500E520 | Brand         |

| STELARA | USTEKINUMAB SOLN PREFILLED SYRINGE 90 MG/ML | 9025058500E540 | Brand |
|---------|---|----------------|-------|
| STELARA | USTEKINUMAB INJ 45 MG/0.5ML                 | 90250585002020 | Brand |

1 - Diagnosis of moderate to severe plaque psoriasis

#### **AND**

- **2** ONE of the following:
  - Significant functional disability
  - Body surface area (BSA) involvement of ≥ 3%
  - Debilitating palmer/plantar psoriasis or other vulnerable areas that are difficult to treat (e.g., nails, scalp, genitals, or intertriginous areas

## **AND**

**3** - Prescribed by or in consultation with a dermatologist

## AND

**4** - Trial and failure, contraindication, or intolerance to topical treatment (e.g. topical corticosteroids, calcipotriene, retinoids)

## **AND**

**5** - Not used in combination with other biologic disease modifying anti-rheumatic drugs (DMARDs) (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

#### AND

6 - Medication will be self-administered

| Product Name: Stelara SC |                                       |  |  |
|--------------------------|---------------------------------------|--|--|
| Diagnosis                | Plaque Psoriasis                      |  |  |
| Approval Length          | 12 month(s)                           |  |  |
| Therapy Stage            | Initial Authorization                 |  |  |
| Guideline Type           | Prior Authorization - IL and MN Plans |  |  |

| Product<br>Name | Generic Name                                      | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| STELARA         | USTEKINUMAB SOLN PREFILLED SYRINGE 45<br>MG/0.5ML | 9025058500E520 | Brand         |
| STELARA         | USTEKINUMAB SOLN PREFILLED SYRINGE 90 MG/ML       | 9025058500E540 | Brand         |
| STELARA         | USTEKINUMAB INJ 45 MG/0.5ML                       | 90250585002020 | Brand         |

1 - Diagnosis of moderate to severe plaque psoriasis

## AND

- 2 ONE of the following:
  - Significant functional disability
  - Body surface area (BSA) involvement of ≥ 3%
  - Debilitating palmer/plantar psoriasis or other vulnerable areas that are difficult to treat (e.g., nails, scalp, genitals, or intertriginous areas

## AND

**3** - Prescribed by or in consultation with a dermatologist

## AND

**4** - Trial and failure, contraindication, or intolerance to topical treatment (e.g. topical corticosteroids, calcipotriene, retinoids)

**5** - Not used in combination with other biologic disease modifying anti-rheumatic drugs (DMARDs) (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

### **AND**

6 - Medication will be self-administered

| Product Name: Stelara SC |  |  |
|--------------------------|--|--|
| Diagnosis                | Psoriatic Arthritis (PsA)                              |  |
| Approval Length          | 12/31/2039   |  |
| Guideline Type           | Prior Authorization - All Plans except IL and MN Plans |  |

| Product<br>Name | Generic Name                                      | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| STELARA         | USTEKINUMAB SOLN PREFILLED SYRINGE 45<br>MG/0.5ML | 9025058500E520 | Brand         |
| STELARA         | USTEKINUMAB SOLN PREFILLED SYRINGE 90 MG/ML       | 9025058500E540 | Brand         |
| STELARA         | USTEKINUMAB INJ 45 MG/0.5ML                       | 90250585002020 | Brand         |

## **Approval Criteria**

**1** - Diagnosis of moderate to severely active psoriatic arthritis (PsA)

## **AND**

2 - Prescribed by or in consultation with a dermatologist or rheumatologist

- **3** Submission of medical records (e.g., chart notes) documenting at least ONE of the following:
  - actively inflamed joints
  - axial disease
  - active skin, nail, or scalp psoriasis involvement
  - dactylitis

| • | ntr | es | ıtı | ıc |
|---|-----|----|-----|----|
|   |     |    |     |    |

**4** - Not used in combination with other biologic DMARDs (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

## AND

**5** - Medication will be self-administered

| Product Name: Stelara SC                             |                       |  |
|--|-----------------------|--|
| Diagnosis Psoriatic Arthritis (PsA)                  |                       |  |
| Approval Length                                      | 12 month(s)           |  |
| Therapy Stage  | Initial Authorization |  |
| Guideline Type Prior Authorization - IL and MN Plans |                       |  |

| Product<br>Name | Generic Name                                      | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| STELARA         | USTEKINUMAB SOLN PREFILLED SYRINGE 45<br>MG/0.5ML | 9025058500E520 | Brand         |
| STELARA         | USTEKINUMAB SOLN PREFILLED SYRINGE 90 MG/ML       | 9025058500E540 | Brand         |
| STELARA         | USTEKINUMAB INJ 45 MG/0.5ML                       | 90250585002020 | Brand         |

## **Approval Criteria**

**1** - Diagnosis of moderate to severely active psoriatic arthritis (PsA)

## **AND**

**2** - Prescribed by or in consultation with a dermatologist or rheumatologist

- **3** Submission of medical records (e.g., chart notes) documenting at least ONE of the following:
  - · actively inflamed joints
  - axial disease
  - active skin, nail, or scalp psoriasis involvement
  - dactylitis
  - enthesitis

**4** - Not used in combination with other biologic DMARDs (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

## **AND**

5 - Medication will be self-administered

| Product Name: Stelara SC  |  |  |
|---|--|--|
| Diagnosis Moderate to Severely Active Crohn's Disease (CD)            |  |  |
| Approval Length 12/31/2039  |  |  |
| Guideline Type Prior Authorization - All Plans except IL and MN Plans |  |  |

| Product<br>Name | Generic Name                                      | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| STELARA         | USTEKINUMAB SOLN PREFILLED SYRINGE 45<br>MG/0.5ML | 9025058500E520 | Brand         |
| STELARA         | USTEKINUMAB SOLN PREFILLED SYRINGE 90 MG/ML       | 9025058500E540 | Brand         |
| STELARA         | USTEKINUMAB INJ 45 MG/0.5ML                       | 90250585002020 | Brand         |

## **Approval Criteria**

1 - Diagnosis of moderate to severely active Crohn's Disease (CD)

## AND

2 - Prescribed by or in consultation with a gastroenterologist

- 3 One of the following:
- **3.1** Patient is considered high-risk based on at least ONE of the following characteristics:
  - Age less than 30 years at diagnosis
  - Extensive anatomic involvement
  - Perianal and/or severe rectal disease
  - Deep ulcers
  - Prior surgical resection
  - Stricturing and/or penetrating behavior
  - Fistulizing disease
  - Extraintestinal manifestations of inflammation (i.e. uveitis, erythema nodosum, pyoderma gangrenosum, spondyloarthropathy, etc.)

OR

- **3.2** Both of the following:
- **3.2.1** Patient is considered low-risk

### **AND**

- **3.2.2** At least ONE of the following:
  - Intolerance/contraindication to 1 conventional therapy (ex. azathioprine, balsalazide, corticosteroids, mesalamine, mercaptopurine, methotrexate, sulfasalazine)
  - Inadequate disease control or inability to achieve remission after an adequate trial of 3 months with 1 conventional therapy
  - Demonstrated steroid dependence
  - Conventional therapy clinically inappropriate based on location of disease

#### AND

**4** - Not used in combination with other biologic DMARDs (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

5 - Medication will be self-administered

## **AND**

**6** - Prescriber attests patient has been established on therapy with ustekinumab for Crohn's disease through the medical benefit

| Product Name: Stelara SC |  |  |
|--------------------------|--|--|
| Diagnosis                | Moderate to Severely Active Crohn's Disease (CD) |  |
| Approval Length          | 12 month(s)                                      |  |
| Therapy Stage            | Initial Authorization                            |  |
| Guideline Type           | Prior Authorization - IL and MN Plans            |  |

| Product<br>Name | Generic Name                                      | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| STELARA         | USTEKINUMAB SOLN PREFILLED SYRINGE 45<br>MG/0.5ML | 9025058500E520 | Brand         |
| STELARA         | USTEKINUMAB SOLN PREFILLED SYRINGE 90 MG/ML       | 9025058500E540 | Brand         |
| STELARA         | USTEKINUMAB INJ 45 MG/0.5ML                       | 90250585002020 | Brand         |

## **Approval Criteria**

1 - Diagnosis of moderate to severely active Crohn's Disease (CD)

## **AND**

2 - Prescribed by or in consultation with a gastroenterologist

- 3 One of the following:
- 3.1 Patient is considered high-risk based on at least ONE of the following characteristics:

- Age less than 30 years at diagnosisExtensive anatomic involvement
- Perianal and/or severe rectal disease
- Deep ulcers
- Prior surgical resection
- Stricturing and/or penetrating behavior
- Fistulizing disease
- Extraintestinal manifestations of inflammation (i.e. uveitis, erythema nodosum, pyoderma gangrenosum, spondyloarthropathy, etc.)

OR

- **3.2** Both of the following:
- 3.2.1 Patient is considered low-risk

**AND** 

- **3.2.2** At least ONE of the following:
  - Intolerance/contraindication to 1 conventional therapy (ex. azathioprine, balsalazide, corticosteroids, mesalamine, mercaptopurine, methotrexate, sulfasalazine)
  - Inadequate disease control or inability to achieve remission after an adequate trial of 3 months with 1 conventional therapy
  - Demonstrated steroid dependence
  - Conventional therapy clinically inappropriate based on location of disease

AND

**4** - Not used in combination with other biologic DMARDs (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

AND

5 - Medication will be self-administered

**6** - Prescriber attests patient has been established on therapy with ustekinumab for Crohn's disease through the medical benefit

| Product Name: Stelara SC                                      |                                       |  |
|---|---------------------------------------|--|
| Diagnosis Moderate to Severely Active Ulcerative Colitis (UC) |                                       |  |
| Approval Length   | 12 month(s)                           |  |
| Therapy Stage Initial Authorization                           |                                       |  |
| Guideline Type  | Prior Authorization - IL and MN Plans |  |

| Product<br>Name | Generic Name                                      | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| STELARA         | USTEKINUMAB SOLN PREFILLED SYRINGE 45<br>MG/0.5ML | 9025058500E520 | Brand         |
| STELARA         | USTEKINUMAB SOLN PREFILLED SYRINGE 90 MG/ML       | 9025058500E540 | Brand         |
| STELARA         | USTEKINUMAB INJ 45 MG/0.5ML                       | 90250585002020 | Brand         |

## **Approval Criteria**

1 - Diagnosis of moderate to severely active ulcerative colitis (UC)

## **AND**

2 - Prescribed by or in consultation with a gastroenterologist

- 3 Patient is considered high-risk based on ONE of the following characteristics:
  - Extensive colitis
  - Deep ulcers
  - Age less than 40 years
  - High CRP and ESR
  - Steroid-requiring disease
  - History of hospitalization
  - C. difficile infection
  - CMV infection

**4** - Trial and failure, contraindication, or intolerance to a short course (2 to 4 weeks) of oral corticosteroids

## **AND**

**5** - Not used in combination with other biologic DMARDs (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

## **AND**

6 - Medication will be self-administered

## **AND**

**7** - Prescriber attests patient has been established on therapy with ustekinumab for ulcerative colitis through the medical benefit

| Product Name: Stelara SC  |            |  |
|---|------------|--|
| Diagnosis Moderate to Severely Active Ulcerative Colitis (UC)         |            |  |
| Approval Length   | 12/31/2039 |  |
| Guideline Type Prior Authorization - All Plans except IL and MN Plans |            |  |

| Product<br>Name | Generic Name                                      | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| STELARA         | USTEKINUMAB SOLN PREFILLED SYRINGE 45<br>MG/0.5ML | 9025058500E520 | Brand         |
| STELARA         | USTEKINUMAB SOLN PREFILLED SYRINGE 90 MG/ML       | 9025058500E540 | Brand         |
| STELARA         | USTEKINUMAB INJ 45 MG/0.5ML                       | 90250585002020 | Brand         |

## **Approval Criteria**

1 - Diagnosis of moderate to severely active ulcerative colitis (UC)

| AND  |
|--|
| 2 - Prescribed by or in consultation with a gastroenterologist   |
| AND  |
| <b>3</b> - Patient is considered high-risk based on ONE of the following characteristics:  |
| <ul> <li>Extensive colitis</li> <li>Deep ulcers</li> <li>Age less than 40 years</li> <li>High CRP and ESR</li> <li>Steroid-requiring disease</li> <li>History of hospitalization</li> <li>C. difficile infection</li> <li>CMV infection</li> </ul> |
| AND  |
| 4 - Trial and failure, contraindication, or intolerance to a short course (2 to 4 weeks) of oral corticosteroids   |
| AND  |
| <b>5</b> - Not used in combination with other biologic DMARDs (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)   |
| AND  |
| 6 - Medication will be self-administered   |
| AND  |
| 7 - Prescriber attests patient has been established on therapy with ustekinumab for ulcerative colitis through the medical benefit   |
|  |

| Product Name: Stelara SC      |                                       |  |
|-------------------------------|---------------------------------------|--|
| Diagnosis All Indications     |                                       |  |
| Approval Length               | 12 month(s)                           |  |
| Therapy Stage Reauthorization |                                       |  |
| Guideline Type                | Prior Authorization - IL and MN Plans |  |

| Product<br>Name | Generic Name                                      | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| STELARA         | USTEKINUMAB SOLN PREFILLED SYRINGE 45<br>MG/0.5ML | 9025058500E520 | Brand         |
| STELARA         | USTEKINUMAB SOLN PREFILLED SYRINGE 90 MG/ML       | 9025058500E540 | Brand         |
| STELARA         | USTEKINUMAB INJ 45 MG/0.5ML                       | 90250585002020 | Brand         |

**1** - Prescriber provides clinical documentation from the previous 12 months of the member's response to therapy including individual improvements in functional status related to therapeutic response

| Product Name: Stelara SC |                |
|--------------------------|----------------|
| Approval Length          | 12 month(s)    |
| Guideline Type           | Quantity Limit |

| Product<br>Name | Generic Name                                      | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| STELARA         | USTEKINUMAB SOLN PREFILLED SYRINGE 45<br>MG/0.5ML | 9025058500E520 | Brand         |
| STELARA         | USTEKINUMAB SOLN PREFILLED SYRINGE 90 MG/ML       | 9025058500E540 | Brand         |
| STELARA         | USTEKINUMAB INJ 45 MG/0.5ML                       | 90250585002020 | Brand         |

# **Approval Criteria**

- **1** One of the following:
- **1.1** For members with diagnoses of Ulcerative Colitis (UC) or Crohn's Disease (CD) requesting reduced interval or increased dose (dose other than 90mg, interval less than every 8 weeks), ALL of the following:
  - 1.1.1 Failure of a two-month trial of every 8-week dosing regimen after completion of

induction dosing regimen

## **AND**

**1.1.2** Based on subtherapeutic drug concentrations and absence (or low levels) of drug antibodies

## **AND**

**1.1.3** Provision of published literature supporting dose increase and/or frequency

## OR

**1.2** For members with diagnoses of Psoriatic Arthritis (PsA) or Plaque Psoriasis (PP), Failure of an adherent 3-month trial of standard maintenance dosing with concomitant methotrexate (unless contraindicated or not appropriate for indication being requested)

| Date       | Notes                   |
|------------|-------------------------|
| 11/30/2023 | 2024 New Implementation |

| S | Strensiq   | (asfota  | se alfa                       | 1) |  |
|---|--|--|-------------------------------|----|--|
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|   |  |  |                               |    |  |
|   |  |  |                               |    |  |

| Guideline ID          | GL-133238                |
|-----------------------|--------------------------|
| <b>Guideline Name</b> | Strensiq (asfotase alfa) |
| Formulary             | Quartz                   |

# **Guideline Note:**

| Effective Date: |
|-----------------|
|-----------------|

# 1. Criteria

| Product Name: Strensiq |                       |
|------------------------|-----------------------|
| Approval Length        | 12 month(s)           |
| Therapy Stage          | Initial Authorization |
| Guideline Type         | Prior Authorization   |

| Product<br>Name | Generic Name                                | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| STRENSIQ        | ASFOTASE ALFA SUBCUTANEOUS INJ 18 MG/0.45ML | 30905610002020 | Brand         |
| STRENSIQ        | ASFOTASE ALFA SUBCUTANEOUS INJ 28 MG/0.7ML  | 30905610002030 | Brand         |
| STRENSIQ        | ASFOTASE ALFA SUBCUTANEOUS INJ 40 MG/ML     | 30905610002040 | Brand         |
| STRENSIQ        | ASFOTASE ALFA SUBCUTANEOUS INJ 80 MG/0.8ML  | 30905610002050 | Brand         |

- **1** Diagnosis of perinatal, infantile, or juvenile-onset hypophosphatasia (HPP) with submission of medical records (e.g., chart notes) of one of the following symptom onset by age 6 months:
- **1.1** Both of the following:
  - Serum alkaline phosphatase (ALP) levels below the age/gender-adjusted normal range
  - Elevated tissue non-specific alkaline phosphatase (TNSALP) substrate (e.g. serum pyridoxal 5'-phosphate (PLP) level, serum or urine phosphoethanolamine (PEA) level, or urinary inorganic pyrophosphate level)

## OR

1.2 Documentation of TNSALP gene mutation by ALPL genomic DNA testing

#### **AND**

**2** - Prescribed by or in consultation with an endocrinologist or other specialist in the treatment of inborn errors of metabolism

### **AND**

**3** - Submission of medical records (e.g., chart notes) documenting radiographic evidence supporting the diagnosis (e.g. infantile rickets, craniosynotosis, non-traumatic fractures, osteoporosis or low bone mineral content for age, etc.)

| Product Name: Strensiq |                     |
|------------------------|---------------------|
| Approval Length        | 12 month(s)         |
| Therapy Stage          | Reauthorization     |
| Guideline Type         | Prior Authorization |

| Product<br>Name | Generic Name                                | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| STRENSIQ        | ASFOTASE ALFA SUBCUTANEOUS INJ 18 MG/0.45ML | 30905610002020 | Brand         |
| STRENSIQ        | ASFOTASE ALFA SUBCUTANEOUS INJ 28 MG/0.7ML  | 30905610002030 | Brand         |
| STRENSIQ        | ASFOTASE ALFA SUBCUTANEOUS INJ 40 MG/ML     | 30905610002040 | Brand         |
| STRENSIQ        | ASFOTASE ALFA SUBCUTANEOUS INJ 80 MG/0.8ML  | 30905610002050 | Brand         |

**1** - Submission of medical records (e.g., chart notes) within the past 12 months documenting objective improvements in skeletal quality and labs from baseline such as improvement in respiratory status, improved growth, improved radiographic findings, or decrease in TNSALP substrate levels

| Date      | Notes       |
|-----------|-------------|
| 9/24/2023 | New Program |

| Sunosi (solriamfetol)  |
|--|
| [2] The Market range search subsplayed. The Bost Search second, research, seated, and the best best purchase for seconds and the Search |
|  |
|  |

| Guideline ID          | GL-131364             |
|-----------------------|-----------------------|
| <b>Guideline Name</b> | Sunosi (solriamfetol) |
| Formulary             | Quartz                |

## **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

## Note:

\*Member new to the plan (as evidenced by coverage effective date of less than or equal to 90 days) who initiated therapy using a manufacturer-sponsored free drug program, provider samples, and/or vouchers will go through initial criteria, otherwise for continuation of therapy for new to plan, reauthorization criteria applies

## 1. Criteria

| Product Na                 | Product Name: Sunosi                            |  |                |               |
|----------------------------|---|--|----------------|---------------|
| Approval Length            |   | 12/31/2039   |                |               |
| Guideline Type             |   | Prior Authorization - All plans except IL and MN Plans |                |               |
| Product Generic Na<br>Name |   | ime  | GPI            | Brand/Generic |
| SUNOSI SOLRIAMFETO         |   | TOL HCL TAB 75 MG (BASE EQUIV)                         | 61370070200320 | Brand         |
| SUNOSI                     | SUNOSI SOLRIAMFETOL HCL TAB 150 MG (BASE EQUIV) |  | 61370070200340 | Brand         |
|                            |   |  |                | _             |

- 1 One of the following:
- 1.1 Diagnosis of narcolepsy

OR

1.2 Diagnosis of excessive daytime sleepiness in narcolepsy

OR

- **1.3** All of the following:
  - Diagnosis of obstructive sleep apnea (OSA)
  - Current or prior treatment of the underlying obstruction (e.g. continuous positive airway pressure [CPAP], mandibular advancement device or surgical intervention, etc.)
  - If using CPAP, it will be used concomitantly with solriamfetol

## **AND**

2 - Prescribed by or in consultation with a Sleep Specialist, Neurologist or Psychiatrist

**AND** 

**3** - Member is 18 years of age or older

**AND** 

**4** - Inadequate clinical response after a 3-month trial and failure, contraindication or intolerance to one other first line alternative (e.g., modafinil, armodafinil)

| Product Name: Sunosi        |                       |
|-----------------------------|-----------------------|
| Approval Length 12 month(s) |                       |
| Therapy Stage               | Initial Authorization |

| Guideline Type                                  |   | Prior Authorization - IL and MN Plans |                |               |
|---|---|---------------------------------------|----------------|---------------|
| Product Generic Na<br>Name                      |   | me                                    | GPI            | Brand/Generic |
| SUNOSI  | SOLRIAMFETOL HCL TAB 75 MG (BASE EQUIV) |                                       | 61370070200320 | Brand         |
| SUNOSI SOLRIAMFETOL HCL TAB 150 MG (BASE EQUIV) |   | TOL HCL TAB 150 MG (BASE EQUIV)       | 61370070200340 | Brand         |
|   | -                                       |                                       |                |               |

| <b>1</b> - One of the following | g | : |
|---------------------------------|---|---|
|---------------------------------|---|---|

1.1 Diagnosis of narcolepsy

OR

**1.2** Diagnosis of excessive daytime sleepiness in narcolepsy

OR

## **1.3** All of the following:

- Diagnosis of obstructive sleep apnea (OSA)
- Current or prior treatment of the underlying obstruction (e.g. continuous positive airway pressure [CPAP], mandibular advancement device or surgical intervention, etc.)
- If using CPAP, it will be used concomitantly with solriamfetol

## **AND**

2 - Prescribed by or in consultation with a Sleep Specialist, Neurologist or Psychiatrist

AND

3 - Member is 18 years of age or older

**4** - Inadequate clinical response after a 3-month trial and failure, contraindication or intolerance to one other first line alternative (e.g., modafinil, armodafinil)

| Product Name: Sunosi                                 | Product Name: Sunosi |  |
|--|----------------------|--|
| Approval Length 12 month(s)                          |                      |  |
| Therapy Stage Reauthorization                        |                      |  |
| Guideline Type Prior Authorization - IL and MN Plans |                      |  |

| Product<br>Name | Generic Name                             | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| SUNOSI          | SOLRIAMFETOL HCL TAB 75 MG (BASE EQUIV)  | 61370070200320 | Brand         |
| SUNOSI          | SOLRIAMFETOL HCL TAB 150 MG (BASE EQUIV) | 61370070200340 | Brand         |

## **Approval Criteria**

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug

| Date      | Notes                   |
|-----------|-------------------------|
| 8/23/2023 | 2024 New Implementation |

| • | Sympazan (Clobazam) |  |  |
|---|---------------------|--|--|
|   |                     |  |  |
|   |                     |  |  |

| Guideline ID          | GL-129121           |
|-----------------------|---------------------|
| <b>Guideline Name</b> | Sympazan (Clobazam) |
| Formulary             | Quartz              |

# **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

# 1. Criteria

| Product Name: Sympazan      |                                       |
|-----------------------------|---------------------------------------|
| Approval Length 12 month(s) |                                       |
| Therapy Stage               | Initial Authorization                 |
| Guideline Type              | Prior Authorization - IL and MN Plans |

| Product<br>Name | Generic Name             | GPI            | Brand/Generic |
|-----------------|--------------------------|----------------|---------------|
| SYMPAZAN        | CLOBAZAM ORAL FILM 5 MG  | 72100007008205 | Brand         |
| SYMPAZAN        | CLOBAZAM ORAL FILM 10 MG | 72100007008210 | Brand         |
| SYMPAZAN        | CLOBAZAM ORAL FILM 20 MG | 72100007008220 | Brand         |

# **Approval Criteria**

**1** - Person with a diagnosis of Lennox-Gastaut syndrome with continued seizure activity despite adequate trial and failure, contraindication or intolerance to at least two preferred antiepileptic drugs (e.g., levetiracetam, lamotrigine)

## **AND**

**2** - A trial of generic clobazam (tablets and solution) was not tolerated due to physical inability to swallow

| Product Name: Sympazan                               |  |
|--|--|
| Approval Length 12 month(s)                          |  |
| Therapy Stage Reauthorization                        |  |
| Guideline Type Prior Authorization - IL and MN Plans |  |

| Product<br>Name | Generic Name             | GPI            | Brand/Generic |
|-----------------|--------------------------|----------------|---------------|
| SYMPAZAN        | CLOBAZAM ORAL FILM 5 MG  | 72100007008205 | Brand         |
| SYMPAZAN        | CLOBAZAM ORAL FILM 10 MG | 72100007008210 | Brand         |
| SYMPAZAN        | CLOBAZAM ORAL FILM 20 MG | 72100007008220 | Brand         |

## **Approval Criteria**

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug.

| Product Name: Sympazan  |  |
|---|--|
| Approval Length 12/31/2039  |  |
| Guideline Type Prior Authorization - All Plans except IL and MN Plans |  |

| Product<br>Name | Generic Name             | GPI            | Brand/Generic |
|-----------------|--------------------------|----------------|---------------|
| SYMPAZAN        | CLOBAZAM ORAL FILM 5 MG  | 72100007008205 | Brand         |
| SYMPAZAN        | CLOBAZAM ORAL FILM 10 MG | 72100007008210 | Brand         |
| SYMPAZAN        | CLOBAZAM ORAL FILM 20 MG | 72100007008220 | Brand         |

**1** - Member with a diagnosis of Lennox-Gastaut syndrome with continued seizure activity despite adequate trial and failure, contraindication or intolerance to at least two preferred antiepileptic drugs (e.g., levetiracetam, lamotrigine)

## **AND**

**2** - A trial of generic clobazam (tablets and solution) was not tolerated due to physical inability to swallow

| Date      | Notes       |
|-----------|-------------|
| 9/11/2023 | New program |

|   | systemic Lupus Erytnematosus (SLE) Ir  | eatment |
|---|--|---------|
| - | The Mandalings are tradeport. The drop, Section cond., commer, commer day that the prime to consult and testing. |         |
|   |  |         |

| Guideline ID          | GL-129872                                     |  |
|-----------------------|---|--|
| <b>Guideline Name</b> | Systemic Lupus Erythematosus (SLE) Treatments |  |
| Formulary             | Quartz  |  |

# **Guideline Note:**

| Effective Date: |
|-----------------|
|-----------------|

# 1. Criteria

| Product Name: Benlysta SC |                       |
|---------------------------|-----------------------|
| Approval Length           | 12 month(s)           |
| Therapy Stage             | Initial Authorization |
| Guideline Type            | Prior Authorization   |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| BENLYSTA        | BELIMUMAB SUBCUTANEOUS SOLUTION AUTO-<br>INJECTOR 200 MG/ML | 9942201500D520 | Brand         |
| BENLYSTA        | BELIMUMAB SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 200 MG/ML | 9942201500E520 | Brand         |

# **Approval Criteria**

- 1 All of the following:
  - Diagnosis of Systemic Lupus Erythematosus (SLE) with or without lupus nephritis
  - Member does not have severe central nervous system lupus

**2** - Prescribed by or in consultation with a rheumatologist or other specialist in the treatment of SLE

### **AND**

- 3 Trial and failure, contraindication, or intolerance to ALL of the following:
  - Hydroxychloroquine
  - Nonsteroidal anti-inflammatories (NSAIDs) (e.g., ibuprofen, naproxen)
  - A steroid-sparing immunosuppressive (e.g., azathioprine, methotrexate)
  - A short course of oral steroids

## **AND**

4 - Medication will not be used in combination with Saphnelo (anifrolumab)

## **AND**

## 5 - Drug will be self-administered

| Notes | *Member new to the plan (as evidenced by coverage effective date of I ess than or equal to 90 days) who initiated therapy using a manufactur er-sponsored free drug program, provider samples, and/or vouchers wil I go through initial criteria, otherwise for continuation of therapy for new to plan, reauthorization criteria applies  **Continuation of therapy/coverage criteria will not be applied to person s who were not previously approved for coverage whose therapy was i nitiated using a manufacturer-sponsored free drug program, provider s amples, and/or vouchers. |
|-------|---|

| Product Name: Benlysta SC |             |
|---------------------------|-------------|
| Approval Length           | 12 month(s) |

| Therapy Stage  | Reauthorization     |
|----------------|---------------------|
| Guideline Type | Prior Authorization |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| BENLYSTA        | BELIMUMAB SUBCUTANEOUS SOLUTION AUTO-<br>INJECTOR 200 MG/ML | 9942201500D520 | Brand         |
| BENLYSTA        | BELIMUMAB SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 200 MG/ML | 9942201500E520 | Brand         |

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member demonstrates beneficial response from therapy with the requested drug

| Notes | *Member new to the plan (as evidenced by coverage effective date of I ess than or equal to 90 days) who initiated therapy using a manufactur er-sponsored free drug program, provider samples, and/or vouchers wil I go through initial criteria, otherwise for continuation of therapy for new to plan, reauthorization criteria applies  **Continuation of therapy/coverage criteria will not be applied to person s who were not previously approved for coverage whose therapy was i nitiated using a manufacturer-sponsored free drug program, provider s amples, and/or vouchers. |
|-------|---|

| Date       | Notes                   |
|------------|-------------------------|
| 10/12/2023 | 2024 New Implementation |

| Tadalatil for Benign Prostate Hyperp   |  |  |  |
|--|--|--|--|
| The Section per an incident. Nothing has been read county or state and back to part to be county are been. |  |  |  |
|  |  |  |  |

| Guideline ID          | GL-131928                                 |  |
|-----------------------|---|--|
| <b>Guideline Name</b> | Tadalafil for Benign Prostate Hyperplasia |  |
| Formulary             | Quartz                                    |  |

# **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

# 1. Criteria

| Product Name: Generic Tadalafil |  |
|---------------------------------|--|
| Approval Length                 | 12 month(s)                              |
| Therapy Stage                   | Initial Authorization                    |
| Guideline Type                  | Prior Authorization-IL and MN Plans Only |

| Product<br>Name | Generic Name         | GPI            | Brand/Generic |
|-----------------|----------------------|----------------|---------------|
| TADALAFIL       | TADALAFIL TAB 2.5 MG | 40304080000302 | Generic       |
| TADALAFIL       | TADALAFIL TAB 5 MG   | 40304080000305 | Generic       |

# **Approval Criteria**

**1** - Diagnosis of benign prostatic hyperplasia (BPH)

| Product Name: Generic Tadalafil |  |
|---------------------------------|--|
| Approval Length                 | 12 month(s)                              |
| Therapy Stage                   | Reauthorization                          |
| Guideline Type                  | Prior Authorization-IL and MN Plans Only |

| Product<br>Name | Generic Name         | GPI            | Brand/Generic |
|-----------------|----------------------|----------------|---------------|
| TADALAFIL       | TADALAFIL TAB 2.5 MG | 40304080000302 | Generic       |
| TADALAFIL       | TADALAFIL TAB 5 MG   | 40304080000305 | Generic       |

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug.

| Product Name: Generic Tadalafil                               |  |  |
|---|--|--|
| Approval Length 12/31/2039                                    |  |  |
| Guideline Type Prior Authorization-All plans except IL and MN |  |  |

| Product<br>Name | Generic Name         | GPI            | Brand/Generic |
|-----------------|----------------------|----------------|---------------|
| TADALAFIL       | TADALAFIL TAB 2.5 MG | 40304080000302 | Generic       |
| TADALAFIL       | TADALAFIL TAB 5 MG   | 40304080000305 | Generic       |

## **Approval Criteria**

1 - Diagnosis of benign prostatic hyperplasia (BPH)

| Date       | Notes       |
|------------|-------------|
| 10/31/2023 | New Program |

| • | Tavalisse (Fostamatinib)   |  |  |  |
|---|--|--|--|--|
| 1 | The little language control that England, The Box has been stood, control, or added, both for his joins in the proceeds and incubes. |  |  |  |
|   |  |  |  |  |
|   |  |  |  |  |
| - |  |  |  |  |

| Guideline ID          | GL-128905                |
|-----------------------|--------------------------|
| <b>Guideline Name</b> | Tavalisse (Fostamatinib) |
| Formulary             | Quartz                   |

# **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

# 1. Criteria

| Product Name: Tavalisse    |  |  |
|----------------------------|--|--|
| Approval Length 12/31/2039 |  |  |
| Guideline Type             | Prior authorization - All plans except IL and MN |  |

| Product<br>Name | Generic Name                                       | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| TAVALISSE       | FOSTAMATINIB DISODIUM TAB 100 MG (BASE EQUIVALENT) | 85756040100310 | Brand         |
| TAVALISSE       | FOSTAMATINIB DISODIUM TAB 150 MG (BASE EQUIVALENT) | 85756040100320 | Brand         |

# **Approval Criteria**

**1** - Diagnosis of chronic immune thrombocytopenia (ITP)

|   |   | _ |
|---|---|---|
| Δ | N |   |
|   |   |   |

2 - Member's platelet count < 50,000/mL

## **AND**

**3** - Trial and failure of 2 prior ITP therapies (e.g. corticosteroids, rituximab, azathioprine, danazol, splenectomy, or eltrombopag)

## **AND**

4 - Prescribed by, or in consultation with hematology

| Product Name: Tavalisse                              |                       |  |
|--|-----------------------|--|
| Approval Length                                      | 12 month(s)           |  |
| Therapy Stage  | Initial Authorization |  |
| Guideline Type Prior authorization - IL and MN Plans |                       |  |

| Product<br>Name | Generic Name                                       | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| TAVALISSE       | FOSTAMATINIB DISODIUM TAB 100 MG (BASE EQUIVALENT) | 85756040100310 | Brand         |
| TAVALISSE       | FOSTAMATINIB DISODIUM TAB 150 MG (BASE EQUIVALENT) | 85756040100320 | Brand         |

## **Approval Criteria**

**1** - Diagnosis of chronic immune thrombocytopenia (ITP)

## **AND**

2 - Member's platelet count < 50,000/mL

**3** - Trial and failure of 2 prior ITP therapies (e.g. corticosteroids, rituximab, azathioprine, danazol, splenectomy, or eltrombopag)

## **AND**

4 - Prescribed by, or in consultation with hematology

| Product Name: Tavalisse                                |  |
|--|--|
| Approval Length 12 month(s)                            |  |
| Therapy Stage Reauthorization                          |  |
| Guideline Type Prior Authorization for IL and MN Plans |  |

| Product<br>Name | Generic Name                                       | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| TAVALISSE       | FOSTAMATINIB DISODIUM TAB 100 MG (BASE EQUIVALENT) | 85756040100310 | Brand         |
| TAVALISSE       | FOSTAMATINIB DISODIUM TAB 150 MG (BASE EQUIVALENT) | 85756040100320 | Brand         |

## **Approval Criteria**

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug

| Date     | Notes       |
|----------|-------------|
| 9/7/2023 | New Program |

| Tegsedi (i   | notersen)   |  |
|--|---|--|
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|  |   |  |

| Guideline ID          | GL-131604           |
|-----------------------|---------------------|
| <b>Guideline Name</b> | Tegsedi (inotersen) |
| Formulary             | Quartz              |

## **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

## Note:

Member new to the plan (as evidenced by coverage effective date of less than or equal to 90 days) who initiated therapy using a manufacturer-sponsored free drug program, provider samples, and/or vouchers will go through initial criteria, otherwise for continuation of therapy for new to plan, reauthorization criteria applies.

## 1. Criteria

| Product Name: Tegsedi  |  |             |                |               |
|--|--|-------------|----------------|---------------|
| Diagnosis Neuropathy due to hereditary transthyretin (hATTR) amyloidosis |  | nyloidosis  |                |               |
| Approval Le  | ength  | 12 month(s) |                |               |
| Therapy Stage Initial Authorization                                      |  |             |                |               |
| Guideline Type Prior Authorization                                       |  |             |                |               |
| Product<br>Name  | Generic Name                                     |             | GPI            | Brand/Generic |
| TEGSEDI  | INOTERSEN SOD SUBCUTANEOUS PREF SYR 284 62701040 |             | 6270104010E520 | Brand         |

| г |                    |  |
|---|--------------------|--|
|   | MG/1.5ML (BASE EQ) |  |

**1** - Diagnosis of neuropathy due to hereditary transthyretin (hATTR) amyloidosis with documentation of TTR gene mutation and biopsy proven amyloid deposits

## **AND**

**2** - Prescribed by, or in consultation with, a Neurologist, Cardiologist, or other expert in hereditary transthyretin-mediated amyloidosis (hATTR)

### **AND**

**3** - Member is 18 years of age or older

## **AND**

**4** - Drug is not being used in combination with another TTR-lowering agent (e.g., patisiran, vutrisiran)

## **AND**

**5** - Drug is not being used in combination with a TTR-stabilizing agent (e.g., diflunisal, tafamidis, tafamidis meglumine)

| Product Name: Tegsed                | Product Name: Tegsedi                |     |   |  |  |
|-------------------------------------|--------------------------------------|-----|---|--|--|
| Diagnosis                           | Continuation of Coverage if New to F | lan |   |  |  |
| Approval Length                     | 12 month(s)                          |     |   |  |  |
| Therapy Stage Initial Authorization |                                      |     |   |  |  |
| Guideline Type Prior Authorization  |                                      |     |   |  |  |
|                                     |                                      |     | _ |  |  |

| Product<br>Name | Generic Name                            | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| TEGSEDI         | INOTERSEN SOD SUBCUTANEOUS PREF SYR 284 | 6270104010E520 | Brand         |

|--|

**1** - Diagnosis of neuropathy due to hereditary transthyretin (hATTR) amyloidosis with documentation of TTR gene mutation and biopsy proven amyloid deposits

## **AND**

**2** - Prescribed by, or in consultation with, a Neurologist, Cardiologist, or other expert in hereditary transthyretin-mediated amyloidosis (hATTR)

### **AND**

**3** - Member is 18 years of age or older

### **AND**

**4** - Drug is not being used in combination with another TTR-lowering agent (e.g., patisiran, vutrisiran)

## **AND**

**5** - Drug is not being used in combination with a TTR-stabilizing agent (e.g., diflunisal, tafamidis, tafamidis meglumine)

## **AND**

**6** - The prescriber must provide clinical documentation of the member's initial response to therapy (e.g. clinical manifestation stability/improvement)

| Product Name: Tegsedi  |            |  |
|--|------------|--|
| Diagnosis Neuropathy due to hereditary transthyretin (hATTR) amyloidosis |            |  |
| Approval Length  | 12/31/2039 |  |

| Therapy Stage   | Reauthorization |   |  |
|---|-----------------|---|--|
| Guideline Type Prior Authorization - All Plans except IL and MN Plans |                 |   |  |
|   |                 | 1 |  |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| TEGSEDI         | INOTERSEN SOD SUBCUTANEOUS PREF SYR 284<br>MG/1.5ML (BASE EQ) | 6270104010E520 | Brand         |

**1** - Submission of medical records (e.g., chart notes) documenting response to therapy or documentation of clinical stability for the previous 12 months

| Product Name: Tegsedi                                |  |  |
|--|--|--|
| Diagnosis  | Neuropathy due to hereditary transthyretin (hATTR) amyloidosis |  |
| Approval Length                                      | 12 month(s)  |  |
| Therapy Stage  | Reauthorization  |  |
| Guideline Type Prior Authorization - IL and MN Plans |  |  |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| TEGSEDI         | INOTERSEN SOD SUBCUTANEOUS PREF SYR 284<br>MG/1.5ML (BASE EQ) | 6270104010E520 | Brand         |

# **Approval Criteria**

**1** - Submission of medical records (e.g., chart notes) documenting response to therapy or documentation of clinical stability for the previous 12 months

| Date      | Notes                   |
|-----------|-------------------------|
| 8/24/2023 | 2024 New Implementation |

| lestosterone |   |  |  |  |  |  |
|--------------|---|--|--|--|--|--|
|              | The Mandempower behavior from the section treat, a dated to the first his prime the country and behavior below. |  |  |  |  |  |
|              |   |  |  |  |  |  |

| Guideline ID          | GL-129874    |
|-----------------------|--------------|
| <b>Guideline Name</b> | Testosterone |
| Formulary             | Quartz       |

## **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

### Note:

Member new to the plan (as evidenced by coverage effective date of less than or equal to 90 days) who initiated therapy using a manufacturer-sponsored free drug program, provider samples, and/or vouchers will go through initial criteria, otherwise for continuation of therapy for new to plan, reauthorization criteria applies

### 1. Criteria

| Product Name: Preferred Testosterone Products: generic testosterone 1% gel, generic testosterone 1.6% gel, generic testosterone cypionate, generic testosterone enanthate |  |                                       |                |               |
|---|--|---------------------------------------|----------------|---------------|
| Approval Length   |  | 12 month(s)                           |                |               |
| Therapy Stage   |  | Initial Authorization                 |                |               |
| Guideline Type  |  | Prior Authorization - IL and MN Plans |                |               |
| Product Name Gener  |  | ic Name                               | GPI            | Brand/Generic |
| TESTOSTERONE TESTOSTERONE TD GE TESTOSTERONE TESTOSTERONE TD GE   |  | STERONE TD GEL 20.25 MG/ACT (1.62%)   | 23100030004050 | Generic       |
|   |  | STERONE TD GEL 20.25 MG/ACT (1.62%)   | 23100030004050 | Generic       |

| PUMP                      |  |                |         |
|---------------------------|--|----------------|---------|
| TESTOSTERONE              | TESTOSTERONE TD GEL 50 MG/5GM (1%)                       | 23100030004030 | Generic |
| TESTOSTERONE<br>PUMP      | TESTOSTERONE TD GEL 12.5 MG/ACT (1%)                     | 23100030004040 | Generic |
| TESTOSTERONE              | TESTOSTERONE TD GEL 25 MG/2.5GM (1%)                     | 23100030004025 | Generic |
| TESTOSTERONE              | TESTOSTERONE TD GEL 40.5 MG/2.5GM (1.62%)                | 23100030004047 | Generic |
| TESTOSTERONE              | TESTOSTERONE TD GEL 20.25 MG/1.25GM (1.62%)              | 23100030004044 | Generic |
| TESTOSTERONE<br>ENANTHATE | TESTOSTERONE ENANTHATE IM INJ IN OIL 200 MG/ML           | 23100030202010 | Generic |
| TESTOSTERONE<br>CYPIONATE | TESTOSTERONE CYPIONATE IM INJ IN OIL 100 MG/ML           | 23100030102010 | Generic |
| TESTOSTERONE<br>CYPIONATE | TESTOSTERONE CYPIONATE IM INJ IN OIL 200 MG/ML           | 23100030102015 | Generic |
| TESTOSTERONE<br>CYPIONATE | TESTOSTERONE CYP IM OR SUBCUTANEOUS INJ IN OIL 200 MG/ML | 23100030102070 | Brand   |

- **1** One of the following:
- 1.1 Diagnosis of gender dysphoria or transsexualism

OR

- **1.2** Both of the following:
- **1.2.1** Submission of medical records (e.g., chart notes) demonstrating androgen deficiency\*\* in one of the following diagnoses:
  - Primary or secondary hypogonadism
  - Mixed hypogonadism

#### **AND**

**1.2.2** Submission of medical records (e.g., chart notes) documenting symptoms due to low testosterone other than decreased libido and/or other sexual dysfunction

| Notes | *Continuation of therapy/coverage criteria will not be applied to person |
|-------|--|
|       | s who were not previously approved for                                   |
|       | coverage but whose therapy was initiated using a manufacturer-spons      |

| Product Name: Preferred Testosterone Products: generic testosterone 1% gel, generic testosterone 1.6% gel, generic testosterone cypionate, generic testosterone enanthate |  |  |
|---|--|--|
| Approval Length 12 month(s)   |  |  |
| Therapy Stage Reauthorization   |  |  |
| Guideline Type Prior Authorization - IL and MN Plans  |  |  |

| Product Name              | Generic Name   | GPI            | Brand/Generic |
|---------------------------|--|----------------|---------------|
| TESTOSTERONE              | TESTOSTERONE TD GEL 20.25 MG/ACT (1.62%)                 | 23100030004050 | Generic       |
| TESTOSTERONE<br>PUMP      | TESTOSTERONE TD GEL 20.25 MG/ACT (1.62%)                 | 23100030004050 | Generic       |
| TESTOSTERONE              | TESTOSTERONE TD GEL 50 MG/5GM (1%)                       | 23100030004030 | Generic       |
| TESTOSTERONE<br>PUMP      | TESTOSTERONE TD GEL 12.5 MG/ACT (1%)                     | 23100030004040 | Generic       |
| TESTOSTERONE              | TESTOSTERONE TD GEL 25 MG/2.5GM (1%)                     | 23100030004025 | Generic       |
| TESTOSTERONE              | TESTOSTERONE TD GEL 40.5 MG/2.5GM (1.62%)                | 23100030004047 | Generic       |
| TESTOSTERONE              | TESTOSTERONE TD GEL 20.25 MG/1.25GM (1.62%)              | 23100030004044 | Generic       |
| TESTOSTERONE<br>ENANTHATE | TESTOSTERONE ENANTHATE IM INJ IN OIL 200 MG/ML           | 23100030202010 | Generic       |
| TESTOSTERONE<br>CYPIONATE | TESTOSTERONE CYPIONATE IM INJ IN OIL 100 MG/ML           | 23100030102010 | Generic       |
| TESTOSTERONE<br>CYPIONATE | TESTOSTERONE CYPIONATE IM INJ IN OIL 200 MG/ML           | 23100030102015 | Generic       |
| TESTOSTERONE<br>CYPIONATE | TESTOSTERONE CYP IM OR SUBCUTANEOUS INJ IN OIL 200 MG/ML | 23100030102070 | Brand         |

1 - Member is new to the plan (as evidenced by coverage effective date of less than or equal to 90 days) and established on therapy will have coverage under their drug benefit for the remainder of the current treatment course

| *Continuation of therapy/coverage criteria will not be applied to person s who were not previously approved for coverage but whose therapy was initiated using a manufacturer-spons ored free drug program, provider samples, and/or vouchers.  **Androgen deficiency is defined as a fasting, morning testosterone lev el (drawn between 7 and 10 AM or within 3 hours of waking for shift workers) below the lower limit of normal as defined by the laboratory reference range. A single low testosterone is not diagnostic for androgen deficiency and must be confirmed with a second fasting, morning |
|---|
| testosterone level.   |

| Product Name: Non-Preferred Testosterone Products: Brand Androderm, generic testosterone topical solution |  |  |  |
|---|--|--|--|
| Approval Length 12 month(s)   |  |  |  |
| Therapy Stage Initial Authorization   |  |  |  |
| Guideline Type Prior Authorization - IL and MN Plans  |  |  |  |

| Product Name                        | Generic Name                         | GPI            | Brand/Generic |
|-------------------------------------|--------------------------------------|----------------|---------------|
| TESTOSTERONE                        | TESTOSTERONE TD SOLN 30 MG/ACT       | 23100030002020 | Generic       |
| TESTOSTERONE<br>TOPICAL<br>SOLUTION | TESTOSTERONE TD SOLN 30 MG/ACT       | 23100030002020 | Generic       |
| ANDRODERM                           | TESTOSTERONE TD PATCH 24HR 2 MG/24HR | 23100030008503 | Brand         |
| ANDRODERM                           | TESTOSTERONE TD PATCH 24HR 4 MG/24HR | 23100030008510 | Brand         |

- **1** One of the following:
- **1.1** Diagnosis of gender dysphoria or transsexualism

OR

- **1.2** Both of the following:
- **1.2.1** Submission of medical records (e.g., chart notes) demonstrating androgen deficiency\*\* in one of the following diagnoses:
  - Primary or secondary hypogonadism

Mixed hypogonadism

#### **AND**

**1.2.2** Submission of medical records (e.g., chart notes) documenting symptoms due to low testosterone other than decreased libido and/or other sexual dysfunction

#### **AND**

**2** - Trial and failure, contraindication, or intolerance to at least one preferred testosterone option (with the same route of administration if available)

| *Continuation of therapy/coverage criteria value who were not previously approved for coverage but whose therapy was initiated used free drug program, provider samples, vouchers.  **Androgen deficiency is defined as a fasting el (drawn between 7 and 10 AM or within 3 of waking for shift workers) below the lowery the laboratory reference range. A single lettestosterone is not diagnostic for androgen firmed with a second fasting, morning testosterone level. | using a manufacturer-spons and/or ng, morning testosterone level hours r limit of normal as defined bow |
|---|---|

| Product Name: Non-Preferred Testosterone Products: Brand Androderm, generic testosterone topical solution |  |  |
|---|--|--|
| Approval Length 12 month(s)   |  |  |
| Therapy Stage Reauthorization   |  |  |
| Guideline Type Prior Authorization - IL and MN Plans  |  |  |

| Product Name                        | Generic Name                         | GPI            | Brand/Generic |
|-------------------------------------|--------------------------------------|----------------|---------------|
| TESTOSTERONE                        | TESTOSTERONE TD SOLN 30 MG/ACT       | 23100030002020 | Generic       |
| TESTOSTERONE<br>TOPICAL<br>SOLUTION | TESTOSTERONE TD SOLN 30 MG/ACT       | 23100030002020 | Generic       |
| TESTOSTERONE                        | TESTOSTERONE TD GEL 10MG/ACT (2%)    | 23100030004070 | Generic       |
| ANDRODERM                           | TESTOSTERONE TD PATCH 24HR 2 MG/24HR | 23100030008503 | Brand         |
| ANDRODERM                           | TESTOSTERONE TD PATCH 24HR 4 MG/24HR | 23100030008510 | Brand         |

- **1** One of the following:
- **1.1** Both of the following:
  - Member is new to the plan (as evidenced by coverage effective date of less than or equal to 90 days) and established on therapy will have coverage under their drug benefit for the remainder of the current treatment course
  - Submission of medical records (e.g., chart notes) documenting intolerance to at least one preferred testosterone formulation

#### OR

**1.2** Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug

| S   C   C   C   C   C   C   C   C   C | *Continuation of therapy/coverage criteria will not be applied to person s who were not previously approved for coverage but whose therapy was initiated using a manufacturer-spons ored free drug program, provider samples, and/or vouchers.  **Androgen deficiency is defined as a fasting, morning testosterone lev el (drawn between 7 and 10 AM or within 3 hours of waking for shift workers) below the lower limit of normal as defined by the laboratory reference range. A single low testosterone is not diagnostic for androgen deficiency and must be con firmed with a second fasting, morning testosterone level. |
|---------------------------------------|--|

| Product Name: Preferred Testosterone Products: generic testosterone 1% gel, generic testosterone 1.6% gel, generic testosterone cypionate, generic testosterone enanthate |   |   |                |               |
|---|---|---|----------------|---------------|
| Approval Length   |   | 12/31/2039  |                |               |
| Guideline Type  | Guideline Type Prior Authorization - All Plans Except IL and MN Plans |   |                |               |
| Product Name  | Gener   | ic Name   | GPI            | Brand/Generic |
| TESTOSTERONE  | TESTO   | STERONE TD GEL 20.25 MG/ACT (1.62%)                         | 23100030004050 | Generic       |
| TESTOSTERONE<br>PUMP  | TESTOSTERONE TD GEL 20.25 MG/ACT (1.62%) 23100030004050 Generic       |   | Generic        |               |
| TESTOSTERONE  | TESTOSTERONE TD GEL 50 MG/5GM (1%) 23100030004030 Generic             |   | Generic        |               |
| TESTOSTERONE<br>PUMP  | TESTO   | TESTOSTERONE TD GEL 12.5 MG/ACT (1%) 23100030004040 Generic |                |               |

| TESTOSTERONE              | TESTOSTERONE TD GEL 25 MG/2.5GM (1%)                     | 23100030004025 | Generic |
|---------------------------|--|----------------|---------|
| TESTOSTERONE              | TESTOSTERONE TD GEL 40.5 MG/2.5GM (1.62%)                | 23100030004047 | Generic |
| TESTOSTERONE              | TESTOSTERONE TD GEL 20.25 MG/1.25GM (1.62%)              | 23100030004044 | Generic |
| TESTOSTERONE<br>ENANTHATE | TESTOSTERONE ENANTHATE IM INJ IN OIL 200 MG/ML           | 23100030202010 | Generic |
| TESTOSTERONE<br>CYPIONATE | TESTOSTERONE CYPIONATE IM INJ IN OIL 100 MG/ML           | 23100030102010 | Generic |
| TESTOSTERONE<br>CYPIONATE | TESTOSTERONE CYPIONATE IM INJ IN OIL 200 MG/ML           | 23100030102015 | Generic |
| TESTOSTERONE<br>CYPIONATE | TESTOSTERONE CYP IM OR SUBCUTANEOUS INJ IN OIL 200 MG/ML | 23100030102070 | Brand   |

- **1** One of the following:
- **1.1** Diagnosis of gender dysphoria or transsexualism

OR

- **1.2** Both of the following:
- **1.2.1** Submission of medical records (e.g., chart notes) demonstrating androgen deficiency\*\* in one of the following diagnoses:
  - Primary or secondary hypogonadism
  - Mixed hypogonadism

#### **AND**

**1.2.2** Submission of medical records (e.g., chart notes) documenting symptoms due to low testosterone other than decreased libido and/or other sexual dysfunction

| Notes | *Continuation of therapy/coverage criteria will not be applied to person s who were not previously approved for coverage but whose therapy was initiated using a manufacturer-spons ored free drug program, provider samples, and/or vouchers.  **Androgen deficiency is defined as a fasting, morning testosterone level (drawn between 7 and 10 AM or within 3 hours |
|-------|--|
|       | of waking for shift workers) below the lower limit of normal as defined b  |

|  | y the laboratory reference range. A single low testosterone is not diagnostic for androgen deficiency and must be con firmed with a second fasting, morning testosterone level. |
|--|---|
|--|---|

| Product Name: Non-Preferred Testosterone Products: Brand Androderm, generic testosterone topical solution |            |
|---|------------|
| Approval Length   | 12/31/2039 |
| Guideline Type Prior Authorization - All Plans Except IL and MN Plans                                     |            |

| Product Name                        | Generic Name                         | GPI            | Brand/Generic |
|-------------------------------------|--------------------------------------|----------------|---------------|
| TESTOSTERONE                        | TESTOSTERONE TD SOLN 30 MG/ACT       | 23100030002020 | Generic       |
| TESTOSTERONE<br>TOPICAL<br>SOLUTION | TESTOSTERONE TD SOLN 30 MG/ACT       | 23100030002020 | Generic       |
| TESTOSTERONE                        | TESTOSTERONE TD GEL 10MG/ACT (2%)    | 23100030004070 | Generic       |
| ANDRODERM                           | TESTOSTERONE TD PATCH 24HR 2 MG/24HR | 23100030008503 | Brand         |
| ANDRODERM                           | TESTOSTERONE TD PATCH 24HR 4 MG/24HR | 23100030008510 | Brand         |

- **1** One of the following:
- **1.1** Diagnosis of gender dysphoria or transsexualism

OR

- **1.2** Both of the following:
- **1.2.1** Submission of medical records (e.g., chart notes) demonstrating androgen deficiency\*\* in one of the following diagnoses:
  - Primary or secondary hypogonadism
  - Mixed hypogonadism

#### **AND**

**1.2.2** Submission of medical records (e.g., chart notes) documenting symptoms due to low testosterone other than decreased libido and/or other sexual dysfunction

| AND  2 - Trial and failure, contraindication, or intolerance to at least one preferred testosterone option |   |  |
|--|---|--|
| (with the same route of administration if available)   |   |  |
| Notes  | *Continuation of therapy/coverage criteria will not be applied to person s who were not previously approved for coverage but whose therapy was initiated using a manufacturer-spons ored free drug program, provider samples, and/or vouchers.  **Androgen deficiency is defined as a fasting, morning testosterone lev el (drawn between 7 and 10 AM or within 3 hours of waking for shift workers) below the lower limit of normal as defined by the laboratory reference range. A single low testosterone is not diagnostic for androgen deficiency and must be confirmed with a second fasting, morning testosterone level. |  |

# 2. Revision History

| Date      | Notes                   |
|-----------|-------------------------|
| 8/16/2023 | 2024 New Implementation |

| Tezspire (tezepelumab)  |  |  |  |  |
|---|--|--|--|--|
| (2) The interface can be depicted. Such as the last consist of control of the first the control of the control |  |  |  |  |
|   |  |  |  |  |

| Guideline ID          | GL-137010              |
|-----------------------|------------------------|
| <b>Guideline Name</b> | Tezspire (tezepelumab) |
| Formulary             | Quartz                 |

## **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

### Note:

Member new to the plan (as evidenced by coverage effective date of less than or equal to 90 days) who initiated therapy using a manufacturer-sponsored free drug program, provider samples, and/or vouchers will go through initial criteria, otherwise for continuation of therapy for new to plan, reauthorization criteria applies

### 1. Criteria

| Product Name: Tezspire     |                           |  |                |               |
|----------------------------|---------------------------|--|----------------|---------------|
| Approval Length            |                           | 12 month(s)                              |                |               |
| Therapy Stage              |                           | Initial Authorization                    |                |               |
| Guideline Type             |                           | Prior Authorization - IL and MN Plans    |                |               |
| Product Generic Na<br>Name |                           | me                                       | GPI            | Brand/Generic |
| TEZSPIRE                   | TEZEPELUM<br>INJ 210 MG/1 | AB-EKKO SUBCUTANEOUS SOLN AUTO-<br>.91ML | 4460807525D520 | Brand         |

| TEZSPIRE          | TEZEPELUMAB-EKKO SUBCUTANEOUS SOLN PREF<br>SYR 210 MG/1.91ML | 4460807525E520 | Brand |  |
|-------------------|--|----------------|-------|--|
|                   |  |                |       |  |
| Approval Criteria |  |                |       |  |

1 - Requested medication will be self-administered

**AND** 

- **2** Prescribed by or in consultation with one of the following:
  - Allergist
  - Immunologist
  - Pulmonologist

AND

**3** - Member is 12 years of age or older

**AND** 

- **4** One of the following:
- **4.1** Symptoms are not well controlled or poorly controlled (refer to Table 1 in background section) despite an adherent ‡ ≥ 3-month trial of medium to high-dose inhaled corticosteroids in combination with a long-acting bronchodilator, long-acting muscarinic antagonist, or leukotriene modifier

OR

- **4.2** One of the following:
- **4.2.1** Member has an intolerance to medium to high dose inhaled corticosteroids (ICS) in combination with long-acting bronchodilator or leukotriene modifier

OR

4.2.2 Member has one or more of the following comorbid conditions that increase long-term risks of adverse effects from high dose ICS or oral corticosteroids: Cataracts in patients > 40 years of age Glaucoma Recurrent thrush Dysphonia Growth inhibition, after evaluation by endocrine consult Diagnosis of osteoporosis, treatment resistant to FDA approved osteoporosis treatment **AND 5** - One of the following: **5.1** All of the following: **5.1.1** Diagnosis of eosinophilic asthma **AND 5.1.2** Submission of medical records (e.g., chart notes) documenting a blood eosinophil count of ≥ 150 cells/mm3 **AND 5.1.3** All other causes of eosinophilia such as hypereosinophilic syndromes, neoplastic

**5.1.3** All other causes of eosinophilia such as hypereosinophilic syndromes, neoplastic disease, or parasitic disease have been ruled out

#### AND

**5.1.4** Trial and failure or intolerance to at least two preferred self-administered biologic therapies for eosinophilic asthma (i.e. dupilumab, benralizumab, mepolizumab)

OR

- **5.2** All of the following:
- **5.2.1** Diagnosis of moderate-to-severe persistent allergic asthma as defined by Global Initiative for Asthma (GINA) Global Strategy for Asthma Management and Prevention

| Guidelines (Step 5)  |  |  |
|--|--|--|
| AND  |  |  |
| <b>5.2.2</b> Serum IgE level ≥30 international units/mL  |  |  |
| AND  |  |  |
| <b>5.2.3</b> Positive skin tests or in vitro reactivity to common aeroallergens (e.g. dust mites, pet dander, cockroaches, etc.)                 |  |  |
| AND  |  |  |
| <b>5.2.4</b> Trial and failure or intolerance to at least one preferred self-administered biologic therapy for allergic asthma (i.e. omalizumab) |  |  |
| OR   |  |  |
| 5.3 All the following:   |  |  |
| 5.3.1 Diagnosis of severe asthma   |  |  |
| AND  |  |  |
| 5.3.2 One of the following:  |  |  |
| <ul> <li>History of ≥ 2 asthma exacerbations requiring systemic corticosteroids within the past<br/>12 months</li> </ul>                         |  |  |
| One asthma exacerbation requiring hospitalization in the past 12 months  |  |  |
| AND  |  |  |
| 5.3.3 Asthma is non-eosinophilic (example: blood eosinophil counts of  |  |  |
| AND  |  |  |

**5.3.4** Asthma is non-allergic (example: Serum IgE level

#### AND

**5.3.5** For oral corticosteroid dependent asthma (requiring daily oral steroids): trial and failure or intolerance to at least one preferred self-administered biologic therapy for corticosteroid dependent asthma (i.e. dupilumab)

| •     | ( 1 /   |
|-------|---|
| Notes | ‡Adherent treatment is defined as a medication possession ratio (MPR ) ≥ 70% based on the previous 120 days of prescription claims.   |
|       | NOTE: II-5 inhibitor drugs in combination with omalizumab will be considered on a case-by-case basis if each individual agent with combination high dose ICS/LABA did not control symptoms. Tezepelumab, in combination with other biologics, has not been studied and coverage is not allowed except in extenuating circumstances (applies to both eosinophilic or non-eosinophilic asthma populations). |
|       | *Continuation of therapy/coverage criteria will not be applied to person s who were not previously approved for coverage whose therapy was i nitiated using a manufacturer-sponsored free drug program, provider s amples, and/or vouchers.   |

| Product Name: Tezspire                               |  |  |
|--|--|--|
| Approval Length 12 month(s)                          |  |  |
| Therapy Stage Reauthorization                        |  |  |
| Guideline Type Prior Authorization - IL and MN Plans |  |  |

| Product<br>Name | Generic Name   | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| TEZSPIRE        | TEZEPELUMAB-EKKO SUBCUTANEOUS SOLN AUTO-INJ 210 MG/1.91ML    | 4460807525D520 | Brand         |
| TEZSPIRE        | TEZEPELUMAB-EKKO SUBCUTANEOUS SOLN PREF<br>SYR 210 MG/1.91ML | 4460807525E520 | Brand         |

### **Approval Criteria**

- **1** Submission of medical records (e.g., chart notes) documenting positive clinical response to therapy within the previous 12 months defined by one of the following:
  - Decreased frequency of use of, or ability to lower the chronic daily dose, of oral

- corticosteroids to treat/prevent exacerbations
- Decreased frequency of use of unscheduled emergency department/urgent care visits for exacerbations
- Reduction in reported symptoms such as chest tightness, coughing, shortness of breath, nocturnal awakenings, nasal congestion, obstruction, etc.
- Sustained (at least six months) improvement in Asthma Control Test (ACT) scores

| Notes | NOTE: Continuation of case-by case-approved IgE inhibitor and IL-5 in hibitor, or tezepelumab combination therapy will only be considered if ICS/LABA therapy was also continued AND there was reduction in oral steroid dose, exacerbations, or hospitalizations. |
|-------|--|
|       | *Continuation of therapy/coverage criteria will not be applied to person s who were not previously approved for coverage whose therapy was i nitiated using a manufacturer-sponsored free drug program, provider s amples, and/or vouchers.                        |

| Product Name: Tezspire  |  |  |
|---|--|--|
| Approval Length 12/31/2039  |  |  |
| Guideline Type Prior Authorization - All Plans Except IL and MN Plans |  |  |

| Product<br>Name | Generic Name   | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| TEZSPIRE        | TEZEPELUMAB-EKKO SUBCUTANEOUS SOLN AUTO-INJ 210 MG/1.91ML    | 4460807525D520 | Brand         |
| TEZSPIRE        | TEZEPELUMAB-EKKO SUBCUTANEOUS SOLN PREF<br>SYR 210 MG/1.91ML | 4460807525E520 | Brand         |

1 - Requested medication will be self-administered

#### AND

- **2** Prescribed by or in consultation with one of the following:
  - Allergist
  - Immunologist
  - Pulmonologist

| AND   |  |  |  |  |
|---|--|--|--|--|
| <b>3</b> - Member is 12 years of age or older   |  |  |  |  |
| AND   |  |  |  |  |
| 4 - One of the following:   |  |  |  |  |
| <b>4.1</b> Symptoms are not well controlled or poorly controlled (refer to Table 1 in background section) despite an adherent ‡ ≥ 3-month trial of medium to high-dose inhaled corticosteroids in combination with a long-acting bronchodilator, long-acting muscarinic antagonist, or leukotriene modifier |  |  |  |  |
| OR  |  |  |  |  |
| <ul><li>4.2 One of the following:</li><li>4.2.1 Member has an intolerance to medium to high dose inhaled corticosteroids (ICS) in combination with long-acting bronchodilator or leukotriene modifier</li></ul>   |  |  |  |  |
| OR  |  |  |  |  |
| <b>4.2.2</b> Member has one or more of the following comorbid conditions that increase long-term risks of adverse effects from high dose ICS or oral corticosteroids:   |  |  |  |  |
| <ul> <li>Cataracts in patients &gt; 40 years of age</li> <li>Glaucoma</li> <li>Recurrent thrush</li> </ul>  |  |  |  |  |
| <ul> <li>Dysphonia</li> <li>Growth inhibition, after evaluation by Endocrine Consult</li> <li>Diagnosis of osteoporosis, treatment resistant to FDA approved osteoporosis treatment</li> </ul>  |  |  |  |  |
| AND   |  |  |  |  |
| <b>5</b> - One of the following:  |  |  |  |  |
| 5.1 All of the following:   |  |  |  |  |
| 5.1.1 Diagnosis of eosinophilic asthma  |  |  |  |  |
|   |  |  |  |  |

| n 0 | chart notes) documenting a blood eosinophil coun |
|-----|--|

**5.1.2** Submission of medical records (e.g., chart notes) documenting a blood eosinophil count of ≥ 150 cells/mm3

AND

#### **AND**

**5.1.3** All other causes of eosinophilia such as hypereosinophilic syndromes, neoplastic disease, or parasitic disease have been ruled out

#### **AND**

**5.1.4** Trial and failure or intolerance to at least two preferred self-administered biologic therapies for eosinophilic asthma (i.e. dupilumab, benralizumab, mepolizumab)

#### OR

- **5.2** All of the following:
- **5.2.1** Diagnosis of moderate-to-severe persistent allergic asthma as defined by Global Initiative for Asthma (GINA) Global Strategy for Asthma Management and Prevention Guidelines (Step 5)

#### **AND**

**5.2.2** Serum IgE level ≥30 international units/mL

#### **AND**

**5.2.3** Positive skin tests or in vitro reactivity to common aeroallergens (e.g. dust mites, pet dander, cockroaches, etc.)

#### **AND**

| <b>5.2.4</b> Trial and failure or intolerance to at least one preferred self-administered biologic therapy for allergic asthma (i.e. omalizumab)  |   |  |  |  |
|---|---|--|--|--|
|   | OR  |  |  |  |
| <b>5.3</b> All the following:   |   |  |  |  |
| 5.3.1 Diagnosis of sev  | vere asthma   |  |  |  |
|   | AND   |  |  |  |
| 5.3.2 One of the follow   | ving:   |  |  |  |
| 12 months   | thma exacerbations requiring systemic corticosteroids within the past cerbation requiring hospitalization in the past 12 months   |  |  |  |
|   | AND   |  |  |  |
| 5.3.3 Asthma is non-e   | osinophilic (example: blood eosinophil counts of  |  |  |  |
|   | AND   |  |  |  |
| 5.3.4 Asthma is non-allergic (example: Serum IgE level  |   |  |  |  |
| AND   |   |  |  |  |
| <b>5.3.5</b> For oral corticosteroid dependent asthma (requiring daily oral steroids): trial and failure or intolerance to at least one preferred self-administered biologic therapy for corticosteroid dependent asthma (i.e. dupilumab) |   |  |  |  |
| Notes   | ‡Adherent treatment is defined as a medication possession ratio (MPR ) ≥ 70% based on the previous 120 days of prescription claims.   |  |  |  |
|   | NOTE: II-5 inhibitor drugs in combination with omalizumab will be consi dered on a case-by-case basis if each individual agent with combination high dose ICS/LABA did not control symptoms. Tezepelumab, in combination with other biologics, has not been studied and coverage is not allowed except in e |  |  |  |

| xtenuating circumstances (applies to both             |
|---|
| eosinophilic or non-eosinophilic asthma populations). |

\*Continuation of therapy/coverage criteria will not be applied to person s who were not previously approved for coverage whose therapy was i nitiated using a manufacturer-sponsored free drug program, provider s amples, and/or vouchers.

# 2. Background

## Benefit/Coverage/Program Information

Table 1. Outcome Measure values for uncontrolled asthma

| Measure   | Not Well Controlled               | Very Poorly<br>Controlled        |
|---|-----------------------------------|----------------------------------|
| Baseline symptoms (outside of exacerbation)       | > 2 days/week                     | Throughout the day               |
| Nighttime awakening                               | 1-3 times/week                    | ≥ 4 times/week                   |
| Interference with normal activity                 | Some limitation                   | Extremely limited                |
| Short acting beta agonist use for symptom control | > 2 days/week                     | Several times per day            |
|   | 00 000/                           | 4 COO/                           |
| FEV1  | 60-80% predicted or personal best | < 60% predicted or personal best |
| Asthma<br>exacerbations<br>requiring oral         | Yes                               | Yes                              |
| steroids ≥ 2 times in<br>the past year            |                                   |                                  |
| Asthma Control Test<br>(ACT)                      | 16-19                             | ≤ 15                             |

# 3. Revision History

| Date       | Notes                |
|------------|----------------------|
| 12/11/2023 | Updated criteria 4.2 |

| Thrombopoietin Receptor Agonist   | S |
|---|---|
| (S) had compared residually for the tensor and course a seek of distribution contributions. |   |

| Guideline ID GL-137245 |                                  |  |
|------------------------|----------------------------------|--|
| <b>Guideline Name</b>  | Thrombopoietin Receptor Agonists |  |
| Formulary              | ormulary • Quartz                |  |

## **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

### Note:

Member new to the plan (as evidenced by coverage effective date of less than or equal to 90 days) who initiated therapy using a manufacturer-sponsored free drug program, provider samples, and/or vouchers will go through initial criteria, otherwise for continuation of therapy for new to plan, reauthorization criteria applies.

### 1. Criteria

| Product Name: Doptelet, Promacta                     |  |   |       |               |
|--|--|---|-------|---------------|
| Diagnosis  |  | Thrombocytopenia in Patients with Chronic Immune Thrombocytopenia (ITP) |       |               |
| Approval Length                                      |  | 12 month(s)   |       |               |
| Guideline Type                                       |  | Prior Authorization   |       |               |
| Product Generic Name                                 |  | ame   | GPI   | Brand/Generic |
| DOPTELET AVATROMBOPAG MALEATE TAB 20 MG (BASE EQUIV) |  | 82405010200320  | Brand |               |

| PROMACTA | ELTROMBOPAG OLAMINE TAB 12.5 MG (BASE EQUIV)                | 82405030100310 | Brand |
|----------|---|----------------|-------|
| PROMACTA | ELTROMBOPAG OLAMINE TAB 25 MG (BASE EQUIV)                  | 82405030100320 | Brand |
| PROMACTA | ELTROMBOPAG OLAMINE TAB 50 MG (BASE EQUIV)                  | 82405030100330 | Brand |
| PROMACTA | ELTROMBOPAG OLAMINE TAB 75 MG (BASE EQUIV)                  | 82405030100340 | Brand |
| PROMACTA | ELTROMBOPAG OLAMINE POWDER PACK FOR SUSP 25 MG (BASE EQUIV) | 82405030103020 | Brand |
| PROMACTA | ELTROMBOPAG OLAMINE POWDER PACK FOR SUSP 12.5 MG (BASE EQ)  | 82405030103030 | Brand |

1 - Diagnosis of chronic ITP with a platelet count less than 50,000/mcL

#### AND

2 - Prescribed by or in consultation with a hematologist

#### AND

**3** - Trial and failure, contraindication, or intolerance to at least TWO prior ITP therapies (e.g., corticosteroids, rituximab, azathioprine, danazol, or splenectomy)

| Product Name: Doptelet                                    |   |  |
|---|---|--|
| Diagnosis   | Thrombocytopenia in Patients with Chronic Liver Disease (CLD) |  |
| Approval Length   | 12 month(s)   |  |
| Guideline Type Prior Authorization - IL and MN Plans Only |   |  |

| Product<br>Name | Generic Name                                | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| DOPTELET        | AVATROMBOPAG MALEATE TAB 20 MG (BASE EQUIV) | 82405010200320 | Brand         |

### **Approval Criteria**

1 - Diagnosis of liver cirrhosis with a platelet count less than 50,000/mcL

#### **AND**

2 - Prescribed by or in consultation with a hematologist or gastroenterologist

#### **AND**

**3** - Member is scheduled for a procedure with a moderate to high bleeding risk within the next 14 days

| Product Name: Doptelet  |          |  |  |
|---|----------|--|--|
| Diagnosis Thrombocytopenia in Patients with Chronic Liver Disease (CLD) |          |  |  |
| Approval Length   | 5 Day(s) |  |  |
| Guideline Type Prior Authorization - All plans except IL and MN         |          |  |  |

| Product<br>Name | Generic Name                                | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| DOPTELET        | AVATROMBOPAG MALEATE TAB 20 MG (BASE EQUIV) | 82405010200320 | Brand         |

### **Approval Criteria**

1 - Diagnosis of liver cirrhosis with a platelet count less than 50,000/mcL

#### **AND**

2 - Prescribed by or in consultation with a hematologist or gastroenterologist

#### AND

**3** - Member is scheduled for a procedure with a moderate to high bleeding risk within the next 14 days

| Product Name: Mulpleta |   |  |
|------------------------|---|--|
| Diagnosis              | Thrombocytopenia in Patients with Chronic Liver Disease (CLD) |  |

| Approval Length | 12 month(s)                                |
|-----------------|--|
| Guideline Type  | Prior Authorization - IL and MN Plans Only |

| Product<br>Name | Generic Name           | GPI            | Brand/Generic |
|-----------------|------------------------|----------------|---------------|
| MULPLETA        | LUSUTROMBOPAG TAB 3 MG | 82405045000320 | Brand         |

1 - Diagnosis of liver cirrhosis with a platelet count less than 50,000/mcL

#### AND

2 - Prescribed by or in consultation with a hematologist or gastroenterologist

#### AND

**3** - Member is scheduled for a procedure with a moderate to high bleeding risk within the next 14 days

| Product Name: Mulpleta  |  |  |  |
|---|--|--|--|
| Diagnosis Thrombocytopenia in Patients with Chronic Liver Disease (CLD) |  |  |  |
| Approval Length 1 Time(s)   |  |  |  |
| Guideline Type Prior Authorization - All plans except IL and MN         |  |  |  |

| Product<br>Name | Generic Name           | GPI            | Brand/Generic |
|-----------------|------------------------|----------------|---------------|
| MULPLETA        | LUSUTROMBOPAG TAB 3 MG | 82405045000320 | Brand         |

### **Approval Criteria**

1 - Diagnosis of liver cirrhosis with a platelet count less than 50,000/mcL

### AND

2 - Prescribed by or in consultation with a hematologist or gastroenterologist

#### **AND**

**3** - Member is scheduled for a procedure with a moderate to high bleeding risk within the next 14 days

| Product Name: Promacta                                    |             |  |  |
|---|-------------|--|--|
| Diagnosis Chronic Hepatitis C-Associated Thrombocytopenia |             |  |  |
| Approval Length   | 12 month(s) |  |  |
| Guideline Type Prior Authorization                        |             |  |  |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| PROMACTA        | ELTROMBOPAG OLAMINE TAB 12.5 MG (BASE EQUIV)                | 82405030100310 | Brand         |
| PROMACTA        | ELTROMBOPAG OLAMINE TAB 25 MG (BASE EQUIV)                  | 82405030100320 | Brand         |
| PROMACTA        | ELTROMBOPAG OLAMINE TAB 50 MG (BASE EQUIV)                  | 82405030100330 | Brand         |
| PROMACTA        | ELTROMBOPAG OLAMINE TAB 75 MG (BASE EQUIV)                  | 82405030100340 | Brand         |
| PROMACTA        | ELTROMBOPAG OLAMINE POWDER PACK FOR SUSP 25 MG (BASE EQUIV) | 82405030103020 | Brand         |
| PROMACTA        | ELTROMBOPAG OLAMINE POWDER PACK FOR SUSP 12.5 MG (BASE EQ)  | 82405030103030 | Brand         |

### **Approval Criteria**

**1** - Diagnosis of chronic hepatitis C virus (HCV) undergoing treatment with pegylated interferon/ribavirin

#### AND

**2** - Prescribed by or in consultation with a hematologist, gastroenterologist, or infectious disease specialist

### **AND**

3 - Platelet count is less than 75,000/mcL

| Product Name: Promacta |                     |  |
|------------------------|---------------------|--|
| Diagnosis              | Aplastic Anemia     |  |
| Approval Length        | 12 month(s)         |  |
| Guideline Type         | Prior Authorization |  |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| PROMACTA        | ELTROMBOPAG OLAMINE TAB 12.5 MG (BASE EQUIV)                | 82405030100310 | Brand         |
| PROMACTA        | ELTROMBOPAG OLAMINE TAB 25 MG (BASE EQUIV)                  | 82405030100320 | Brand         |
| PROMACTA        | ELTROMBOPAG OLAMINE TAB 50 MG (BASE EQUIV)                  | 82405030100330 | Brand         |
| PROMACTA        | ELTROMBOPAG OLAMINE TAB 75 MG (BASE EQUIV)                  | 82405030100340 | Brand         |
| PROMACTA        | ELTROMBOPAG OLAMINE POWDER PACK FOR SUSP 25 MG (BASE EQUIV) | 82405030103020 | Brand         |
| PROMACTA        | ELTROMBOPAG OLAMINE POWDER PACK FOR SUSP 12.5 MG (BASE EQ)  | 82405030103030 | Brand         |

1 - Diagnosis of severe aplastic anemia

#### **AND**

2 - Prescribed by or in consultation with a hematologist

#### AND

**3** - Trial and failure, contraindication, or intolerance to at least one immunosuppressive therapy (e.g., glucocorticoids, cyclosporine)

# 2. Revision History

| Date      | Notes       |
|-----------|-------------|
| 12/6/2023 | New program |

| - | Tiglutik (riluzole)   |  |
|---|---|--|
| 1 | The Marketing sensel to displayed. The firms that have been bound, or solved, and don't delicable protection would not display. |  |
|   |   |  |

| Guideline ID          | GL-131424           |
|-----------------------|---------------------|
| <b>Guideline Name</b> | Tiglutik (riluzole) |
| Formulary             | Quartz              |

# **Guideline Note:**

| Effective Date: |
|-----------------|
|-----------------|

# 1. Criteria

| Product Name: Tiglutik |  |
|------------------------|--|
| Approval Length        | 12 month(s)                              |
| Therapy Stage          | Initial Authorization                    |
| Guideline Type         | Prior Authorization-IL and MN Plans Only |

| Product<br>Name | Generic Name             | GPI            | Brand/Generic |
|-----------------|--------------------------|----------------|---------------|
| TIGLUTIK        | RILUZOLE SUSP 50 MG/10ML | 74503070001820 | Brand         |

# **Approval Criteria**

1 - Diagnosis of amyotrophic lateral sclerosis (ALS)

#### AND

**2** - A trial of generic riluzole tablets was not tolerated due to an inability to swallow solid dosage forms

| Product Name: Tiglutik |  |
|------------------------|--|
| Approval Length        | 12 month(s)                              |
| Therapy Stage          | Reauthorization                          |
| Guideline Type         | Prior Authorization-IL and MN Plans Only |

| Product<br>Name | Generic Name             | GPI            | Brand/Generic |
|-----------------|--------------------------|----------------|---------------|
| TIGLUTIK        | RILUZOLE SUSP 50 MG/10ML | 74503070001820 | Brand         |

### **Approval Criteria**

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug.

| Product Name: Tiglutik |  |
|------------------------|--|
| Approval Length        | 12/31/2039                                     |
| Guideline Type         | Prior Authorization-All plans except IL and MN |

| Product<br>Name | Generic Name             | GPI            | Brand/Generic |
|-----------------|--------------------------|----------------|---------------|
| TIGLUTIK        | RILUZOLE SUSP 50 MG/10ML | 74503070001820 | Brand         |

### **Approval Criteria**

1 - Diagnosis of amyotrophic lateral sclerosis (ALS)

#### AND

**2** - A trial of generic riluzole tablets was not tolerated due to an inability to swallow solid dosage forms

# 2. Revision History

| Date       | Notes       |
|------------|-------------|
| 10/10/2023 | New program |

| Tobacco Cessation Therapy  |  |
|--|--|
| Section Proprietation Study from The Section record, created, and dark last find that has prime to concern and hardware. |  |
|  |  |

| Guideline ID          | GL-136666                 |  |
|-----------------------|---------------------------|--|
| <b>Guideline Name</b> | Tobacco Cessation Therapy |  |
| Formulary             | Quartz                    |  |

# **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

## Note:

Effective 2/1/2023 these restrictions and quantity limits do not apply to persons with IL plans

## 1. Criteria

| Product Name: NICOTROL INHALER, NICOTROL NS   |                       |
|---|-----------------------|
| Approval Length 12 month(s)                   |                       |
| Therapy Stage                                 | Initial Authorization |
| Guideline Type Prior Authorization – MN plans |                       |

| Product<br>Name | Generic Name                                      | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
|                 | NICOTINE INHALER SYSTEM 10 MG (4 MG<br>DELIVERED) | 62100005002410 | Brand         |
| NICOTROL<br>NS  | NICOTINE NASAL SPRAY 10 MG/ML (0.5 MG/SPRAY)      | 62100005002020 | Brand         |

- **1** Both of the following:
- **1.1** Person requires a smoking cessation product that is designed to alleviate acute cravings and/or replace behavioral activities of smoking

#### AND

**1.2** Trial and failure, contraindication, or intolerance to nicotine gum or nicotine lozenges

#### OR

**2** - Member with stage four metastatic cancer and smoking cessation therapy is supportive care related to their cancer diagnosis

| Product Name: NICOTROL INHALER, NICOTROL NS  Approval Length 12 month(s)  Therapy Stage Reauthorization  Guideline Type Prior Authorization – MN plans |  |
|--|--|
|--|--|

| Product<br>Name     | Generic Name                                   | GPI            | Brand/Generic |
|---------------------|--|----------------|---------------|
| NICOTROL<br>INHALER | NICOTINE INHALER SYSTEM 10 MG (4 MG DELIVERED) | 62100005002410 | Brand         |
| NICOTROL<br>NS      | NICOTINE NASAL SPRAY 10 MG/ML (0.5 MG/SPRAY)   | 62100005002020 | Brand         |

### **Approval Criteria**

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug

| Product Name: NICOTROL INHALER, NICOTROL NS  Approval Length 12/31/2039 |  |
|---|--|
|   |  |

| Product<br>Name     | Generic Name                                      | GPI            | Brand/Generic |
|---------------------|---|----------------|---------------|
| NICOTROL<br>INHALER | NICOTINE INHALER SYSTEM 10 MG (4 MG<br>DELIVERED) | 62100005002410 | Brand         |
| NICOTROL<br>NS      | NICOTINE NASAL SPRAY 10 MG/ML (0.5 MG/SPRAY)      | 62100005002020 | Brand         |

**1** - Person requires a smoking cessation product that is designed to alleviate acute cravings and/or replace behavioral activities of smoking

#### **AND**

2 - Trial and failure, contraindication, or intolerance to nicotine gum or nicotine lozenges

# 2. Revision History

| Date       | Notes            |
|------------|------------------|
| 11/21/2023 | Criteria updated |

| • | Tobramycin for Inhalation  |  |  |  |  |
|---|--|--|--|--|--|
|   | (3) Nationage with digitals. With the least read, were a mile and least the personal and an extended |  |  |  |  |

| Guideline ID          | GL-130574                 |  |
|-----------------------|---------------------------|--|
| <b>Guideline Name</b> | Tobramycin for Inhalation |  |
| Formulary             | Quartz                    |  |

## **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

### Note:

Member new to the plan (as evidenced by coverage effective date of less than or equal to 90 days) who initiated therapy using a manufacturer-sponsored free drug program, provider samples, and/or vouchers will go through initial criteria, otherwise for continuation of therapy for new to plan, reauthorization criteria applies

### 1. Criteria

| Product Name    | e: generic | tobramycin inhalation solution        |                |               |
|-----------------|------------|---------------------------------------|----------------|---------------|
| Approval Len    | gth        | 12 month(s)                           |                |               |
| Therapy Stag    | е          | Initial Authorization                 |                |               |
| Guideline Typ   | е          | Prior Authorization - IL and MN Plans | 3              |               |
| Product<br>Name | Generic I  | Name                                  | GPI            | Brand/Generic |
| TOBRAMYCIN      | TOBRAMY    | CIN NEBU SOLN 300 MG/5ML              | 07000070002520 | Generic       |
|                 |            |                                       |                |               |

1 - Diagnosis of cystic fibrosis

#### **AND**

**2** - Submission of medical records (e.g., chart notes) documenting a current culture positive for, or history of recurrent Pseudomonas aeruginosa lung infections

#### AND

3 - Requested medication will be used for inhalation only

| Notes | *Continuation of therapy/coverage criteria will not be applied to person |
|-------|--|
|       | s who were not previously approved for coverage whose therapy was i      |
|       | nitiated using a manufacturer-sponsored free drug program, provider s    |
|       | amples, and/or vouchers.   |

| Product Name: generic | Product Name: generic tobramycin inhalation solution |  |
|-----------------------|--|--|
| Approval Length       | 12 month(s)  |  |
| Therapy Stage         | Reauthorization                                      |  |
| Guideline Type        | Prior Authorization - IL and MN Plans                |  |

| Product<br>Name | Generic Name                    | GPI            | Brand/Generic |
|-----------------|---------------------------------|----------------|---------------|
| TOBRAMYCIN      | TOBRAMYCIN NEBU SOLN 300 MG/5ML | 07000070002520 | Generic       |

### **Approval Criteria**

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug

| Notes | *Continuation of therapy/coverage criteria will not be applied to person |
|-------|--|
|       | s who were not previously approved for coverage whose therapy was i      |
|       | nitiated using a manufacturer-sponsored free drug program, provider s    |
|       | amples, and/or vouchers.   |

Product Name: generic tobramycin inhalation solution

| Approval Length | 12/31/2039   |
|-----------------|--|
| Guideline Type  | Prior Authorization - All Plans Except IL and MN Plans |

| Product<br>Name | Generic Name                    | GPI            | Brand/Generic |
|-----------------|---------------------------------|----------------|---------------|
| TOBRAMYCIN      | TOBRAMYCIN NEBU SOLN 300 MG/5ML | 07000070002520 | Generic       |

1 - Diagnosis of cystic fibrosis

#### **AND**

**2** - Submission of medical records (e.g., chart notes) documenting a current culture positive for, or history of recurrent Pseudomonas aeruginosa lung infections

#### **AND**

3 - Requested medication will be used for inhalation only

| Notes | *Continuation of therapy/coverage criteria will not be applied to person s who were not previously approved for coverage whose therapy was i |
|-------|--|
|       | nitiated using a manufacturer-sponsored free drug program, provider s amples, and/or vouchers.   |

# 2. Revision History

| Date      | Notes                   |
|-----------|-------------------------|
| 8/16/2023 | 2024 New Implementation |

| Tremfya  | (guselkumab)   |  |
|--|--|--|
| Darlicked Inage current hardsplayed. The file may have | ion record, records, or didded, Selfy that he his politics the cornection and invalen. |  |
|  |  |  |

| Guideline ID          | GL-129744            |
|-----------------------|----------------------|
| <b>Guideline Name</b> | Tremfya (guselkumab) |
| Formulary             | Quartz               |

# **Guideline Note:**

| Effective Date: |
|-----------------|
|-----------------|

# 1. Criteria

| Product Name: Tremfya |                                       |  |  |
|-----------------------|---------------------------------------|--|--|
| Diagnosis             | Moderate to Severe Plaque Psoriasis   |  |  |
| Approval Length       | 12 month(s)                           |  |  |
| Therapy Stage         | Initial Authorization                 |  |  |
| Guideline Type        | Prior Authorization - IL and MN Plans |  |  |

| Product<br>Name | Generic Name                                | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| TREMFYA         | GUSELKUMAB SOLN PEN-INJECTOR 100 MG/ML      | 9025054200D220 | Brand         |
| TREMFYA         | GUSELKUMAB SOLN PREFILLED SYRINGE 100 MG/ML | 9025054200E520 | Brand         |

## **Approval Criteria**

1 - Diagnosis of moderate to severe plaque psoriasis

#### AND

- 2 Patient has one of the following:
  - Significant functional disability
  - Body surface area (BSA) involvement of greater than 3%
  - Debilitating palmar or plantar psoriasis or other vulnerable areas that are difficult to treat such as nails, hairy/scalp areas, genitals, or intertriginous areas

### **AND**

3 - Prescribed by or in consultation with a dermatologist

#### AND

**4** - Submission of medical records (e.g., chart notes) documenting trial and failure (minimum 4 week trial duration), or contraindication to topical therapy (e.g., topical corticosteroids, calcipotriene, retinoids, calcineurin inhibitor, tazarotene)

### AND

**5** - Not used in combination with other biologic DMARDs (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

#### **AND**

**6** - Medication must be self-administered (not in clinic or provider office)

| Product Name: Tremfya |  |
|-----------------------|--|
| Diagnosis             | Moderate to Severe Plaque Psoriasis                                      |
| Approval Length       | 12/31/2039   |
| Guideline Type        | Prior AuthorizatioPrior Authorization - All Plans except IL and MN Plans |

| Product<br>Name | Generic Name                                | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| TREMFYA         | GUSELKUMAB SOLN PEN-INJECTOR 100 MG/ML      | 9025054200D220 | Brand         |
| TREMFYA         | GUSELKUMAB SOLN PREFILLED SYRINGE 100 MG/ML | 9025054200E520 | Brand         |

1 - Diagnosis of moderate to severe plaque psoriasis

### **AND**

- **2** Patient has one of the following:
  - Significant functional disability
  - Body surface area (BSA) involvement of greater than 3%
  - Debilitating palmar or plantar psoriasis or other vulnerable areas that are difficult to treat such as nails, hairy/scalp areas, genitals, or intertriginous areas

### AND

**3** - Prescribed by or in consultation with a dermatologist

### AND

**4** - Submission of medical records (e.g., chart notes) documenting trial and failure (minimum 4 week trial duration), or contraindication to topical therapy (e.g., topical corticosteroids, calcipotriene, retinoids, calcineurin inhibitor, tazarotene)

### **AND**

**5** - Not used in combination with other biologic DMARDs (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

#### AND

**6** - Medication must be self-administered (not in clinic or provider office)

| Product Name: Tremfya                                |                       |
|--|-----------------------|
| Diagnosis Psoriatic Arthritis (PsA)                  |                       |
| Approval Length                                      | 12 month(s)           |
| Therapy Stage  | Initial Authorization |
| Guideline Type Prior Authorization - IL and MN Plans |                       |

| Product<br>Name | Generic Name                                | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| TREMFYA         | GUSELKUMAB SOLN PEN-INJECTOR 100 MG/ML      | 9025054200D220 | Brand         |
| TREMFYA         | GUSELKUMAB SOLN PREFILLED SYRINGE 100 MG/ML | 9025054200E520 | Brand         |

## **Approval Criteria**

1 - Diagnosis of moderate to severely active psoriatic arthritis (PsA)

### **AND**

**2** - Symptoms include actively inflamed joints, axial disease, active skin/nail/scalp psoriasis involvement, dactylitis, or enthesitis

### **AND**

3 - Prescribed by or in consultation with a dermatologist or rheumatologist

### **AND**

**4** - Not used in combination with other biologic disease modifying anti-rheumatic drugs (DMARDs) (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

### **AND**

**5** - Medication must be self-administered (not in clinic or provider office)

| Product Name: Tremfya   |            |
|---|------------|
| Diagnosis Psoriatic Arthritis (PsA)                                   |            |
| Approval Length   | 12/31/2039 |
| Guideline Type Prior Authorization - All Plans except IL and MN Plans |            |

| Product<br>Name | Generic Name                                | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| TREMFYA         | GUSELKUMAB SOLN PEN-INJECTOR 100 MG/ML      | 9025054200D220 | Brand         |
| TREMFYA         | GUSELKUMAB SOLN PREFILLED SYRINGE 100 MG/ML | 9025054200E520 | Brand         |

1 - Diagnosis of moderate to severely active psoriatic arthritis (PsA)

### **AND**

**2** - Symptoms include actively inflamed joints, axial disease, active skin/nail/scalp psoriasis involvement, dactylitis, or enthesitis

### **AND**

3 - Prescribed by or in consultation with a dermatologist or rheumatologist

### **AND**

**4** - Not used in combination with other biologic disease modifying anti-rheumatic drugs (DMARDs) (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

### AND

5 - Medication must be self-administered (not in clinic or provider office)

### Product Name: Tremfya

| Diagnosis       | All Indications Listed Above          |
|-----------------|---------------------------------------|
| Approval Length | 12 month(s)                           |
| Therapy Stage   | Reauthorization                       |
| Guideline Type  | Prior Authorization - IL and MN Plans |

| Product<br>Name | Generic Name                                | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| TREMFYA         | GUSELKUMAB SOLN PEN-INJECTOR 100 MG/ML      | 9025054200D220 | Brand         |
| TREMFYA         | GUSELKUMAB SOLN PREFILLED SYRINGE 100 MG/ML | 9025054200E520 | Brand         |

**1** - Submission of medical records (e.g., chart notes) documenting positive clinical response to therapy within the previous 12 months

| *Member new to the plan (as evidenced by coverage effective date of I ess than or equal to 90 days) who initiated therapy using a manufactur er-sponsored free drug program, provider samples, and/or vouchers wil I go through initial criteria, otherwise for continuation of therapy for new |
|---|
| to plan, reauthorization criteria applies   |

| Date      | Notes                   |
|-----------|-------------------------|
| 11/1/2023 | 2024 New Implementation |

| Tresiba (insulin degludec)   |  |  |
|--|--|--|
| (2) The Market Angelor and The Stage (and The Stage Annual of country of collection (b) Start for the Stage (and the Stage Annual Stage (and the Stage (and |  |  |
|  |  |  |

| Guideline ID          | GL-129810                  |
|-----------------------|----------------------------|
| <b>Guideline Name</b> | Tresiba (insulin degludec) |
| Formulary             | Quartz                     |

# **Guideline Note:**

| Effective Date: |
|-----------------|
|-----------------|

# 1. Criteria

| Product Name: Brand Insulin Degludec U100 |                                       |
|---|---------------------------------------|
| Approval Length 12 month(s)               |                                       |
| Therapy Stage                             | Initial Authorization                 |
| Guideline Type                            | Prior Authorization - IL and MN Plans |

| Product<br>Name                  | Generic Name                                   | GPI            | Brand/Generic |
|----------------------------------|--|----------------|---------------|
| INSULIN<br>DEGLUDEC<br>FLEXTOUCH | INSULIN DEGLUDEC SOLN PEN-INJECTOR 100 UNIT/ML | 2710400700D210 | Brand         |
| INSULIN<br>DEGLUDEC              | INSULIN DEGLUDEC INJ 100 UNIT/ML               | 27104007002020 | Brand         |

## **Approval Criteria**

1 - Diagnosis of diabetes mellitus

### AND

- 2 Prescribed by or in consultation with one of the following:
  - Endocrinologist
  - Diabetes specialist

### **AND**

- **3** One of the following:
- **3.1** Member cannot meet their glycemic goals despite adequate trials of insulin glargine including:
  - Dose escalation, unless dose increases cannot be tolerated due to nocturnal hypoglycemia or at least one severe low blood sugar event (requiring assistance from another) or would not be appropriate given the person's self-monitoring blood glucose profile
  - Splitting the dose
  - Submission of medical records (e.g., chart notes) documenting use of a specific adherence intervention deployed by a health care provider

OR

3.2 Member is intolerant to insulin glargine

| Product Name: Brand Insulin Degludec U200 |                                       |
|---|---------------------------------------|
| Approval Length                           | 12 month(s)                           |
| Therapy Stage                             | Initial Authorization                 |
| Guideline Type                            | Prior Authorization - IL and MN Plans |

| Product<br>Name | Generic Name                                      | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| _               | INSULIN DEGLUDEC SOLN PEN-INJECTOR 200<br>UNIT/ML | 2710400700D220 | Brand         |

1 - Diagnosis of diabetes mellitus

#### AND

- **2** Prescribed by or in consultation with one of the following:
  - Endocrinologist
  - Diabetes specialist

### **AND**

- **3** One of the following:
- **3.1** Member cannot meet their glycemic goals despite adequate trials of insulin glargine including:
  - Dose escalation, unless dose increases cannot be tolerated due to nocturnal hypoglycemia or at least one severe low blood sugar event (requiring assistance from another) or would not be appropriate given the person's self-monitoring blood glucose profile
  - Splitting the dose
  - Submission of medical records (e.g., chart notes) documenting use of a specific adherence intervention deployed by a health care provider

OR

3.2 Member is intolerant to insulin glargine

### **AND**

4 - Member's daily basal insulin dose is greater than 100 units

| Product Name: Brand Insulin Degludec U100 and U200 |                 |
|--|-----------------|
| Approval Length 12 month(s)                        |                 |
| Therapy Stage                                      | Reauthorization |

| Guideline Type                   |   | Prior Authorization - IL and MN Plans |                |               |
|----------------------------------|---|---------------------------------------|----------------|---------------|
| Product<br>Name                  | Generic Name                                      |                                       | GPI            | Brand/Generic |
| INSULIN<br>DEGLUDEC<br>FLEXTOUCH | INSULIN DEGLUDEC SOLN PEN-INJECTOR 100<br>UNIT/ML |                                       | 2710400700D210 | Brand         |
| INSULIN<br>DEGLUDEC<br>FLEXTOUCH | INSULIN DEGLUDEC SOLN PEN-INJECTOR 200<br>UNIT/ML |                                       | 2710400700D220 | Brand         |
| INSULIN<br>DEGLUDEC              | INSULIN DEGLUDEC INJ 100 UNIT/ML                  |                                       | 27104007002020 | Brand         |

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug

| Product Name: Brand Insulin Degludec U100                             |  |
|---|--|
| Approval Length 12/31/2039  |  |
| Guideline Type Prior Authorization - All Plans Except IL and MN Plans |  |

| Product<br>Name                  | Generic Name                                   | GPI            | Brand/Generic |
|----------------------------------|--|----------------|---------------|
| INSULIN<br>DEGLUDEC<br>FLEXTOUCH | INSULIN DEGLUDEC SOLN PEN-INJECTOR 100 UNIT/ML | 2710400700D210 | Brand         |
| INSULIN<br>DEGLUDEC              | INSULIN DEGLUDEC INJ 100 UNIT/ML               | 27104007002020 | Brand         |

## **Approval Criteria**

1 - Diagnosis of diabetes mellitus

### AND

- **2** Prescribed by or in consultation with one of the following:

  - Endocrinologist Diabetes specialist

### **AND**

- **3** One of the following:
- **3.1** Member cannot meet their glycemic goals despite adequate trials of insulin glargine including:
  - Dose escalation, unless dose increases cannot be tolerated due to nocturnal hypoglycemia or at least one severe low blood sugar event (requiring assistance from another) or would not be appropriate given the person's self-monitoring blood glucose profile
  - Splitting the dose
  - Submission of medical records (e.g., chart notes) documenting use of a specific adherence intervention deployed by a health care provider

OR

**3.2** Member is intolerant to insulin glargine

| Product Name: Brand Insulin Degludec U200                             |  |
|---|--|
| Approval Length 12/31/2039  |  |
| Guideline Type Prior Authorization - All Plans Except IL and MN Plans |  |

| Product<br>Name | Generic Name                                      | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| _               | INSULIN DEGLUDEC SOLN PEN-INJECTOR 200<br>UNIT/ML | 2710400700D220 | Brand         |

### **Approval Criteria**

1 - Diagnosis of diabetes mellitus

### **AND**

- 2 Prescribed by or in consultation with one of the following:
  - Endocrinologist

Diabetes specialist

### **AND**

- **3** One of the following:
- **3.1** Member cannot meet their glycemic goals despite adequate trials of insulin glargine including:
  - Dose escalation, unless dose increases cannot be tolerated due to nocturnal hypoglycemia or at least one severe low blood sugar event (requiring assistance from another) or would not be appropriate given the person's self-monitoring blood glucose profile
  - Splitting the dose
  - Submission of medical records (e.g., chart notes) documenting use of a specific adherence intervention deployed by a health care provider

OR

3.2 Member is intolerant to insulin glargine

AND

4 - Member's daily basal insulin dose is greater than 100 units

| Date       | Notes                   |
|------------|-------------------------|
| 10/12/2023 | 2024 New Implementation |

| Tuc                    | Tudorza Pressair                                |   |                |  |   |
|------------------------|---|---|----------------|--|---|
| The british theapy can | ont kediplipel. The lie nay have been neved, on | ered, or didded. Verily that the list points in the corne | offered holin. |  | _ |
|                        |   |   |                |  |   |
|                        |   |   |                |  |   |

| Guideline ID          | GL-127804        |
|-----------------------|------------------|
| <b>Guideline Name</b> | Tudorza Pressair |
| Formulary             | Quartz           |

## **Guideline Note:**

| Effective Date: |
|-----------------|
|-----------------|

## 1. Criteria

| Product Name: Tudorza Pressair                |                       |
|---|-----------------------|
| Approval Length 12 month(s)                   |                       |
| Therapy Stage                                 | Initial Authorization |
| Guideline Type Step Therapy - IL and MN Plans |                       |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
|                 | ACLIDINIUM BROMIDE AEROSOL POWD BREATH<br>ACTIVATED 400 MCG/ACT | 44100007108020 | Brand         |

## **Approval Criteria**

**1** - Trial and failure, intolerance, or contraindication to both an inhaled tiotropium bromide product and an inhaled umeclidinium product

| Product Name: Tudorza Pressair                |                 |
|---|-----------------|
| Approval Length 12 month(s)                   |                 |
| Therapy Stage                                 | Reauthorization |
| Guideline Type Step Therapy - IL and MN Plans |                 |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
|                 | ACLIDINIUM BROMIDE AEROSOL POWD BREATH<br>ACTIVATED 400 MCG/ACT | 44100007108020 | Brand         |

**1** - Submission of medical notes (e.g. chart notes) from the past 12 months that member is continuing therapy with the requested drug

| Product Name: Tudorza Pressair |   |
|--------------------------------|---|
| Approval Length 12/31/2039     |   |
| Guideline Type                 | Step Therapy - All plans except IL and MN Plans |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
|                 | ACLIDINIUM BROMIDE AEROSOL POWD BREATH<br>ACTIVATED 400 MCG/ACT | 44100007108020 | Brand         |

## **Approval Criteria**

**1** - Trial and failure, intolerance, or contraindication to both an inhaled tiotropium bromide product and an inhaled umeclidinium product

| Date      | Notes       |
|-----------|-------------|
| 8/21/2023 | New Program |

| Vaccines  |
|---|
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| Guideline ID          | GL-136474 |
|-----------------------|-----------|
| <b>Guideline Name</b> | Vaccines  |
| Formulary             | Quartz    |

# Guideline Note:

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

## 1. Criteria

| Product Name: Recombivax-HB, Engerix-B, Arexvy, Abrysvo, Boostrix, Prehevbrio, Twinrix, Prevnar 13, Prevnar 20, Vaxneuvance, Pneumovax, Adacel, Boostrix. Tdvax, Tenivac, Shingrix |                |  |
|--|----------------|--|
| Approval Length  | 12 month(s)    |  |
| Guideline Type   | Administrative |  |

| Product<br>Name  | Generic Name   | GPI            | Brand/Generic |
|------------------|--|----------------|---------------|
| RECOMBIVAX<br>HB | HEPATITIS B VACCINE (RECOMBINANT) SUSP 5 MCG/0.5ML           | 17100010201815 | Brand         |
| RECOMBIVAX<br>HB | HEPATITIS B VACCINE (RECOMBINANT) SUSP 10 MCG/ML             | 17100010201820 | Brand         |
| ENGERIX-B        | HEPATITIS B VACCINE (RECOMBINANT) SUSP<br>PREF SYR 20 MCG/ML | 1710001020E630 | Brand         |
| HEPLISAV-B       | HEPATITIS B VACCINE RECOMB ADJUVANTED PREF SYR 20 MCG/0.5ML  | 1710001030E520 | Brand         |
| AREXVY           | RSVPREF3 VACCINE RECOMB ADJUVANTED FOR                       | 17100072101920 | Brand         |

|                        | IM SUSP 120 MCG/0.5ML   |                |       |
|------------------------|---|----------------|-------|
| ABRYSVO                | RSV PRE-FUSION F A&B VAC RECOMB FOR IM SOLN 120 MCG/0.5ML       | 17100072202120 | Brand |
| BOOSTRIX               | TET-DIPH-ACELL PERTUSS AD PREF SYR 5-2.5-<br>18.5 LF-MCG/0.5ML  | 1899000322E620 | Brand |
| PREHEVBRIO             | HEPATITIS B VACCINE 3-ANTIGEN<br>(RECOMBINANT) SUSP 10 MCG/ML   | 17100010401820 | Brand |
| ENGERIX-B              | HEPATITIS B VACCINE (RECOMBINANT) SUSP 20 MCG/ML                | 17100010201830 | Brand |
| ENGERIX-B              | HEPATITIS B VACCINE (RECOMBINANT) SUSP<br>PREF SYR 10 MCG/0.5ML | 1710001020E625 | Brand |
| RECOMBIVAX<br>HB       | HEPATITIS B VACCINE (RECOMBINANT) SUSP 40 MCG/ML                | 17100010201840 | Brand |
| RECOMBIVAX<br>HB       | HEPATITIS B VACCINE (RECOMBINANT) SUSP<br>PREF SYR 5 MCG/0.5ML  | 1710001020E610 | Brand |
| RECOMBIVAX<br>HB       | HEPATITIS B VACCINE (RECOMBINANT) SUSP<br>PREF SYR 10 MCG/ML    | 1710001020E620 | Brand |
| TWINRIX                | HEP A-HEP B VACCINE SUSP PREF SYR 720-20<br>ELU-MCG/ML          | 1710990205E620 | Brand |
| PREVNAR 13             | PNEUMOCOCCAL 13-VALENT CONJUGATE VACCINE INJ                    | 17200065301800 | Brand |
| VAXNEUVANCE            | PNEUMOCOCCAL 15-VALENT CONJUGATE<br>VACCINE SUS PREF SYR 0.5 ML | 1720006535E620 | Brand |
| PREVNAR 20             | PNEUMOCOCCAL 20-VALENT CONJUGATE<br>VACCINE SUS PREF SYR 0.5 ML | 1720006540E620 | Brand |
| ADACEL                 | TET TOX-DIPH-ACELL PERTUSS AD INJ 5-2-15.5<br>LF-LF-MCG/0.5ML   | 18990003221815 | Brand |
| PNEUMOVAX<br>23        | PNEUMOCOCCAL VACCINE POLYVALENT INJ 25<br>MCG/0.5ML             | 17200065002205 | Brand |
| PNEUMOVAX<br>23/1 DOSE | PNEUMOCOCCAL VACCINE POLYVALENT INJ 25<br>MCG/0.5ML             | 17200065002205 | Brand |
| TDVAX                  | TETANUS-DIPHTHERIA TOXOIDS (TD) INJ 2-2<br>LF/0.5ML             | 18990002201805 | Brand |
| BOOSTRIX               | TET TOX-DIPH-ACELL PERTUSS AD INJ 5-2.5-18.5<br>LF-LF-MCG/0.5ML | 18990003221820 | Brand |
| TENIVAC                | TETANUS-DIPHTHERIA TOXOIDS (TD) INJ 5-2 LFU                     | 18990002202210 | Brand |
| SHINGRIX               | ZOSTER VAC RECOMBINANT ADJUVANTED FOR IM INJ 50 MCG/0.5ML       | 17100095401920 | Brand |

1 - Member is 18 years or older\*

| AND  |  |  |  |
|--|--|--|--|
| 2 - One of the following   | :  |  |  |
| 2.1 The requested vaccination will be used for a Food and Drug Administration (FDA) approved indication                          |  |  |  |
| OR   |  |  |  |
| 2.2 The requested vaccination will be used in accordance with Advisory Committee on Immunization Practices (ACIP) recommendation |  |  |  |
| Notes  | *Vaccines listed above are considered excluded for persons under the age of 18 years. They are covered under the medical benefit |  |  |

| Date      | Notes       |
|-----------|-------------|
| 12/5/2023 | New Program |

| Valtoco (diazepam)                    |   |   |  |  |  |
|---------------------------------------|---|---|--|--|--|
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|                                       |   |   |  |  |  |

| Guideline ID          | GL-129092          |
|-----------------------|--------------------|
| <b>Guideline Name</b> | Valtoco (diazepam) |
| Formulary             | Quartz             |

# **Guideline Note:**

| Effective Date: |
|-----------------|
|-----------------|

# 1. Criteria

| Product Name: Valtoco |  |  |
|-----------------------|--|--|
| Approval Length       | 12/31/2039   |  |
| Guideline Type        | Prior Authorization - All plans except IL and MN Plans |  |

| Product<br>Name          | Generic Name  | GPI            | Brand/Generic |
|--------------------------|---|----------------|---------------|
| VALTOCO<br>15 MG<br>DOSE | DIAZEPAM NASAL SPRAY THER PACK 2 X 7.5<br>MG/0.1ML (15 MG DOSE) | 7210003000C440 | Brand         |
| VALTOCO<br>20 MG<br>DOSE | DIAZEPAM NASAL SPRAY THER PACK 2 X 10<br>MG/0.1ML (20 MG DOSE)  | 7210003000C450 | Brand         |
| VALTOCO<br>5 MG<br>DOSE  | DIAZEPAM NASAL SPRAY 5 MG/0.1 ML                                | 72100030000920 | Brand         |
| VALTOCO<br>10 MG         | DIAZEPAM NASAL SPRAY 10 MG/0.1 ML                               | 72100030000930 | Brand         |

| IIDOSE |  |  |
|--------|--|--|
| IIDOOL |  |  |

1 - Diagnosis of a seizure disorder (epilepsy)

### **AND**

**2** - Prescribed by or in consultation with a neurologist or other specialist with experience in the management of epilepsy

### **AND**

3 - Member is between the ages of 6 and 12 years old

### **AND**

**4** - Submission of medical records (e.g., chart notes) that support history of frequent episodes of acute seizure activity

| Product Name: Valtoco |                                       |  |
|-----------------------|---------------------------------------|--|
| Approval Length       | 12 month(s)                           |  |
| Therapy Stage         | Initial Authorization                 |  |
| Guideline Type        | Prior Authorization - IL and MN Plans |  |

| Product<br>Name          | Generic Name  | GPI            | Brand/Generic |
|--------------------------|---|----------------|---------------|
| VALTOCO<br>15 MG<br>DOSE | DIAZEPAM NASAL SPRAY THER PACK 2 X 7.5<br>MG/0.1ML (15 MG DOSE) | 7210003000C440 | Brand         |
| VALTOCO<br>20 MG<br>DOSE | DIAZEPAM NASAL SPRAY THER PACK 2 X 10 MG/0.1ML (20 MG DOSE)     | 7210003000C450 | Brand         |
| VALTOCO<br>5 MG<br>DOSE  | DIAZEPAM NASAL SPRAY 5 MG/0.1 ML                                | 72100030000920 | Brand         |
| VALTOCO<br>10 MG         | DIAZEPAM NASAL SPRAY 10 MG/0.1 ML                               | 72100030000930 | Brand         |

| IIDOSE |  |  |
|--------|--|--|
| IIDOOL |  |  |

1 - Diagnosis of a seizure disorder (epilepsy)

### **AND**

**2** - Prescribed by or in consultation with a neurologist or other specialist with experience in the management of epilepsy

### **AND**

3 - Member is between the ages of 6 and 12 years old

### **AND**

**4** - Submission of medical records (e.g., chart notes) that support history of frequent episodes of acute seizure activity

| Product Name: Valtoco                                |                 |  |
|--|-----------------|--|
| Approval Length                                      | 12 month(s)     |  |
| Therapy Stage  | Reauthorization |  |
| Guideline Type Prior Authorization - IL and MN Plans |                 |  |

| Product<br>Name          | Generic Name  | GPI            | Brand/Generic |
|--------------------------|---|----------------|---------------|
| VALTOCO<br>15 MG<br>DOSE | DIAZEPAM NASAL SPRAY THER PACK 2 X 7.5<br>MG/0.1ML (15 MG DOSE) | 7210003000C440 | Brand         |
| VALTOCO<br>20 MG<br>DOSE | DIAZEPAM NASAL SPRAY THER PACK 2 X 10 MG/0.1ML (20 MG DOSE)     | 7210003000C450 | Brand         |
| VALTOCO<br>5 MG<br>DOSE  | DIAZEPAM NASAL SPRAY 5 MG/0.1 ML                                | 72100030000920 | Brand         |
| VALTOCO<br>10 MG         | DIAZEPAM NASAL SPRAY 10 MG/0.1 ML                               | 72100030000930 | Brand         |

| DOSE |  |  |  |
|------|--|--|--|

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug

| Date     | Notes                   |
|----------|-------------------------|
| 9/7/2023 | 2024 New Implementation |

| Vascepa (Icosapent Ethyl)   |  |  |  |
|---|--|--|--|
| (3) hadrong-over-shaper below, was associated, and they had be provided as well-between |  |  |  |
|   |  |  |  |

| Guideline ID          | GL-129625                 |
|-----------------------|---------------------------|
| <b>Guideline Name</b> | Vascepa (Icosapent Ethyl) |
| Formulary             | Quartz                    |

# **Guideline Note:**

| Effective Date: |
|-----------------|
|-----------------|

# 1. Criteria

| Product Name: Generic Icosapent Ethyl                |  |  |
|--|--|--|
| Approval Length 12 month(s)                          |  |  |
| Therapy Stage Initial Authorization                  |  |  |
| Guideline Type Prior Authorization - IL and MN Plans |  |  |

| Product<br>Name    | Generic Name               | GPI            | Brand/Generic |
|--------------------|----------------------------|----------------|---------------|
| ICOSAPENT<br>ETHYL | ICOSAPENT ETHYL CAP 0.5 GM | 39500035100110 | Generic       |
| ICOSAPENT<br>ETHYL | ICOSAPENT ETHYL CAP 1 GM   | 39500035100120 | Generic       |

## **Approval Criteria**

**1** - Diagnosis of established cardiovascular disease\* OR diabetes mellitus with  $\geq$  2 additional risk factors for cardiovascular disease\*\*

#### AND

2 - Prescribed by, or in consultation with, a Cardiologist, Endocrinologist, or other lipid specialist

### AND

3 - Triglycerides ≥ 150 mg/dL

### AND

4 - Using as an adjunct to maximally tolerated statin therapy

#### OR

5 - Clinical documentation to support statin intolerance\*\*\*

### Notes

\*ASCVD refers to the following conditions: coronary heart disease such as myocardial infarction, angina, coronary artery stenosis >50%; cerebrovascular disease such as transient ischemic att ack, ischemic stroke, or carotid artery stenosis > 50%; peripheral artery disease such as claudication; and aortic atheros clerotic disease such as abdominal aortic aneurysm and descending thoracic aneurysm.

- \*\*Additional risk factors may include: current smoker, family history of p remature ASCVD, LDL cholesterol persistently ≥ 160 mg/dL, chronic kidney disease, metabolic syndrome, South Asian ancestry, or other guideline supported risk factors
- \*\*\*Statin intolerance is defined as the inability to tolerate at least 2 statins, with:
- one started at the lowest starting dose
- \* statin dose reduction was attempted to resolve symptoms or lab abnormalities (not discontinuation)
- ♣ symptoms or lab abnormalities reversed with statin discontinuation b ut returned with re-challenge of statins
- ♣ symptoms or lab abnormalities are not due to established predisposit ions such as drug interactions, significant

| changes in physical activity, or underlying muscle disease |  |
|--|--|
|--|--|

| Product Name: Generic Icosapent Ethyl                |  |  |  |
|--|--|--|--|
| Approval Length 12 month(s)                          |  |  |  |
| Therapy Stage Reauthorization                        |  |  |  |
| Guideline Type Prior Authorization - IL and MN Plans |  |  |  |

| Product<br>Name    | Generic Name               | GPI            | Brand/Generic |
|--------------------|----------------------------|----------------|---------------|
| ICOSAPENT<br>ETHYL | ICOSAPENT ETHYL CAP 0.5 GM | 39500035100110 | Generic       |
| ICOSAPENT<br>ETHYL | ICOSAPENT ETHYL CAP 1 GM   | 39500035100120 | Generic       |

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug.

|       | 3 17 1   |
|-------|--|
| Notes | *ASCVD refers to the following conditions: coronary heart disease such as myocardial infarction, angina, coronary artery stenosis >50%; cerebrovascular disease such as transient ischemic att ack, ischemic stroke, or carotid artery stenosis > 50%; peripheral artery disease such as claudication; and aortic atheros clerotic disease such as abdominal aortic aneurysm and descending thoracic aneurysm.   |
|       | **Additional risk factors may include: current smoker, family history of p remature ASCVD, LDL cholesterol persistently ≥ 160 mg/dL, chronic kidney disease, metabolic syndrome, South Asian ancestry, or other guideline supported risk factors   |
|       | ***Statin intolerance is defined as the inability to tolerate at least 2 statins, with:  one started at the lowest starting dose  statin dose reduction was attempted to resolve symptoms or lab abnormalities (not discontinuation)  symptoms or lab abnormalities reversed with statin discontinuation but returned with re-challenge of statins  symptoms or lab abnormalities are not due to established predispositions such as drug interactions, significant changes in physical activity, or underlying muscle disease |

| Product Name: Generic Icosapent Ethyl                           |  |  |
|---|--|--|
| Approval Length 12/31/2039                                      |  |  |
| Guideline Type Prior Authorization - All plans except IL and MN |  |  |

| Product<br>Name    | Generic Name               | GPI            | Brand/Generic |
|--------------------|----------------------------|----------------|---------------|
| ICOSAPENT<br>ETHYL | ICOSAPENT ETHYL CAP 0.5 GM | 39500035100110 | Generic       |
| ICOSAPENT<br>ETHYL | ICOSAPENT ETHYL CAP 1 GM   | 39500035100120 | Generic       |

**1** - Diagnosis of established cardiovascular disease\* OR diabetes mellitus with ≥ 2 additional risk factors for cardiovascular disease\*\*

### **AND**

2 - Prescribed by, or in consultation with, a Cardiologist, Endocrinologist, or other lipid specialist

### **AND**

**3** - Triglycerides ≥ 150 mg/dL

### AND

4 - Using as an adjunct to maximally tolerated statin therapy

### OR

5 - Clinical documentation to support statin intolerance\*\*\*

| Notes | *ASCVD refers to the following conditions: coronary heart disease such as myocardial infarction, angina, coronary artery stenosis >50%; cerebrovascular disease such as transient ischemic att |
|-------|--|
|       | ack, ischemic stroke, or carotid artery stenosis >   |
|       | 50%; peripheral artery disease such as claudication; and aortic atheros clerotic disease such as abdominal aortic  |

aneurysm and descending thoracic aneurysm.

\*\*Additional risk factors may include: current smoker, family history of p remature ASCVD, LDL cholesterol persistently ≥ 160 mg/dL, chronic kidney disease, metabolic syndrome, South Asian ancestry, or other guideline supported risk factors

\*\*\*Statin intolerance is defined as the inability to tolerate at least 2 statins, with:

♣ one started at the lowest starting dose

♣ statin dose reduction was attempted to resolve symptoms or lab abnormalities (not discontinuation)

♣ symptoms or lab abnormalities reversed with statin discontinuation b ut returned with re-challenge of statins

♣ symptoms or lab abnormalities are not due to established predisposit ions such as drug interactions, significant changes in physical activity, or underlying muscle disease

| Date       | Notes       |
|------------|-------------|
| 10/25/2023 | New Program |

| Vemlidy (tenofovir alafenamide)  |  |
|--|--|
| The following word schillers for the last section could writte a state of the field appeal to an understanding |  |
|  |  |

| Guideline ID          | GL-131349                       |
|-----------------------|---------------------------------|
| <b>Guideline Name</b> | Vemlidy (tenofovir alafenamide) |
| Formulary             | Quartz                          |

## **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

### Note:

\*Member new to the plan (as evidenced by coverage effective date of less than or equal to 90 days) who initiated therapy using a manufacturer-sponsored free drug program, provider samples, and/or vouchers will go through initial criteria, otherwise for continuation of therapy for new to plan, reauthorization criteria applies

## 1. Criteria

| Product Name: Vemlidy |  |  |     |               |  |  |
|-----------------------|--|--|-----|---------------|--|--|
| Approval L            | ength  | 12/31/2039                               |     | th 12/31/2039 |  |  |
| Guideline 7           | line Type Prior Authorization - All plans except IL and MN Plans |  |     |               |  |  |
| Product<br>Name       | Generic Na   | nme                                      | GPI | Brand/Generic |  |  |
| VEMLIDY               | TENOFOVIR  | TENOFOVIR ALAFENAMIDE FUMARATE TAB 25 MG |     | Brand         |  |  |
|                       |  |  |     |               |  |  |

1 - Diagnosis of chronic hepatitis B

### **AND**

- **2** One of the following:
  - Member has failed entecavir
  - Submission of medical records (e.g., chart notes) documenting member has lamivudine resistance

### AND

3 - Trial and failure, contraindication, or intolerance to tenofovir disoproxil fumarate

| Product Name: Vemlidy       |  |                                       |               |  |
|-----------------------------|--|---------------------------------------|---------------|--|
| Approval Length 12 month(s) |  |                                       |               |  |
| Guideline Type              |  | Prior Authorization - IL and MN Plans | 3             |  |
| Product Generic Name GPI    |  | GPI                                   | Brand/Generic |  |

| Product<br>Name | Generic Name                             | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| VEMLIDY         | TENOFOVIR ALAFENAMIDE FUMARATE TAB 25 MG | 12352083200320 | Brand         |

### **Approval Criteria**

- **1** ALL of the following:
- 1.1 Diagnosis of chronic hepatitis B

### **AND**

- **1.2** One of the following:
  - Member has failed entecavir
  - Submission of medical records (e.g., chart notes) documenting member has lamivudine resistance

### AND

1.3 Trial and failure, contraindication, or intolerance to tenofovir disoproxil fumarate

### OR

**2** - (Minnesota plans only): Member has stage four metastatic cancer and the requested drug is being used to treat cancer-related hepatitis B infection

| Product Name: Vemlidy |                                       |
|-----------------------|---------------------------------------|
| Approval Length       | 12 month(s)                           |
| Therapy Stage         | Reauthorization                       |
| Guideline Type        | Prior Authorization - IL and MN Plans |

| Product<br>Name | Generic Name                             | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| VEMLIDY         | TENOFOVIR ALAFENAMIDE FUMARATE TAB 25 MG | 12352083200320 | Brand         |

## **Approval Criteria**

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug

| Date      | Notes                   |
|-----------|-------------------------|
| 10/8/2023 | 2024 New Implementation |

| Verkazia (cyclosporine ophthalmic emulsion 0.19  |  |  |
|--|--|--|
| (2) White page of Subject Subj |  |  |

| Guideline ID          | GL-129065  |
|-----------------------|--|
| <b>Guideline Name</b> | Verkazia (cyclosporine ophthalmic emulsion 0.1%) |
| Formulary             | Quartz   |

## **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

## 1. Criteria

| Product Name: Verkazia |                        |  |
|------------------------|------------------------|--|
| Approval Length        | 12 month(s)            |  |
| Therapy Stage          | Initial Authorization* |  |
| Guideline Type         | Prior Authorization    |  |

| Product<br>Name | Generic Name                       | GPI            | Brand/Generic |
|-----------------|------------------------------------|----------------|---------------|
| VERKAZIA        | CYCLOSPORINE (OPHTH) EMULSION 0.1% | 86720020001630 | Brand         |

## **Approval Criteria**

**1** - Diagnosis of moderate to severe vernal keratoconjunctivitis (e.g. visual deficit and/or continuous symptoms)

### **AND**

**2** - Positive skin tests or in vitro reactivity to common aeroallergens (e.g. pollen, dust mites, pet dander, cockroaches, etc.)

#### AND

3 - Continued symptoms despite a two-week trial of an ophthalmic steroid

### AND

- **4** Trial and failure with first-line treatments including all of the following:
- **4.1** Lifestyle changes (e.g. cold compresses, trigger avoidance, artificial tears)

### AND

- **4.2** A three-week trial of one of the following, in combination with ophthalmic cyclosporine (0.05 % or 0.09%)
  - Topical ophthalmic mast cell stabilizer (e.g., cromolyn sodium, lodoxamide tromethamine, nedocromil sodium)
  - Topical dual action mast cell stabilizer/antihistamine (e.g., olopatadine, azelastine hydrochloride, epinastine, ketotifen fumarate)

#### AND

5 - Prescribed by or in consultation with an ophthalmologist

| Notes | *Member new to the plan (as evidenced by coverage effective date of I ess than or equal to 90 days) and were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers will go through rea |
|-------|---|
|       | uthorization criteria   |

### Product Name: Verkazia

| Approval Length | 12 month(s)         |
|-----------------|---------------------|
| Therapy Stage   | Reauthorization*    |
| Guideline Type  | Prior Authorization |

| Product<br>Name | Generic Name                       | GPI            | Brand/Generic |
|-----------------|------------------------------------|----------------|---------------|
| VERKAZIA        | CYCLOSPORINE (OPHTH) EMULSION 0.1% | 86720020001630 | Brand         |

**1** - Diagnosis of moderate to severe vernal keratoconjunctivitis (e.g. visual deficit and/or continuous symptoms)

### **AND**

**2** - Positive skin tests or in vitro reactivity to common aeroallergens (e.g. pollen, dust mites, pet dander, cockroaches, etc.)

### **AND**

3 - Continued symptoms despite a two-week trial of an ophthalmic steroid

### **AND**

- **4** Trial and failure with first-line treatments including all of the following:
- **4.1** Lifestyle changes (e.g. cold compresses, trigger avoidance, artificial tears)

### **AND**

- **4.2** A three-week trial of one of the following, in combination with ophthalmic cyclosporine (0.05 % or 0.09%)
  - Topical ophthalmic mast cell stabilizer (e.g., cromolyn sodium, lodoxamide tromethamine, nedocromil sodium)
  - Topical Dual action mast cell stabilizer/antihistamine (e.g., olopatadine, azelastine

hydrochloride, epinastine, ketotifen fumarate)

AND

5 - Prescribed by or in consultation with an ophthalmologist

AND

6 - Submission of medical records (e.g., chart notes) documenting that within the past 12 months, the member has improved while on therapy

Notes

\*Member new to the plan (as evidenced by coverage effective date of I ess than or equal to 90 days) and were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored freedrug program, provider samples, and/or vouchers will go through rea

## 2. Revision History

| Date      | Notes                   |
|-----------|-------------------------|
| 7/28/2023 | 2024 New Implementation |

uthorization criteria

| Verqu                                  | Verquvo (vericiguat)  |  |  |  |  |
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|  |   |  |  |  |  |

| Guideline ID   | GL-141086            |
|----------------|----------------------|
| Guideline Name | Verquvo (vericiguat) |
| Formulary      | Quartz               |

## **Guideline Note:**

| Effective Date: | 2/3/2024 |
|-----------------|----------|
|-----------------|----------|

## 1. Criteria

| Product Name: Verquvo |  |  |
|-----------------------|--|--|
| Approval Length       | 12/31/2039   |  |
| Guideline Type        | Prior Authorization - ALL Plans Except IL and MN Plans |  |

| Product<br>Name | Generic Name          | GPI            | Brand/Generic |
|-----------------|-----------------------|----------------|---------------|
| VERQUVO         | VERICIGUAT TAB 2.5 MG | 40900085000321 | Brand         |
| VERQUVO         | VERICIGUAT TAB 5 MG   | 40900085000330 | Brand         |
| VERQUVO         | VERICIGUAT TAB 10 MG  | 40900085000340 | Brand         |

## **Approval Criteria**

**1** - Diagnosis of symptomatic chronic heart failure (HF)

| AND  |
|--|
| 2 - Ejection fraction less than 45%  |
| AND  |
| 3 - Hospitalization related to HF in the past 6 months   |
| AND  |
| 4 - One of the following:  |
| 4.1 Both of the following:   |
| <b>4.1.1</b> Trial and failure, contraindication or intolerance to one of the following:   |
| <ul> <li>Angiotensin-converting enzyme inhibitor (e.g., enalapril, lisinopril, ramipril)</li> <li>Angiotensin II receptor blocker (e.g., candesartan, losartan, valsartan)</li> <li>Angiotensin receptor neprilysin inhibitors (e.g., sacubitril/valsartan)</li> </ul> |
| AND  |
| <b>4.1.2</b> Trial and failure, contraindication or intolerance to beta-blocker (e.g., bisoprolol, carvedilol, metoprolol succinate)   |
| OR   |
| <b>4.2</b> Trial and failure, contraindication or intolerance to an aldosterone antagonist (e.g., eplerenone, spironolactone)  |
| AND  |
| 5 - Prescribed by or in consultation with a cardiologist   |

| Product Name: Verquvo |                                       |  |
|-----------------------|---------------------------------------|--|
| Approval Length       | 12 month(s)                           |  |
| Therapy Stage         | Initial Authorization                 |  |
| Guideline Type        | Prior Authorization - IL and MN Plans |  |

| Product<br>Name | Generic Name          | GPI            | Brand/Generic |
|-----------------|-----------------------|----------------|---------------|
| VERQUVO         | VERICIGUAT TAB 2.5 MG | 40900085000321 | Brand         |
| VERQUVO         | VERICIGUAT TAB 5 MG   | 40900085000330 | Brand         |
| VERQUVO         | VERICIGUAT TAB 10 MG  | 40900085000340 | Brand         |

1 - Diagnosis of symptomatic chronic heart failure (HF)

AND

2 - Ejection fraction less than 45%

**AND** 

3 - Hospitalization related to HF in the past 6 months

AND

- **4** One of the following:
- **4.1** Both of the following:
- **4.1.1** Trial and failure, contraindication or intolerance to one of the following:
  - Angiotensin-converting enzyme inhibitor (e.g., enalapril, lisinopril, ramipril)
  - Angiotensin II receptor blocker (e.g., candesartan, losartan, valsartan)
  - Angiotensin receptor neprilysin inhibitors (e.g., sacubitril/valsartan)

**AND** 

**4.1.2** Trial and failure, contraindication or intolerance to beta-blocker (e.g., bisoprolol, carvedilol, metoprolol succinate)

### OR

**4.2** Trial and failure, contraindication or intolerance to an aldosterone antagonist (e.g., eplerenone, spironolactone)

### **AND**

**5** - Prescribed by or in consultation with a cardiologist

| Notes | *Member new to the plan (as evidenced by coverage effective date of I ess than or equal to 90 days) who initiated therapy using a manufactur er-sponsored free drug program, provider samples, and/or vouchers wil I go through initial criteria, otherwise for continuation of therapy for new to plan, reauthorization criteria applies |
|-------|---|
|       | to plan, reducine and a applied   |

| Product Name: Verquvo |                                       |  |
|-----------------------|---------------------------------------|--|
| Approval Length       | 12 month(s)                           |  |
| Therapy Stage         | Reauthorization                       |  |
| Guideline Type        | Prior Authorization - IL and MN Plans |  |

| Product<br>Name | Generic Name          | GPI            | Brand/Generic |
|-----------------|-----------------------|----------------|---------------|
| VERQUVO         | VERICIGUAT TAB 2.5 MG | 40900085000321 | Brand         |
| VERQUVO         | VERICIGUAT TAB 5 MG   | 40900085000330 | Brand         |
| VERQUVO         | VERICIGUAT TAB 10 MG  | 40900085000340 | Brand         |

### **Approval Criteria**

**1** - Diagnosis of symptomatic chronic heart failure (HF)

### **AND**

2 - Ejection fraction less than 45%

| AND  |
|--|
| 3 - Hospitalization related to HF in the past 6 months   |
| AND  |
| 4 - One of the following:  |
| <b>4.1</b> BOTH of the following:  |
| <b>4.1.1</b> Trial and failure, contraindication or intolerance to one of the following:   |
| <ul> <li>Angiotensin-converting enzyme inhibitor (e.g., enalapril, lisinopril, ramipril)</li> <li>Angiotensin II receptor blocker (e.g., candesartan, losartan, valsartan)</li> <li>Angiotensin receptor neprilysin inhibitors (e.g., sacubitril/valsartan)</li> </ul> |
| AND  |
| <b>4.1.2</b> Trial and failure, contraindication or intolerance to beta-blocker (e.g., bisoprolol, carvedilol, metoprolol succinate)   |
| OR   |
| <b>4.2</b> Trial and failure, contraindication or intolerance to an aldosterone antagonist (e.g., eplerenone, spironolactone)  |
| AND  |
| 5 - Prescribed by or in consultation with a cardiologist   |
| AND  |
| <b>6</b> - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member's is stable or an improvement is seen while on therapy with the requested drug  |

| Notes  *Member new to the plan (as evidenced by coverage effective dates than or equal to 90 days) who initiated therapy using a manuser-sponsored free drug program, provider samples, and/or vouch I go through initial criteria, otherwise for continuation of therapy for to plan, reauthorization criteria applies | factur<br>ers wil |
|---|-------------------|
|---|-------------------|

| Date     | Notes          |
|----------|----------------|
| 2/3/2024 | Update Program |

| Viag                            | ra (silde  | enafil)   |    |  |   |
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| Guideline ID          | GL-130386           |  |
|-----------------------|---------------------|--|
| <b>Guideline Name</b> | Viagra (sildenafil) |  |
| Formulary             | Quartz              |  |

# **Guideline Note:**

| Effective Date: |
|-----------------|
|-----------------|

# 1. Criteria

| Product Name: Generic sildenafil                                 |  |  |
|--|--|--|
| Approval Length 12/31/2039                                       |  |  |
| Guideline Type Quantity Limit - ALL Plans Except IL and MN Plans |  |  |

| Product<br>Name       | Generic Name                  | GPI            | Brand/Generic |
|-----------------------|-------------------------------|----------------|---------------|
| SILDENAFIL<br>CITRATE | SILDENAFIL CITRATE TAB 25 MG  | 40304070100310 | Generic       |
| SILDENAFIL<br>CITRATE | SILDENAFIL CITRATE TAB 50 MG  | 40304070100320 | Generic       |
| SILDENAFIL<br>CITRATE | SILDENAFIL CITRATE TAB 100 MG | 40304070100330 | Generic       |

## **Approval Criteria**

**1** - Submission of medical records (e.g., chart notes) documenting the actual number of intercourse events within a 30-day period and the dose required to achieve an erection

#### AND

**2** - Submission of medical records (e.g., chart notes) documenting that the quantity for treatment cannot be met with the commercially available dose forms within the quantity limit\*

| Notes | *QTY Limit: MAX 15 doses per 30 days |
|-------|--------------------------------------|
|-------|--------------------------------------|

| Product Name: Viagra, Generic sildenafil |                                  |  |
|--|----------------------------------|--|
| Approval Length                          | 12 month(s)                      |  |
| Therapy Stage                            | Initial Authorization            |  |
| Guideline Type                           | Quantity Limit - IL and MN Plans |  |

| Product<br>Name       | Generic Name                  | GPI            | Brand/Generic |
|-----------------------|-------------------------------|----------------|---------------|
| SILDENAFIL<br>CITRATE | SILDENAFIL CITRATE TAB 25 MG  | 40304070100310 | Generic       |
| SILDENAFIL<br>CITRATE | SILDENAFIL CITRATE TAB 50 MG  | 40304070100320 | Generic       |
| SILDENAFIL<br>CITRATE | SILDENAFIL CITRATE TAB 100 MG | 40304070100330 | Generic       |

#### **Approval Criteria**

**1** - Submission of medical records (e.g., chart notes) documenting the actual number of intercourse events within a 30-day period and the dose required to achieve an erection

#### AND

**2** - Submission of medical records (e.g., chart notes) documenting that the quantity for treatment cannot be met with the commercially available dose forms within the quantity limit\*

| Notes | *QTY Limit: MAX 15 doses per 30 days |
|-------|--------------------------------------|
|       |                                      |

| Product Name: Viagra, Generic sildenafil |             |
|--|-------------|
| Approval Length                          | 12 month(s) |

| Therapy Stage  | Reauthorization                  |
|----------------|----------------------------------|
| Guideline Type | Quantity Limit - IL and MN Plans |

| Product<br>Name       | Generic Name                  | GPI            | Brand/Generic |
|-----------------------|-------------------------------|----------------|---------------|
| SILDENAFIL<br>CITRATE | SILDENAFIL CITRATE TAB 25 MG  | 40304070100310 | Generic       |
| SILDENAFIL<br>CITRATE | SILDENAFIL CITRATE TAB 50 MG  | 40304070100320 | Generic       |
| SILDENAFIL<br>CITRATE | SILDENAFIL CITRATE TAB 100 MG | 40304070100330 | Generic       |

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug

| Date      | Notes                   |
|-----------|-------------------------|
| 10/6/2023 | 2024 New Implementation |

| Viberzi (eluxadoline)                 |   |  |  |  |
|---------------------------------------|---|--|--|--|
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| Guideline ID          | GL-129221             |  |
|-----------------------|-----------------------|--|
| <b>Guideline Name</b> | Viberzi (eluxadoline) |  |
| Formulary             | Quartz                |  |

# **Guideline Note:**

| Effective Date: |
|-----------------|
|-----------------|

## 1. Criteria

| Product Name: Viberzi                                |  |
|--|--|
| Approval Length 12 month(s)                          |  |
| Therapy Stage Initial Authorization                  |  |
| Guideline Type Prior Authorization - IL and MN Plans |  |

| Product<br>Name | Generic Name           | GPI            | Brand/Generic |
|-----------------|------------------------|----------------|---------------|
| VIBERZI         | ELUXADOLINE TAB 75 MG  | 52558020000330 | Brand         |
| VIBERZI         | ELUXADOLINE TAB 100 MG | 52558020000340 | Brand         |

## **Approval Criteria**

1 - Both of the following:

1.1 Covered for persons with diarrhea predominant irritable bowel syndrome (IBS)

#### AND

**1.2** Have failed, or been intolerant to, a one-month trial of conventional therapy (such as loperamide or diphenoxylate/atropine)

| Product Name: Viberzi                                |  |  |
|--|--|--|
| Approval Length 12 month(s)                          |  |  |
| Therapy Stage Reauthorization                        |  |  |
| Guideline Type Prior Authorization - IL and MN Plans |  |  |

| Product<br>Name | Generic Name           | GPI            | Brand/Generic |
|-----------------|------------------------|----------------|---------------|
| VIBERZI         | ELUXADOLINE TAB 75 MG  | 52558020000330 | Brand         |
| VIBERZI         | ELUXADOLINE TAB 100 MG | 52558020000340 | Brand         |

### **Approval Criteria**

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug

| Product Name: Viberzi   |  |  |
|---|--|--|
| Approval Length 12/31/2039                                      |  |  |
| Guideline Type Prior Authorization - All plans except IL and MN |  |  |

| Product<br>Name | Generic Name           | GPI            | Brand/Generic |
|-----------------|------------------------|----------------|---------------|
| VIBERZI         | ELUXADOLINE TAB 75 MG  | 52558020000330 | Brand         |
| VIBERZI         | ELUXADOLINE TAB 100 MG | 52558020000340 | Brand         |

### **Approval Criteria**

**1** - Both of the following:

1.1 Covered for persons with diarrhea predominant irritable bowel syndrome (IBS)

#### **AND**

**1.2** Have failed, or been intolerant to, a one-month trial of conventional therapy (such as loperamide or diphenoxylate/atropine)

| Date      | Notes       |
|-----------|-------------|
| 10/6/2023 | New Program |

| Vimpat (lacosamide)  |
|--|
| The hands the state of the stat |
|  |

| Guideline ID          | GL-128134           |
|-----------------------|---------------------|
| <b>Guideline Name</b> | Vimpat (lacosamide) |
| Formulary             | Quartz              |

# **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

# 1. Criteria

| Product Name: Generic Lacosamide |                                |  |
|----------------------------------|--------------------------------|--|
| Approval Length                  | 12 month(s)                    |  |
| Therapy Stage                    | Initial Authorization          |  |
| Guideline Type                   | Step Therapy - IL and MN Plans |  |

| Product<br>Name | Generic Name          | GPI            | Brand/Generic |
|-----------------|-----------------------|----------------|---------------|
| LACOSAMIDE      | LACOSAMIDE TAB 50 MG  | 72600036000320 | Generic       |
| LACOSAMIDE      | LACOSAMIDE TAB 100 MG | 72600036000330 | Generic       |
| LACOSAMIDE      | LACOSAMIDE TAB 150 MG | 72600036000340 | Generic       |
| LACOSAMIDE      | LACOSAMIDE TAB 200 MG | 72600036000350 | Generic       |

- **1** Trial and failure, contraindication, or intolerance to at least TWO preferred anticonvulsants:
  - lamotrigine
  - levetiracetam
  - carbamazepine
  - valproate
  - oxcarbazepine
  - gabapentin
  - pregabalin
  - topiramate
  - phenytoin
  - zonisamide
  - primidone

| Product Name: Generic Lacosamide |  |                                |     |               |
|----------------------------------|--|--------------------------------|-----|---------------|
| Approval Length                  |  | 12 month(s)                    |     |               |
| Therapy Stage                    |  | Reauthorization                |     |               |
| Guideline Type                   |  | Step Therapy - IL and MN Plans |     |               |
| Product Generic N                |  | Name                           | GPI | Brand/Generic |

| Product<br>Name | Generic Name          | GPI            | Brand/Generic |
|-----------------|-----------------------|----------------|---------------|
| LACOSAMIDE      | LACOSAMIDE TAB 50 MG  | 72600036000320 | Generic       |
| LACOSAMIDE      | LACOSAMIDE TAB 100 MG | 72600036000330 | Generic       |
| LACOSAMIDE      | LACOSAMIDE TAB 150 MG | 72600036000340 | Generic       |
| LACOSAMIDE      | LACOSAMIDE TAB 200 MG | 72600036000350 | Generic       |

### **Approval Criteria**

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug

| Product Name: Generic Lacosamide |           |   |     |               |
|----------------------------------|-----------|---|-----|---------------|
| Approval Length                  |           | 12/31/2039  |     |               |
| Guideline Type                   |           | Step Therapy - All other plans except IL and MN Plans |     |               |
| Product<br>Name                  | Generic N | Name  | GPI | Brand/Generic |

| LACOSAMIDE | LACOSAMIDE TAB 50 MG  | 72600036000320 | Generic |
|------------|-----------------------|----------------|---------|
| LACOSAMIDE | LACOSAMIDE TAB 100 MG | 72600036000330 | Generic |
| LACOSAMIDE | LACOSAMIDE TAB 150 MG | 72600036000340 | Generic |
| LACOSAMIDE | LACOSAMIDE TAB 200 MG | 72600036000350 | Generic |

- **1** Trial and failure, contraindication, or intolerance to at least TWO preferred anticonvulsants:
  - lamotrigine
  - levetiracetam
  - carbamazepine
  - valproate
  - oxcarbazepine
  - gabapentin
  - pregabalin
  - topiramate
  - phenytoin
  - zonisamide
  - primidone

| Date      | Notes       |
|-----------|-------------|
| 8/25/2023 | New Program |

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| Guideline ID          | GL-131955         |
|-----------------------|-------------------|
| <b>Guideline Name</b> | Vitamin D Analogs |
| Formulary             | Quartz            |

# **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

# 1. Criteria

| Product Name: Brand: Rayaldee, Generic: Doxercalciferol, paricalcitol |                       |
|---|-----------------------|
| Approval Length   | 12 month(s)           |
| Therapy Stage   | Initial Authorization |
| Guideline Type Prior Authorization-IL and MN Plans Only               |                       |

| Product Name Generic Name GPI Brand/0 |                             | Brand/Generic  |         |
|---------------------------------------|-----------------------------|----------------|---------|
| RAYALDEE                              | CALCIFEDIOL CAP ER 30 MCG   | 30905025000230 | Brand   |
| PARICALCITOL                          | PARICALCITOL CAP 1 MCG      | 30905070000110 | Generic |
| DOXERCALCIFEROL                       | DOXERCALCIFEROL CAP 0.5 MCG | 30905040000105 | Generic |
| DOXERCALCIFEROL                       | DOXERCALCIFEROL CAP 1 MCG   | 30905040000110 | Generic |
| DOXERCALCIFEROL                       | DOXERCALCIFEROL CAP 2.5 MCG | 30905040000120 | Generic |
| PARICALCITOL                          | PARICALCITOL CAP 2 MCG      | 30905070000120 | Generic |
| PARICALCITOL                          | PARICALCITOL CAP 4 MCG      | 30905070000140 | Generic |

**1** - Dose-adjusted trial and failure (unable to achieve parathyroid hormone level goals), contraindication, or intolerance with calcitriol.

| Product Name: Brand: Rayaldee, Generic: Doxercalciferol, paricalcitol |     |                                     |                |               |
|---|-----|-------------------------------------|----------------|---------------|
| Approval Length   |     | 12 month(s)                         |                |               |
| Therapy Stage   |     | Reauthorization                     |                |               |
| Guideline Type  |     | Prior Authorization-IL and MN Plans | Only           |               |
| Product Name  | Ge  | neric Name                          | GPI            | Brand/Generic |
| RAYALDEE  | CAL | CIFEDIOL CAP ER 30 MCG              | 30905025000230 | Brand         |
| PARICALCITOL  | PAF | RICALCITOL CAP 1 MCG                | 30905070000110 | Generic       |
| DOXERCALCIFEROL   | DO  | XERCALCIFEROL CAP 0.5 MCG           | 30905040000105 | Generic       |
| DOXERCALCIFEROL   | DOX | XERCALCIFEROL CAP 1 MCG             | 30905040000110 | Generic       |
| DOXERCALCIFEROL   | DO  | XERCALCIFEROL CAP 2.5 MCG           | 30905040000120 | Generic       |
| PARICALCITOL  | PAF | RICALCITOL CAP 2 MCG                | 30905070000120 | Generic       |
| PARICALCITOL  | PAF | RICALCITOL CAP 4 MCG                | 30905070000140 | Generic       |

### **Approval Criteria**

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug.

| Product Name: Brand: Rayaldee, Generic: Doxercalciferol, paricalcitol |     |  |                |               |
|---|-----|--|----------------|---------------|
| Approval Length   |     | 12/31/2039                                     | 12/31/2039     |               |
| Guideline Type  |     | Prior Authorization-All plans except IL and MN |                |               |
| Product Name  | Gei | neric Name                                     | GPI            | Brand/Generic |
| RAYALDEE  | CAL | CIFEDIOL CAP ER 30 MCG                         | 30905025000230 | Brand         |
| PARICALCITOL  | PAF | RICALCITOL CAP 1 MCG                           | 30905070000110 | Generic       |
| DOXERCALCIFEROL   | DOX | KERCALCIFEROL CAP 0.5 MCG                      | 30905040000105 | Generic       |
| DOXERCALCIFEROL   | DOX | KERCALCIFEROL CAP 1 MCG                        | 30905040000110 | Generic       |

| DOXERCALCIFEROL DOXERCALCIFEROL CAP 2.5 MCG 3090504 |                        | 30905040000120 | Generic |
|---|------------------------|----------------|---------|
| PARICALCITOL  | PARICALCITOL CAP 2 MCG | 30905070000120 | Generic |
| PARICALCITOL  | PARICALCITOL CAP 4 MCG | 30905070000140 | Generic |

**1** - Dose-adjusted trial and failure (unable to achieve parathyroid hormone level goals), contraindication, or intolerance with calcitriol.

| Date      | Notes       |
|-----------|-------------|
| 11/6/2023 | New program |

| ١ | Vivjoa (Otesecon   | azole)    |  |
|---|--|-----------|--|
| E | State the figure and trade of the first trade of th | rhadhain. |  |
|   |  |           |  |

| Guideline ID          | GL-131407              |  |
|-----------------------|------------------------|--|
| <b>Guideline Name</b> | Vivjoa (Oteseconazole) |  |
| Formulary             | Quartz                 |  |

## **Guideline Note:**

| Effective Date: |
|-----------------|
|-----------------|

## 1. Criteria

| Product Name: Vivjoa        |  |
|-----------------------------|--|
| Approval Length 12 month(s) |  |
| Guideline Type              | Prior Authorization-IL and MN Plans Only |

| Product<br>Name | Generic Name                                     | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| VIVJOA          | OTESECONAZOLE CAP THERAPY PACK 150 MG (12 WEEKS) | 1140805000B220 | Brand         |

# **Approval Criteria**

1 - Current diagnosis of vulvovaginal candidiasis with positive KOH test

#### **AND**

**2** - History of recurrent vulvovaginal candidiasis with ≥ 3 episodes of vulvovaginal candidiasis in the past 12 months

#### **AND**

**3** - Person is not of reproductive potential (i.e. postmenopausal, permanent infertility, tubal ligation, etc.)

#### **AND**

**4** - Trial and failure, contraindication, or intolerance of maintenance fluconazole therapy (at least 6 months)

| Product Name: Vivjoa |  |
|----------------------|--|
| Approval Length      | 3 month(s)                                     |
| Guideline Type       | Prior Authorization-All plans except IL and MN |

| Product<br>Name | Generic Name                                     | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| VIVJOA          | OTESECONAZOLE CAP THERAPY PACK 150 MG (12 WEEKS) | 1140805000B220 | Brand         |

### **Approval Criteria**

1 - Current diagnosis of vulvovaginal candidiasis with positive KOH test

#### **AND**

**2** - History of recurrent vulvovaginal candidiasis with ≥ 3 episodes of vulvovaginal candidiasis in the past 12 months

#### **AND**

**3** - Person is not of reproductive potential (i.e. postmenopausal, permanent infertility, tubal ligation, etc.)

### **AND**

**4** - Trial and failure, contraindication, or intolerance of maintenance fluconazole therapy (at least 6 months)

| Date       | Notes       |
|------------|-------------|
| 10/24/2023 | New Program |

| Vowst (Fecal microbiota spores, live-brp   | )k) |
|--|-----|
| (3) billioning-contributed balls to be be contributed and facility and the contributed and con |     |

| Guideline ID          | GL-143523                                  |
|-----------------------|--|
| <b>Guideline Name</b> | Vowst (Fecal microbiota spores, live-brpk) |
| Formulary             | Quartz                                     |

# **Guideline Note:**

| Effective Date:    | 4/1/2024  |
|--------------------|-----------|
| P&T Approval Date: | 7/18/2023 |
| P&T Revision Date: |           |

# 1. Criteria

| Product Name: Vowst                                |            |                                    |                |               |
|--|------------|------------------------------------|----------------|---------------|
| Approval Length 12 month (s) with a fill count = 1 |            | 12 month (s) with a fill count = 1 |                |               |
| Guideline Type                                     |            | Prior Authorization                |                |               |
| Product<br>Name                                    |            |                                    | GPI            | Brand/Generic |
| VOWST  | FECAL MICR | OBIOTA SPORES, LIVE-BRPK CAPS      | 52522020100120 | Brand         |

# **Approval Criteria**

**1** - One of the following:

- **1.1** Both of the following:
- **1.1.1** Diagnosis of at least 2 recurrent\* episodes of Clostridioides difficile (C diff) infection (≥ 3 C diff infection episodes)

#### AND

**1.1.2** C diff infection is refractory to standard antibiotic therapy (i.e., has received vancomycin or fidaxomicin therapy with previous episodes)

#### OR

**1.2** Diagnosis of recurrent\* C. diff episode after previous treatment with fecal microbiota therapy

#### **AND**

2 - Has a positive stool test for toxigenic C diff from a recent stool sample

#### AND

- **3** Prescribed by or in consultation with one of the following:
  - Infectious Disease specialist
  - Gastroenterologist

#### **AND**

4 - Member is 18 years or older

| Notes | *Recurrent defined as recurrence of diarrhea and positive C diff test wit |
|-------|---|
|       | hin 8 weeks after treatment of prior episode                              |

| Date      | Notes       |
|-----------|-------------|
| 2/29/2024 | New Program |

| Vyndaqel, Vyndamax (tafamidis)  |
|---|
| 3 Nationary was strated. Nation in terms and arms of the fact is provided and arms of the fact in the |
|   |

| Guideline ID          | GL-131932                      |
|-----------------------|--------------------------------|
| <b>Guideline Name</b> | Vyndaqel, Vyndamax (tafamidis) |
| Formulary             | Quartz                         |

## **Guideline Note:**

| Effective Date: |
|-----------------|
|-----------------|

## 1. Criteria

| Product Name: (Vyndad | oduct Name: (Vyndaqel, Vyndamax |  |  |
|-----------------------|---------------------------------|--|--|
| Approval Length       | 12 month(s)                     |  |  |
| Therapy Stage         | nitial Authorization            |  |  |
| Guideline Type        | Prior Authorization             |  |  |

| Product<br>Name | Generic Name                            | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| VYNDAQEL        | TAFAMIDIS MEGLUMINE (CARDIAC) CAP 20 MG | 40550080200120 | Brand         |
| VYNDAMAX        | TAFAMIDIS CAP 61 MG                     | 40550080000120 | Brand         |

## **Approval Criteria**

1 - Diagnosis of cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis

| (A          | TΤ | R- | C١         | A)    |
|-------------|----|----|------------|-------|
| <b>(,</b> , |    |    | <b>O</b> 1 | v : , |

#### **AND**

**2** - Prescribed by, or in consultation with, Cardiology, transthyretin amyloidosis (ATTR) specialist, or medical geneticist

#### **AND**

**3** - Age ≥ 18

#### **AND**

4 - New York Heart Association (NYHA) functional class I, II, or III heart failure

#### **AND**

**5** - No previous history of heart transplantation or estimated glomerular filtration rate less than 25mL per minute per 1.73m2 of body-surface area

| Product Name: (Vyndad | qel, Vyndamax       |  |
|-----------------------|---------------------|--|
| Approval Length       | 12 month(s)         |  |
| Therapy Stage         | Reauthorization     |  |
| Guideline Type        | Prior Authorization |  |

| Product<br>Name | Generic Name                            | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| VYNDAQEL        | TAFAMIDIS MEGLUMINE (CARDIAC) CAP 20 MG | 40550080200120 | Brand         |
| VYNDAMAX        | TAFAMIDIS CAP 61 MG                     | 40550080000120 | Brand         |

### **Approval Criteria**

**1** - Diagnosis of cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis (ATTR-CM)

**2** - Prescribed by, or in consultation with, Cardiology, transthyretin amyloidosis (ATTR) specialist, or medical geneticist

**AND** 

**3** - Age ≥ 18

#### **AND**

4 - New York Heart Association (NYHA) functional class I, II, or III heart failure

#### **AND**

**5** - No previous history of heart transplantation or estimated glomerular filtration rate less than 25mL per minute per 1.73m2 of body-surface area

#### **AND**

**6** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug.

#### **AND**

7 - Individual has not progressed to NYHA Class IV heart failure.

| Date       | Notes       |
|------------|-------------|
| 10/16/2023 | New Program |

| Xcop                                 | ri (ceno   | enobamate)   |  |  |  |
|--------------------------------------|--|--|--|--|--|
| The brided image current for display | ori. The Bormy have been record, unwared, or dichted Verly | that the list points in the constributed involves. |  |  |  |
|                                      |  |  |  |  |  |

| Guideline ID          | GL-127849           |
|-----------------------|---------------------|
| <b>Guideline Name</b> | Xcopri (cenobamate) |
| Formulary             | Quartz              |

# **Guideline Note:**

| Effective Date: |
|-----------------|
|-----------------|

# 1. Criteria

| Product Name: Xcopri |                                |
|----------------------|--------------------------------|
| Approval Length      | 12 month(s)                    |
| Therapy Stage        | Initial Authorization          |
| Guideline Type       | Step Therapy - IL and MN Plans |

| Product<br>Name | Generic Name   | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| XCOPRI          | CENOBAMATE TAB TITRATION PACK 14 X 12.5 MG & 14 X 25 MG      | 7212001000B720 | Brand         |
| XCOPRI          | CENOBAMATE TAB TITRATION PACK 14 X 50 MG & 14 X 100 MG       | 7212001000B725 | Brand         |
| XCOPRI          | CENOBAMATE TAB TITRATION PACK 14 X 150 MG & 14 X 200 MG      | 7212001000B730 | Brand         |
| XCOPRI          | CENOBAMATE TAB PACK 100 MG & 150 MG TABS (250 MG DAILY DOSE) | 7212001000B738 | Brand         |

| XCOPRI | CENOBAMATE TAB PACK 150 MG & 200 MG TABS (350 MG DAILY DOSE) | 7212001000B740 | Brand |
|--------|--|----------------|-------|
| XCOPRI | CENOBAMATE TAB 50 MG   | 72120010000320 | Brand |
| XCOPRI | CENOBAMATE TAB 100 MG  | 72120010000325 | Brand |
| XCOPRI | CENOBAMATE TAB 150 MG  | 72120010000330 | Brand |
| XCOPRI | CENOBAMATE TAB 200 MG  | 72120010000335 | Brand |

- **1** Trial and failure of at least two preferred anticonvulsants:

  - lamotrigine levetiracetam
  - carbamazepine
  - valproate
  - oxcarbazepine
  - gabapentin
  - pregabalin topiramate

  - phenytoin
  - zonisamide
  - primidone

| Product Name: Xcopri |                                |
|----------------------|--------------------------------|
| Approval Length      | 12 month(s)                    |
| Therapy Stage        | Reauthorization                |
| Guideline Type       | Step Therapy - IL and MN Plans |

| Product<br>Name | Generic Name   | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| XCOPRI          | CENOBAMATE TAB TITRATION PACK 14 X 12.5 MG & 14 X 25 MG      | 7212001000B720 | Brand         |
| XCOPRI          | CENOBAMATE TAB TITRATION PACK 14 X 50 MG & 14 X 100 MG       | 7212001000B725 | Brand         |
| XCOPRI          | CENOBAMATE TAB TITRATION PACK 14 X 150 MG & 14 X 200 MG      | 7212001000B730 | Brand         |
| XCOPRI          | CENOBAMATE TAB PACK 100 MG & 150 MG TABS (250 MG DAILY DOSE) | 7212001000B738 | Brand         |
| XCOPRI          | CENOBAMATE TAB PACK 150 MG & 200 MG TABS (350 MG DAILY DOSE) | 7212001000B740 | Brand         |

| XCOPRI | CENOBAMATE TAB 50 MG  | 72120010000320 | Brand |
|--------|-----------------------|----------------|-------|
| XCOPRI | CENOBAMATE TAB 100 MG | 72120010000325 | Brand |
| XCOPRI | CENOBAMATE TAB 150 MG | 72120010000330 | Brand |
| XCOPRI | CENOBAMATE TAB 200 MG | 72120010000335 | Brand |

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug

| Product Name: Xcopri |   |
|----------------------|---|
| Approval Length      | 12/31/2039                                      |
| Guideline Type       | Step Therapy - All plans except IL and MN Plans |

| Product<br>Name | Generic Name   | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| XCOPRI          | CENOBAMATE TAB TITRATION PACK 14 X 12.5 MG & 14 X 25 MG      | 7212001000B720 | Brand         |
| XCOPRI          | CENOBAMATE TAB TITRATION PACK 14 X 50 MG & 14 X 100 MG       | 7212001000B725 | Brand         |
| XCOPRI          | CENOBAMATE TAB TITRATION PACK 14 X 150 MG & 14 X 200 MG      | 7212001000B730 | Brand         |
| XCOPRI          | CENOBAMATE TAB PACK 100 MG & 150 MG TABS (250 MG DAILY DOSE) | 7212001000B738 | Brand         |
| XCOPRI          | CENOBAMATE TAB PACK 150 MG & 200 MG TABS (350 MG DAILY DOSE) | 7212001000B740 | Brand         |
| XCOPRI          | CENOBAMATE TAB 50 MG   | 72120010000320 | Brand         |
| XCOPRI          | CENOBAMATE TAB 100 MG  | 72120010000325 | Brand         |
| XCOPRI          | CENOBAMATE TAB 150 MG  | 72120010000330 | Brand         |
| XCOPRI          | CENOBAMATE TAB 200 MG  | 72120010000335 | Brand         |

## **Approval Criteria**

- **1** Trial and failure of at least two preferred anticonvulsants:
  - lamotrigine
  - levetiracetam
  - carbamazepine

- valproate
- valproate
  oxcarbazepine
  gabapentin
  pregabalin
  topiramate
  phenytoin
  zonisamide
  primidone

| Date      | Notes       |
|-----------|-------------|
| 8/25/2023 | New Program |

| Xdemvy   |                                     |  |
|--|-------------------------------------|--|
| The State of the S | pills is the several to and hastins |  |

| Guideline ID          | GL-135582 |
|-----------------------|-----------|
| <b>Guideline Name</b> | Xdemvy    |
| Formulary             | Quartz    |

## **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

### 1. Criteria

| Product Na         | Product Name: Xdemvy |  |                 |               |
|--------------------|----------------------|--|-----------------|---------------|
| Approval Length    |                      | 2 month(s)                             |                 |               |
| Guideline Type     |                      | Prior Authorization – All plans except | IL and MN plans |               |
| Product Generic Na |                      | ime                                    | GPI             | Brand/Generic |

| Product<br>Name | Generic Name               | GPI            | Brand/Generic |
|-----------------|----------------------------|----------------|---------------|
| XDEMVY          | LOTILANER OPHTH SOLN 0.25% | 86106050002020 | Brand         |

### **Approval Criteria**

- 1 Diagnosis of demodex blepharitis with all of the following:

  - Presence of erythema of the upper eyelid margin Presence of mites upon examination of eyelashes by light microscopy OR presence of

collarettes on slit lamp examination

#### AND

2 - Member is 18 years of age or older

| Product Name: Xdemvy        |                                      |  |
|-----------------------------|--------------------------------------|--|
| Approval Length 12 month(s) |                                      |  |
| Therapy Stage               | Initial Authorization                |  |
| Guideline Type              | Prior Authorization- IL and MN plans |  |

| Product<br>Name | Generic Name               | GPI            | Brand/Generic |
|-----------------|----------------------------|----------------|---------------|
| XDEMVY          | LOTILANER OPHTH SOLN 0.25% | 86106050002020 | Brand         |

### **Approval Criteria**

- 1 Diagnosis of demodex blepharitis with all of the following:

  - Presence of erythema of the upper eyelid margin
    Presence of mites upon examination of eyelashes by light microscopy OR presence of collarettes on slit lamp examination

#### AND

2 - Member is 18 years of age or older

| Product Name: Xdemvy        |                                      |  |  |
|-----------------------------|--------------------------------------|--|--|
| Approval Length 12 month(s) |                                      |  |  |
| Therapy Stage               | Reauthorization                      |  |  |
| Guideline Type              | Prior Authorization- IL and MN plans |  |  |
|                             |                                      |  |  |

| Product<br>Name | Generic Name               | GPI            | Brand/Generic |
|-----------------|----------------------------|----------------|---------------|
| XDEMVY          | LOTILANER OPHTH SOLN 0.25% | 86106050002020 | Brand         |
| <del> </del>    |                            |                | ı             |

- 1 Diagnosis of demodex blepharitis with all of the following:
  - Presence of erythema of the upper eyelid margin
  - Presence of mites upon examination of eyelashes by light microscopy OR presence of collarettes on slit lamp examination

**AND** 

2 - Member is 18 years of age or older

**AND** 

- **3** One of the following:
- **3.1** At least 11 months has elapsed since previous treatment with lotilaner (Xdemvy)

OR

**3.2** Person is established on therapy and has not completed the initial 6 week treatment course

| Date      | Notes       |
|-----------|-------------|
| 11/6/2023 | New Program |

| Xeljanz (tofacitinib)   |  |  |  |  |  |
|---|--|--|--|--|--|
| Similaring unear halppan Turking to the most, sensel, a disset in the facility arms the country bear halppan. |  |  |  |  |  |
|   |  |  |  |  |  |

| Guideline ID          | GL-134602             |
|-----------------------|-----------------------|
| <b>Guideline Name</b> | Xeljanz (tofacitinib) |
| Formulary             | Quartz                |

# **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

# 1. Criteria

| Product Name: Xeljanz, Xeljanz ER                                     |            |
|---|------------|
| Diagnosis Moderate to Severely Active Psoriatic Arthritis (PsA)       |            |
| Approval Length   | 12/31/2039 |
| Guideline Type Prior Authorization - All Plans Except IL and MN Plans |            |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| XELJANZ         | TOFACITINIB CITRATE TAB 5 MG (BASE EQUIVALENT)          | 66603065100320 | Brand         |
| XELJANZ         | TOFACITINIB CITRATE TAB 10 MG (BASE EQUIVALENT)         | 66603065100330 | Brand         |
| XELJANZ         | TOFACITINIB CITRATE ORAL SOLN 1 MG/ML (BASE EQUIVALENT) | 66603065102020 | Brand         |
| XELJANZ<br>XR   | TOFACITINIB CITRATE TAB ER 24HR 11 MG (BASE EQUIVALENT) | 66603065107530 | Brand         |
| XELJANZ         | TOFACITINIB CITRATE TAB ER 24HR 22 MG (BASE             | 66603065107550 | Brand         |

| XR   | EQUIVALENT  | ")   |   |                                 |
|--|---|--|---|---------------------------------|
|  |   |  |   |                                 |
| Approval   | Criteria  |  |   |                                 |
| <b>1</b> - Diagno  | osis of modera  | te to severely active psoriatic arthritis  | <b>S</b>                                  |                                 |
|  |   | AND  |   |                                 |
| <b>2</b> - Submis following:   | ssion of medio  | cal records (e.g., chart notes) docume   | enting at least ONE                       | of the                          |
| <ul> <li>actively inflamed joints</li> <li>axial disease</li> <li>active skin, nail, or scalp psoriasis involvement</li> <li>dactylitis</li> <li>enthesitis</li> </ul> |   |  |   |                                 |
|  |   | AND  |   |                                 |
|  |   | tion with other biologic disease modif<br>stagonist and IL-12/23, apremilast and   |   |                                 |
|  |   | AND  |   |                                 |
|  | <b>4</b> - Trial and failure, contraindication, or intolerance to at least one TNF agent (e.g. adalimumab, etanercept, etc.) as per package label |  |   | e.g.                            |
| AND  |   |  |   |                                 |
| 5 - Prescribed by or in consultation with one of the following:  |   |  |   |                                 |
| <ul> <li>dermatologist</li> <li>rheumatologist</li> </ul>  |   |  |   |                                 |
| Notes  |   | ***Member new to the plan (as evide<br>less than or equal to 90 days) who in<br>rer-sponsored free drug program, pro<br>ill go through initial criteria, otherwise | nitiated therapy us<br>ovider samples, ar | ing a manufactund/or vouchers w |

| w to plan, reauthorization criteria applies |
|---|
|---|

| Product Name: Xeljanz, Xeljanz ER |   |  |
|-----------------------------------|---|--|
| Diagnosis                         | Moderate to Severely Active Psoriatic Arthritis (PsA) |  |
| Approval Length                   | 12 month(s)   |  |
| Therapy Stage                     | Initial Authorization                                 |  |
| Guideline Type                    | Prior Authorization - IL and MN Plans                 |  |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| XELJANZ         | TOFACITINIB CITRATE TAB 5 MG (BASE EQUIVALENT)          | 66603065100320 | Brand         |
| XELJANZ         | TOFACITINIB CITRATE TAB 10 MG (BASE EQUIVALENT)         | 66603065100330 | Brand         |
| XELJANZ         | TOFACITINIB CITRATE ORAL SOLN 1 MG/ML (BASE EQUIVALENT) | 66603065102020 | Brand         |
| XELJANZ<br>XR   | TOFACITINIB CITRATE TAB ER 24HR 11 MG (BASE EQUIVALENT) | 66603065107530 | Brand         |
| XELJANZ<br>XR   | TOFACITINIB CITRATE TAB ER 24HR 22 MG (BASE EQUIVALENT) | 66603065107550 | Brand         |

1 - Diagnosis of moderate to severely active psoriatic arthritis

#### **AND**

- ${\bf 2}$  Submission of medical records (e.g., chart notes) documenting at least ONE of the following:
  - actively inflamed joints
  - axial disease
  - active skin, nail, or scalp psoriasis involvement
  - dactylitis
  - enthesitis

#### AND

**3** - Not used in combination with other biologic disease modifying anti-rheumatic drugs (DMARDs) (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

#### AND

**4** - Trial and failure, contraindication, or intolerance to at least one TNF agent (e.g. adalimumab, etanercept, etc.) as per package label

#### **AND**

- **5** Prescribed by or in consultation with one of the following:
  - dermatologist
  - rheumatologist

| ***Member new to the plan (as evidenced by coverage effective date of less than or equal to 90 days) who initiated therapy using a manufactu rer-sponsored free drug program, provider samples, and/or vouchers w ill go through initial criteria, otherwise for continuation of therapy for ne |
|---|
| w to plan, reauthorization criteria applies   |

| Product Name: Xeljanz, Xeljanz ER |                                       |  |
|-----------------------------------|---------------------------------------|--|
| Diagnosis                         | All Diagnoses                         |  |
| Approval Length                   | 12 month(s)                           |  |
| Therapy Stage                     | Reauthorization                       |  |
| Guideline Type                    | Prior Authorization - IL and MN Plans |  |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| XELJANZ         | TOFACITINIB CITRATE TAB 5 MG (BASE EQUIVALENT)          | 66603065100320 | Brand         |
| XELJANZ         | TOFACITINIB CITRATE TAB 10 MG (BASE EQUIVALENT)         | 66603065100330 | Brand         |
| XELJANZ         | TOFACITINIB CITRATE ORAL SOLN 1 MG/ML (BASE EQUIVALENT) | 66603065102020 | Brand         |
| XELJANZ<br>XR   | TOFACITINIB CITRATE TAB ER 24HR 11 MG (BASE EQUIVALENT) | 66603065107530 | Brand         |
| XELJANZ<br>XR   | TOFACITINIB CITRATE TAB ER 24HR 22 MG (BASE EQUIVALENT) | 66603065107550 | Brand         |

### **Approval Criteria**

|       | cal records (e.g., chart notes), documenting the member's response to 12 months including individual improvements in functional status  |
|-------|---|
| Notes | ***Member new to the plan (as evidenced by coverage effective date of less than or equal to 90 days) who initiated therapy using a manufactu rer-sponsored free drug program, provider samples, and/or vouchers w ill go through initial criteria, otherwise for continuation of therapy for ne w to plan, reauthorization criteria applies |

| Product Name: Xeljanz, Xeljanz ER |  |  |
|-----------------------------------|--|--|
| Diagnosis                         | Moderate to Severely Active Rheumatoid Arthritis       |  |
| Approval Length                   | 12/31/2039   |  |
| Guideline Type                    | Prior Authorization - ALL Plans Except IL and MN Plans |  |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| XELJANZ         | TOFACITINIB CITRATE TAB 5 MG (BASE EQUIVALENT)          | 66603065100320 | Brand         |
| XELJANZ         | TOFACITINIB CITRATE TAB 10 MG (BASE EQUIVALENT)         | 66603065100330 | Brand         |
| XELJANZ         | TOFACITINIB CITRATE ORAL SOLN 1 MG/ML (BASE EQUIVALENT) | 66603065102020 | Brand         |
| XELJANZ<br>XR   | TOFACITINIB CITRATE TAB ER 24HR 11 MG (BASE EQUIVALENT) | 66603065107530 | Brand         |
| XELJANZ<br>XR   | TOFACITINIB CITRATE TAB ER 24HR 22 MG (BASE EQUIVALENT) | 66603065107550 | Brand         |

1 - Diagnosis of moderate to severely active rheumatoid arthritis (RA)

#### **AND**

- **2** Submission of medical records (e.g., chart notes) documenting a 3-month trial and failure, intolerance, or contraindication to ONE of the following:
  - methotrexate (MTX)\*\*
  - leflunomide
  - hydroxychloroquine
  - sulfasalazine

#### AND

**3** - Not used in combination with other biologic disease modifying anti-rheumatic drugs (DMARDs) (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

#### **AND**

**4** - Trial and failure, contraindication, or intolerance to at least one TNF agent (e.g. adalimumab, etanercept, etc.) as per package label

#### **AND**

**5** - Prescribed by or in consultation with a rheumatologist

|       | <del>U</del>   |
|-------|--|
| Notes | **Absolute contraindications to methotrexate are pregnancy, nursing, al coholism, alcoholic liver disease or other chronic liver disease, immuno deficiency syndromes, bone marrow hyperplasia, leukopenia, thromboc ytopenia or significant anemia, or hypersensitivity to methotrexate ***Member new to the plan (as evidenced by coverage effective date of less than or equal to 90 days) who initiated therapy using a manufactu rer-sponsored free drug program, provider samples, and/or vouchers w ill go through initial criteria, otherwise for continuation of therapy for ne w to plan, reauthorization criteria applies |

| Product Name: Xeljanz, Xeljanz ER |  |
|-----------------------------------|--|
| Diagnosis                         | Moderate to Severely Active Rheumatoid Arthritis |
| Approval Length                   | 12 month(s)                                      |
| Therapy Stage                     | Initial Authorization                            |
| Guideline Type                    | Prior Authorization - IL and MN Plans            |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| XELJANZ         | TOFACITINIB CITRATE TAB 5 MG (BASE EQUIVALENT)          | 66603065100320 | Brand         |
| XELJANZ         | TOFACITINIB CITRATE TAB 10 MG (BASE EQUIVALENT)         | 66603065100330 | Brand         |
| XELJANZ         | TOFACITINIB CITRATE ORAL SOLN 1 MG/ML (BASE EQUIVALENT) | 66603065102020 | Brand         |
| XELJANZ<br>XR   | TOFACITINIB CITRATE TAB ER 24HR 11 MG (BASE EQUIVALENT) | 66603065107530 | Brand         |
| XELJANZ         | TOFACITINIB CITRATE TAB ER 24HR 22 MG (BASE             | 66603065107550 | Brand         |

| XR EQUIVALENT   | Γ)   |  |  |
|---|--|--|--|
|   |  |  |  |
| Approval Criteria   |  |  |  |
|   | ate to severely active rheumatoid arth   | ritie (RA)   |  |
| T - Diagnosis of Modera   | ate to severely active medinatoid aitin  | nus (IVA)  |  |
|   | AND  |  |  |
|   |  |  |  |
|   | cal records (e.g., chart notes) docume<br>dication to ONE of the following:  | enting a 3-month tr  | ial and failure,   |
| <ul><li>methotrexate (M</li><li>leflunomide</li></ul>   | ITX)**   |  |  |
| <ul><li>hydroxychloroqu</li><li>sulfasalazine</li></ul>   | uine   |  |  |
|   | AND  |  |  |
|   | AND  |  |  |
|   | ation with other biologic disease modif<br>ntagonist and IL-12/23, apremilast and  |  |  |
|   | AND  |  |  |
| <b>4</b> - Trial and failure, contraindication, or intolerance to at least one TNF agent (e.g. adalimumab, etanercept, etc.) as per package label |  |  |  |
|   | AND  |  |  |
|   |  |  |  |
| 5 - Prescribed by or in o   | consultation with a rheumatologist   |  |  |
| Notes   | **Absolute contraindications to methodoholism, alcoholic liver disease or of deficiency syndromes, bone marrow ytopenia or significant anemia, or hyperitary markets with the plan (as evidence less than or equal to 90 days) who is rer-sponsored free drug program, profill go through initial criteria, otherwise with the plan of the | ther chronic liver of<br>hyperplasia, leuko<br>persensitivity to me<br>enced by coverage<br>nitiated therapy us<br>ovider samples, ar<br>e for continuation of | disease, immuno openia, thromboc ethotrexate effective date of ing a manufactund/or vouchers w |

| Product Name: Xeljanz, Xeljanz ER |  |
|-----------------------------------|--|
| Diagnosis                         | Moderate to Severely Active Rheumatoid Arthritis |
| Approval Length                   | 12 month(s)                                      |
| Therapy Stage                     | Reauthorization                                  |
| Guideline Type                    | Prior Authorization - IL and MN Plans            |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| XELJANZ         | TOFACITINIB CITRATE TAB 5 MG (BASE EQUIVALENT)          | 66603065100320 | Brand         |
| XELJANZ         | TOFACITINIB CITRATE TAB 10 MG (BASE EQUIVALENT)         | 66603065100330 | Brand         |
| XELJANZ         | TOFACITINIB CITRATE ORAL SOLN 1 MG/ML (BASE EQUIVALENT) | 66603065102020 | Brand         |
| XELJANZ<br>XR   | TOFACITINIB CITRATE TAB ER 24HR 11 MG (BASE EQUIVALENT) | 66603065107530 | Brand         |
| XELJANZ<br>XR   | TOFACITINIB CITRATE TAB ER 24HR 22 MG (BASE EQUIVALENT) | 66603065107550 | Brand         |

**1** - Submission of medical records (e.g., chart notes), documenting the member's response to therapy within the past 12 months including individual improvements in functional status

| ***Member new to the plan (as evidenced by coverage effective date of         |
|---|
| less than or equal to 90 days) who initiated therapy using a manufactu        |
| rer-sponsored free drug program, provider samples, and/or vouchers w          |
| ill go through initial criteria, otherwise for continuation of therapy for ne |
| w to plan, reauthorization criteria applies                                   |
|   |

| Product Name: Xeljanz, Xeljanz ER |  |
|-----------------------------------|--|
| Diagnosis                         | Polyarticular Juvenile Idiopathic Arthritis (PJIA)     |
| Approval Length                   | 12/31/2039   |
| Guideline Type                    | Prior Authorization - ALL Plans Except IL and MN Plans |

| Product<br>Name | Generic Name                                    | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| XELJANZ         | TOFACITINIB CITRATE TAB 5 MG (BASE EQUIVALENT)  | 66603065100320 | Brand         |
| XELJANZ         | TOFACITINIB CITRATE TAB 10 MG (BASE EQUIVALENT) | 66603065100330 | Brand         |

| XELJANZ       | TOFACITINIB CITRATE ORAL SOLN 1 MG/ML (BASE EQUIVALENT) | 66603065102020 | Brand |
|---------------|---|----------------|-------|
| XELJANZ<br>XR | TOFACITINIB CITRATE TAB ER 24HR 11 MG (BASE EQUIVALENT) | 66603065107530 | Brand |
| XELJANZ<br>XR | TOFACITINIB CITRATE TAB ER 24HR 22 MG (BASE EQUIVALENT) | 66603065107550 | Brand |

1 - Diagnosis of polyarticular juvenile idiopathic arthritis (PJIA)

#### **AND**

- **2** Submission of medical records (e.g., chart notes) documenting a 3-month trial and failure, intolerance, or contraindication to ONE of the following:
  - methotrexate (MTX)\*\*
  - leflunomide
  - hydroxychloroquine
  - sulfasalazine

#### **AND**

**3** - Not used in combination with other biologic disease modifying anti-rheumatic drugs (DMARDs) (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

### AND

**4** - Trial and failure, contraindication, or intolerance to at least one TNF agent (e.g. adalimumab, etanercept, etc.) as per package label

#### **AND**

**5** - Prescribed by or in consultation with a rheumatologist

| Notes | **Absolute contraindications to methotrexate are pregnancy, nursing, al |
|-------|---|
|       | coholism, alcoholic liver disease or other                              |
|       | chronic liver disease, immunodeficiency syndromes, bone marrow hyp      |
|       | erplasia, leukopenia, thrombocytopenia or                               |

| significant anemia, or hypersensitivity to methotrexate.  ***Member new to the plan (as evidenced by coverage effective date of less than or equal to 90 days) who initiated therapy using a manufactu rer-sponsored free drug program, provider samples, and/or vouchers w ill go through initial criteria, otherwise for continuation of therapy for new to plan reauthorization criteria applies |
|---|
| w to plan, reauthorization criteria applies   |

| Product Name: Xeljanz, Xeljanz ER |  |
|-----------------------------------|--|
| Diagnosis                         | Polyarticular Juvenile Idiopathic Arthritis (PJIA) |
| Approval Length                   | 12 month(s)  |
| Therapy Stage                     | Initial Authorization                              |
| Guideline Type                    | Prior Authorization - IL and MN Plans              |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| XELJANZ         | TOFACITINIB CITRATE TAB 5 MG (BASE EQUIVALENT)          | 66603065100320 | Brand         |
| XELJANZ         | TOFACITINIB CITRATE TAB 10 MG (BASE EQUIVALENT)         | 66603065100330 | Brand         |
| XELJANZ         | TOFACITINIB CITRATE ORAL SOLN 1 MG/ML (BASE EQUIVALENT) | 66603065102020 | Brand         |
| XELJANZ<br>XR   | TOFACITINIB CITRATE TAB ER 24HR 11 MG (BASE EQUIVALENT) | 66603065107530 | Brand         |
| XELJANZ<br>XR   | TOFACITINIB CITRATE TAB ER 24HR 22 MG (BASE EQUIVALENT) | 66603065107550 | Brand         |

**1** - Diagnosis of polyarticular juvenile idiopathic arthritis (PJIA)

### AND

- 2 Submission of medical records (e.g., chart notes) documenting a 3-month trial and failure, intolerance, or contraindication to ONE of the following:
  - methotrexate (MTX)\*\*leflunomide

  - hydroxychloroquine
  - sulfasalazine

**2** - Not used in combination with other biologic disease modifying anti-rheumatic drugs (DMARDs) (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

#### AND

**4** - Trial and failure, contraindication, or intolerance to at least one TNF agent (e.g. adalimumab, etanercept, etc.) as per package label

#### **AND**

**5** - Prescribed by or in consultation with a rheumatologist

| <u>-</u>                              | <del>-</del>  |
|---------------------------------------|---|
| ( ( ( ( ( ( ( ( ( ( ( ( ( ( ( ( ( ( ( | **Absolute contraindications to methotrexate are pregnancy, nursing, al coholism, alcoholic liver disease or other chronic liver disease, immunodeficiency syndromes, bone marrow hyp erplasia, leukopenia, thrombocytopenia or significant anemia, or hypersensitivity to methotrexate.  ***Member new to the plan (as evidenced by coverage effective date of less than or equal to 90 days) who initiated therapy using a manufactu rer-sponsored free drug program, provider samples, and/or vouchers w ill go through initial criteria, otherwise for continuation of therapy for ne w to plan, reauthorization criteria applies |

| Product Name: Xeljanz, Xeljanz ER |  |
|-----------------------------------|--|
| Diagnosis                         | Polyarticular Juvenile Idiopathic Arthritis (PJIA) |
| Approval Length                   | 12 month(s)  |
| Therapy Stage                     | Reauthorization                                    |
| Guideline Type                    | Prior Authorization - IL and MN Plans              |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| XELJANZ         | TOFACITINIB CITRATE TAB 5 MG (BASE EQUIVALENT)          | 66603065100320 | Brand         |
| XELJANZ         | TOFACITINIB CITRATE TAB 10 MG (BASE EQUIVALENT)         | 66603065100330 | Brand         |
| XELJANZ         | TOFACITINIB CITRATE ORAL SOLN 1 MG/ML (BASE EQUIVALENT) | 66603065102020 | Brand         |
| XELJANZ<br>XR   | TOFACITINIB CITRATE TAB ER 24HR 11 MG (BASE EQUIVALENT) | 66603065107530 | Brand         |

| XELJANZ<br>XR | TOFACITINIB CITRATE TAB ER 24HR 22 MG (BASE EQUIVALENT) | 66603065107550 | Brand |
|---------------|---|----------------|-------|
|---------------|---|----------------|-------|

**1** - Submission of medical records (e.g., chart notes), documenting the member's response to therapy within the past 12 months including individual improvements in functional status

| less than or equal to 90 days) who initiated therapy using a manufactu rer-sponsored free drug program, provider samples, and/or vouchers w | trierapy within the past | 12 months including individual improvements in functional status  |
|---|--------------------------|---|
| w to plan, reauthorization criteria applies   | Notes                    | coholism, alcoholic liver disease or other chronic liver disease, immunodeficiency syndromes, bone marrow hyp erplasia, leukopenia, thrombocytopenia or significant anemia, or hypersensitivity to methotrexate.  ***Member new to the plan (as evidenced by coverage effective date of less than or equal to 90 days) who initiated therapy using a manufactu rer-sponsored free drug program, provider samples, and/or vouchers w ill go through initial criteria, otherwise for continuation of therapy for ne |

| Product Name: Xeljanz, Xeljanz ER |  |
|-----------------------------------|--|
| Diagnosis                         | Ankylosing Spondylitis (AS)                            |
| Approval Length                   | 12/31/2039   |
| Guideline Type                    | Prior Authorization - ALL Plans Except IL and MN Plans |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| XELJANZ         | TOFACITINIB CITRATE TAB 5 MG (BASE EQUIVALENT)          | 66603065100320 | Brand         |
| XELJANZ         | TOFACITINIB CITRATE TAB 10 MG (BASE EQUIVALENT)         | 66603065100330 | Brand         |
| XELJANZ         | TOFACITINIB CITRATE ORAL SOLN 1 MG/ML (BASE EQUIVALENT) | 66603065102020 | Brand         |
| XELJANZ<br>XR   | TOFACITINIB CITRATE TAB ER 24HR 11 MG (BASE EQUIVALENT) | 66603065107530 | Brand         |
| XELJANZ<br>XR   | TOFACITINIB CITRATE TAB ER 24HR 22 MG (BASE EQUIVALENT) | 66603065107550 | Brand         |

# **Approval Criteria**

**1** - Diagnosis of ankylosing spondylitis (AS)

**2** - Minimum duration of a 1-month trial and failure, contraindication, or intolerance of scheduled prescription doses of TWO different NSAIDs (e.g., naproxen, nabumetone, diclofenac)

#### **AND**

**3** - Not used in combination with other biologic disease modifying anti-rheumatic drugs (DMARDs) (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

#### **AND**

**4** - Trial and failure, contraindication, or intolerance to at least one TNF agent (e.g. adalimumab, etanercept, etc.) as per package label

#### **AND**

**5** - Prescribed by or in consultation with a rheumatologist

| ***Member new to the plan (as evidenced by coverage effective date of less than or equal to 90 days) who initiated therapy using a manufactu rer-sponsored free drug program, provider samples, and/or vouchers w ill go through initial criteria, otherwise for continuation of therapy for ne |
|---|
| w to plan, reauthorization criteria applies   |

| Product Name: Xeljanz, Xeljanz ER |                                       |
|-----------------------------------|---------------------------------------|
| Diagnosis                         | Ankylosing Spondylitis (AS)           |
| Approval Length                   | 12 month(s)                           |
| Therapy Stage                     | Initial Authorization                 |
| Guideline Type                    | Prior Authorization - IL and MN Plans |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| XELJANZ         | TOFACITINIB CITRATE TAB 5 MG (BASE EQUIVALENT)          | 66603065100320 | Brand         |
| XELJANZ         | TOFACITINIB CITRATE TAB 10 MG (BASE EQUIVALENT)         | 66603065100330 | Brand         |
| XELJANZ         | TOFACITINIB CITRATE ORAL SOLN 1 MG/ML (BASE EQUIVALENT) | 66603065102020 | Brand         |

| XELJANZ<br>XR | TOFACITINIB CITRATE TAB ER 24HR 11 MG (BASE<br>EQUIVALENT) | 66603065107530 | Brand |
|---------------|--|----------------|-------|
| XELJANZ<br>XR | TOFACITINIB CITRATE TAB ER 24HR 22 MG (BASE EQUIVALENT)    | 66603065107550 | Brand |

**1** - Diagnosis of ankylosing spondylitis (AS)

#### **AND**

**2** - Minimum duration of a 1-month trial and failure, contraindication, or intolerance of scheduled prescription doses of TWO different NSAIDs (e.g., naproxen, nabumetone, diclofenac)

#### **AND**

**3** - Not used in combination with other biologic disease modifying anti-rheumatic drugs (DMARDs) (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

#### AND

**4** - Trial and failure, contraindication, or intolerance to at least one TNF agent (e.g. adalimumab, etanercept, etc.) as per package label

#### **AND**

**5** - Prescribed by or in consultation with a rheumatologist

| ill go through initial criteria, otherwise for continuation of therapy for ne w to plan, reauthorization criteria applies |
|---|
|---|

| Product Name: Xeljanz, Xeljanz ER     |             |
|---------------------------------------|-------------|
| Diagnosis Ankylosing Spondylitis (AS) |             |
| Approval Length                       | 12 month(s) |

| Therapy Stage  | Reauthorization                       |
|----------------|---------------------------------------|
| Guideline Type | Prior Authorization - IL and MN Plans |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| XELJANZ         | TOFACITINIB CITRATE TAB 5 MG (BASE EQUIVALENT)          | 66603065100320 | Brand         |
| XELJANZ         | TOFACITINIB CITRATE TAB 10 MG (BASE EQUIVALENT)         | 66603065100330 | Brand         |
| XELJANZ         | TOFACITINIB CITRATE ORAL SOLN 1 MG/ML (BASE EQUIVALENT) | 66603065102020 | Brand         |
| XELJANZ<br>XR   | TOFACITINIB CITRATE TAB ER 24HR 11 MG (BASE EQUIVALENT) | 66603065107530 | Brand         |
| XELJANZ<br>XR   | TOFACITINIB CITRATE TAB ER 24HR 22 MG (BASE EQUIVALENT) | 66603065107550 | Brand         |

**1** - Submission of medical records (e.g., chart notes), documenting the member's response to therapy within the past 12 months including individual improvements in functional status

| ***Member new to the plan (as evidenced by coverage effective date of less than or equal to 90 days) who initiated therapy using a manufactu rer-sponsored free drug program, provider samples, and/or vouchers w ill go through initial criteria, otherwise for continuation of therapy for new to plan reauthorization criteria applies |
|---|
| w to plan, reauthorization criteria applies   |

| Product Name: Xeljanz, Xeljanz ER                                     |            |  |
|---|------------|--|
| Diagnosis Moderate to Severely Active Crohn's Disease (CD)            |            |  |
| Approval Length   | 12/31/2039 |  |
| Guideline Type Prior Authorization - ALL Plans Except IL and MN Plans |            |  |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| XELJANZ         | TOFACITINIB CITRATE TAB 5 MG (BASE EQUIVALENT)          | 66603065100320 | Brand         |
| XELJANZ         | TOFACITINIB CITRATE TAB 10 MG (BASE EQUIVALENT)         | 66603065100330 | Brand         |
| XELJANZ         | TOFACITINIB CITRATE ORAL SOLN 1 MG/ML (BASE EQUIVALENT) | 66603065102020 | Brand         |
| XELJANZ<br>XR   | TOFACITINIB CITRATE TAB ER 24HR 11 MG (BASE EQUIVALENT) | 66603065107530 | Brand         |
| XELJANZ<br>XR   | TOFACITINIB CITRATE TAB ER 24HR 22 MG (BASE EQUIVALENT) | 66603065107550 | Brand         |

1 - Diagnosis of moderate to severely active Crohn's disease (CD)

#### **AND**

- **2** One of the following:
- **2.1** Member is considered high-risk based on at least one of the following characteristics:
  - Age less than 30 years at diagnosis
  - Extensive anatomic involvement
  - Perianal and/or severe rectal disease
  - Deep ulcers
  - Prior surgical resection
  - Stricturing and/or penetrating behavior
  - Fistulizing disease
  - Extraintestinal manifestations of inflammation (e.g., uveitis, erythema nodosum, pyoderma gangrenosum, spondyloarthropathy)

OR

- **2.2** Both of the following:
- **2.2.1** Member is considered low-risk

#### **AND**

### **2.2.2** One of the following:

- Trial and failure, contraindication, or intolerance to two conventional therapies (e.g., azathioprine, balsalazide, corticosteroids, mesalamine, mercaptopurine, methotrexate, sulfasalazine)
- Inadequate disease control or inability to achieve remission after an adequate trial of 3 months with one conventional therapy
- Demonstrated steroid dependence
- Conventional therapy clinically inappropriate based on location of disease

**3** - Trial and failure, contraindication, or intolerance to at least one TNF agent (e.g. adalimumab, etanercept, etc.) as per package label

#### **AND**

**4** - Not used in combination with other biologic disease modifying anti-rheumatic drugs (DMARDs) (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

#### **AND**

**5** - Trial and failure, contraindication, or intolerance to at least one TNF agent (e.g. adalimumab, etanercept, etc.) as per package label

#### **AND**

**6** - Prescribed by or in consultation with a gastroenterologist

| ***Member new to the plan (as evidenced by coverage effective date of less than or equal to 90 days) who initiated therapy using a manufactu rer-sponsored free drug program, provider samples, and/or vouchers w ill go through initial criteria, otherwise for continuation of therapy for ne |
|---|
| w to plan, reauthorization criteria applies   |

| Product Name: Xeljanz, Xeljanz ER |  |  |
|-----------------------------------|--|--|
| Diagnosis                         | Moderate to Severely Active Crohn's Disease (CD) |  |
| Approval Length                   | 12 month(s)                                      |  |
| Therapy Stage                     | Initial Authorization                            |  |
| Guideline Type                    | Prior Authorization - IL and MN Plans            |  |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| XELJANZ         | TOFACITINIB CITRATE TAB 5 MG (BASE EQUIVALENT)          | 66603065100320 | Brand         |
| XELJANZ         | TOFACITINIB CITRATE TAB 10 MG (BASE EQUIVALENT)         | 66603065100330 | Brand         |
| XELJANZ         | TOFACITINIB CITRATE ORAL SOLN 1 MG/ML (BASE EQUIVALENT) | 66603065102020 | Brand         |

| XELJANZ<br>XR | TOFACITINIB CITRATE TAB ER 24HR 11 MG (BASE<br>EQUIVALENT) | 66603065107530 | Brand |
|---------------|--|----------------|-------|
| XELJANZ<br>XR | TOFACITINIB CITRATE TAB ER 24HR 22 MG (BASE EQUIVALENT)    | 66603065107550 | Brand |

1 - Diagnosis of moderate to severely active Crohn's disease (CD)

#### AND

- 2 One of the following:
- **2.1** Member is considered high-risk based on at least one of the following characteristics:
  - Age less than 30 years at diagnosis
  - Extensive anatomic involvement
  - Perianal and/or severe rectal disease
  - Deep ulcers
  - Prior surgical resection
  - Stricturing and/or penetrating behavior
  - Fistulizing disease
  - Extraintestinal manifestations of inflammation (e.g., uveitis, erythema nodosum, pyoderma gangrenosum, spondyloarthropathy)

OR

- **2.2** Both of the following:
- **2.2.1** Member is considered low-risk

#### AND

#### **2.2.2** One of the following:

- Trial and failure, contraindication, or intolerance to two conventional therapies (e.g., azathioprine, balsalazide, corticosteroids, mesalamine, mercaptopurine, methotrexate, sulfasalazine)
- Inadequate disease control or inability to achieve remission after an adequate trial of 3 months with one conventional therapy
- Demonstrated steroid dependence

• Conventional therapy clinically inappropriate based on location of disease

#### **AND**

**3** - Trial and failure, contraindication, or intolerance to at least one TNF agent (e.g. adalimumab, etanercept, etc.) as per package label

#### **AND**

**4** - Not used in combination with other biologic disease modifying anti-rheumatic drugs (DMARDs) (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

#### AND

**5** - Trial and failure, contraindication, or intolerance to at least one TNF agent (e.g. adalimumab, etanercept, etc.) as per package label

#### **AND**

6 - Prescribed by or in consultation with a gastroenterologist

| ***Member new to the plan (as evidenced by coverage effective date of less than or equal to 90 days) who initiated therapy using a manufactu rer-sponsored free drug program, provider samples, and/or vouchers w ill go through initial criteria, otherwise for continuation of therapy for ne |
|---|
| w to plan, reauthorization criteria applies   |

| Product Name: Xeljanz, Xeljanz ER |  |  |
|-----------------------------------|--|--|
| Diagnosis                         | Moderate to Severely Active Crohn's Disease (CD) |  |
| Approval Length                   | 12 month(s)                                      |  |
| Therapy Stage                     | Reauthorization                                  |  |
| Guideline Type                    | Prior Authorization - IL and MN Plans            |  |

| Product<br>Name | Generic Name                                   | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| XELJANZ         | TOFACITINIB CITRATE TAB 5 MG (BASE EQUIVALENT) | 66603065100320 | Brand         |
| XELJANZ         | TOFACITINIB CITRATE TAB 10 MG (BASE            | 66603065100330 | Brand         |

|               | EQUIVALENT)   |                |       |
|---------------|---|----------------|-------|
| XELJANZ       | TOFACITINIB CITRATE ORAL SOLN 1 MG/ML (BASE EQUIVALENT) | 66603065102020 | Brand |
| XELJANZ<br>XR | TOFACITINIB CITRATE TAB ER 24HR 11 MG (BASE EQUIVALENT) | 66603065107530 | Brand |
| XELJANZ<br>XR | TOFACITINIB CITRATE TAB ER 24HR 22 MG (BASE EQUIVALENT) | 66603065107550 | Brand |

**1** - Submission of medical records (e.g., chart notes), documenting the member's response to therapy within the past 12 months including individual improvements in functional status

|  | ***Member new to the plan (as evidenced by coverage effective date of less than or equal to 90 days) who initiated therapy using a manufactu rer-sponsored free drug program, provider samples, and/or vouchers w ill go through initial criteria, otherwise for continuation of therapy for ne w to plan, reauthorization criteria applies |
|--|---|
|--|---|

| Product Name: Xeljanz, Xeljanz ER |  |  |
|-----------------------------------|--|--|
| Diagnosis                         | Moderate to Severely Active Ulcerative Colitis (UC)    |  |
| Approval Length                   | 12/31/2039   |  |
| Guideline Type                    | Prior Authorization - ALL Plans Except IL and MN Plans |  |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| XELJANZ         | TOFACITINIB CITRATE TAB 5 MG (BASE EQUIVALENT)          | 66603065100320 | Brand         |
| XELJANZ         | TOFACITINIB CITRATE TAB 10 MG (BASE EQUIVALENT)         | 66603065100330 | Brand         |
| XELJANZ         | TOFACITINIB CITRATE ORAL SOLN 1 MG/ML (BASE EQUIVALENT) | 66603065102020 | Brand         |
| XELJANZ<br>XR   | TOFACITINIB CITRATE TAB ER 24HR 11 MG (BASE EQUIVALENT) | 66603065107530 | Brand         |
| XELJANZ<br>XR   | TOFACITINIB CITRATE TAB ER 24HR 22 MG (BASE EQUIVALENT) | 66603065107550 | Brand         |

# **Approval Criteria**

1 - Diagnosis of moderate to severely active ulcerative colitis (UC)

- 2 Member is considered high-risk based on at least one of the following characteristics:
  - Extensive colitis
  - Deep ulcers
  - Age less than 40 years
  - High CRP and ESR
  - Steroid-requiring disease
  - History of hospitalization
  - C. difficile infection
  - CMV infection

#### **AND**

**3** - Trial and failure, contraindication, or intolerance to a short course (2 to 4 weeks) of oral corticosteroids

#### AND

**4** - Not used in combination with other biologic disease modifying anti-rheumatic drugs (DMARDs) (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

#### AND

**5** - Trial and failure, contraindication, or intolerance to at least one TNF agent (e.g. adalimumab, etanercept, etc.) as per package label

#### **AND**

**6** - Prescribed by or in consultation with a gastroenterologist

| Notes  ***Member new to the plan (as evidenced by coverage effective date of less than or equal to 90 days) who initiated therapy using a manufactu rer-sponsored free drug program, provider samples, and/or vouchers w ill go through initial criteria, otherwise for continuation of therapy for ne w to plan, reauthorization criteria applies |
|--|
| I to pissi, rosasino i actiona appiso  |

Product Name: Xeljanz, Xeljanz ER

| Diagnosis       | Moderate to Severely Active Ulcerative Colitis (UC) |
|-----------------|---|
| Approval Length | 12 month(s)   |
| Therapy Stage   | Initial Authorization                               |
| Guideline Type  | Prior Authorization - IL and MN Plans               |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| XELJANZ         | TOFACITINIB CITRATE TAB 5 MG (BASE EQUIVALENT)          | 66603065100320 | Brand         |
| XELJANZ         | TOFACITINIB CITRATE TAB 10 MG (BASE EQUIVALENT)         | 66603065100330 | Brand         |
| XELJANZ         | TOFACITINIB CITRATE ORAL SOLN 1 MG/ML (BASE EQUIVALENT) | 66603065102020 | Brand         |
| XELJANZ<br>XR   | TOFACITINIB CITRATE TAB ER 24HR 11 MG (BASE EQUIVALENT) | 66603065107530 | Brand         |
| XELJANZ<br>XR   | TOFACITINIB CITRATE TAB ER 24HR 22 MG (BASE EQUIVALENT) | 66603065107550 | Brand         |

1 - Diagnosis of moderate to severely active ulcerative colitis (UC)

#### **AND**

- 2 Member is considered high-risk based on at least one of the following characteristics:
  - Extensive colitis
  - Deep ulcers
  - Age less than 40 yearsHigh CRP and ESR

  - Steroid-requiring diseaseHistory of hospitalization

  - C. difficile infection
  - CMV infection

#### AND

3 - Trial and failure, contraindication, or intolerance to a short course (2 to 4 weeks) of oral corticosteroids

**4** - Not used in combination with other biologic disease modifying anti-rheumatic drugs (DMARDs) (i.e., TNF antagonist and IL-12/23, apremilast and TNF antagonist, etc.)

#### AND

**5** - Trial and failure, contraindication, or intolerance to at least one TNF agent (e.g. adalimumab, etanercept, etc.) as per package label

#### **AND**

6 - Prescribed by or in consultation with a gastroenterologist

| ***Member new to the plan (as evidenced by coverage effective date of less than or equal to 90 days) who initiated therapy using a manufactu rer-sponsored free drug program, provider samples, and/or vouchers w ill go through initial criteria, otherwise for continuation of therapy for ne |
|---|
| w to plan, reauthorization criteria applies   |

| Product Name: Xeljanz, Xeljanz ER |   |  |
|-----------------------------------|---|--|
| Diagnosis                         | Moderate to Severely Active Ulcerative Colitis (UC) |  |
| Approval Length                   | 12 month(s)   |  |
| Therapy Stage                     | Reauthorization                                     |  |
| Guideline Type                    | Prior Authorization - IL and MN Plans               |  |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| XELJANZ         | TOFACITINIB CITRATE TAB 5 MG (BASE EQUIVALENT)          | 66603065100320 | Brand         |
| XELJANZ         | TOFACITINIB CITRATE TAB 10 MG (BASE EQUIVALENT)         | 66603065100330 | Brand         |
| XELJANZ         | TOFACITINIB CITRATE ORAL SOLN 1 MG/ML (BASE EQUIVALENT) | 66603065102020 | Brand         |
| XELJANZ<br>XR   | TOFACITINIB CITRATE TAB ER 24HR 11 MG (BASE EQUIVALENT) | 66603065107530 | Brand         |
| XELJANZ<br>XR   | TOFACITINIB CITRATE TAB ER 24HR 22 MG (BASE EQUIVALENT) | 66603065107550 | Brand         |

| Approval Criteria  |   |  |
|--|---|--|
| 1 - Submission of medical records (e.g., chart notes), documenting the member's response to therapy within the past 12 months including individual improvements in functional status |   |  |
| Notes  | ***Member new to the plan (as evidenced by coverage effective date of less than or equal to 90 days) who initiated therapy using a manufactu rer-sponsored free drug program, provider samples, and/or vouchers w ill go through initial criteria, otherwise for continuation of therapy for ne w to plan, reauthorization criteria applies |  |

# 2. Definitions

| Definition   | Description  |
|--|--|
| Inadequate Disease Control of UC/CD:                                   | Worsening of baseline symptoms (i.e. bowel frequency, presence of blood, abdominal pain or tenderness, fever, etc.), extraintestinal manifestations (i.e. fatigue, joint pain, skin rash, and ocular symptoms), laboratory assessment (i.e. Creactive protein (CRP), hemoglobin, ESR white blood count (WBC), albumin, platelets, fecal calprotectin, etc.) and/or recent endoscopy results demonstrating ongoing inflammation |
| Steroid Dependence:  | Demonstrated steroid dependence (defined as equivalent to prednisone 10mg daily for >3 months) with the inability to taper or when tapering of dose leads to loss of symptom control   |
| Inflammatory status:<br>Signs/Symptoms/Labs/Endoscopy<br>for diagnosis | -Bloody diarrhea, weight loss, tenesmus, urgency, abdominal pain, fever, joint swelling/redness, localized abdominal tenderness, anemia, cutaneous signs -CBC, CMP, CRP, ESR, stool cultures, C difficile assay, fecal calprotectin -endoscopy, colonoscopy, sigmoidoscopy   |
| Ulcerative Colitis Disease<br>Severity:                                | Based on the degree of presentation of the signs and symptoms and change in baseline inflammatory status Moderate disease - more than four stools per day with minimal signs of toxicity, anemia, abdominal pain, low grade fever Severe disease - more than six bloody stools per day, fever, tachycardia, anemia, elevated ESR or CRP  |
| Crohn's Disease Classification:  | Stricturing - narrowing of bowel that may cause bowel obstruction; Penetrating - fistulae may form between bowel and other structures; Inflammatory - nonstricturing,  |

| nonpenetrating - inflammation without strictures or fistula |
|---|
|   |

# 3. Revision History

| Date      | Notes                   |
|-----------|-------------------------|
| 12/1/2023 | 2024 New Implementation |

| Xenleta (   | Lefamulin)  |  |
|---|---|--|
| The like of image content for ellipsique. The fire may have been non- | nd, maranid, or didded. Welly that the life points in the concentificant leading. |  |
|   |   |  |

# **Prior Authorization Guideline**

| Guideline ID          | GL-129632           |
|-----------------------|---------------------|
| <b>Guideline Name</b> | Xenleta (Lefamulin) |
| Formulary             | Quartz              |

# **Guideline Note:**

| Effective Date: |
|-----------------|
|-----------------|

# 1. Criteria

| Product Name: Xenleta                                |            |                    |                |               |
|--|------------|--------------------|----------------|---------------|
| Approval Le  | ength      | *See Note          |                |               |
| Guideline Type Prior Authorization - IL and MN Plans |            |                    |                |               |
| Product<br>Name                                      | Generic Na | ime                | GPI            | Brand/Generic |
| XENLETA  | LEFAMULIN  | ACETATE TAB 600 MG | 16240040100320 | Brand         |

## **Approval Criteria**

1 - Person has been receiving drug during hospitalization and needs to complete the course of therapy as an outpatient.

| $\boldsymbol{\cap}$ |  |
|---------------------|--|
|                     |  |
| $\mathbf{}$         |  |

- 2 Both of the following:
- **2.1** Outpatient treatment of bacterial resistant strains as ordered by or in consultation with an Infectious Disease Specialist

2.2 Report of susceptibilities documenting resistance to preferred alternatives

#### OR

**3** - (Illinois plans only) – the requested FDA approved drug is being used for the long-term treatment of tick-borne disease.

| Approval Length-12 months Fill Limit- 1 Fill |
|--|
|  |

| Product Name: Xenleta |  |
|-----------------------|--|
| Approval Length       | One fill   |
| Guideline Type        | Prior Authorization - All plans except IL and MN |

| Product<br>Name | Generic Name                 | GPI            | Brand/Generic |
|-----------------|------------------------------|----------------|---------------|
| XENLETA         | LEFAMULIN ACETATE TAB 600 MG | 16240040100320 | Brand         |

### **Approval Criteria**

**1** - Person has been receiving drug during hospitalization and needs to complete the course of therapy as an outpatient.

#### OR

**2** - Outpatient treatment of bacterial resistant strains as ordered by or in consultation with an Infectious Disease Specialist

3 - Report of susceptibilities documenting resistance to preferred alternatives

# 2. Revision History

| Date       | Notes       |
|------------|-------------|
| 10/25/2023 | New program |

| Xermelo (telotristat)   |  |  |  |  |
|---|--|--|--|--|
| [2] The Materiang owner to diagone. The form the best most, warrant, a state, left for the first points from a country and desired. |  |  |  |  |
|   |  |  |  |  |

# **Prior Authorization Guideline**

| Guideline ID          | GL-131938             |  |
|-----------------------|-----------------------|--|
| <b>Guideline Name</b> | Xermelo (telotristat) |  |
| Formulary             | Quartz                |  |

# **Guideline Note:**

| Effective Date: |
|-----------------|
|-----------------|

# 1. Criteria

| Product Name: Xermelo |  |
|-----------------------|--|
| Approval Length       | 12 month(s)                              |
| Therapy Stage         | Initial Authorization                    |
| Guideline Type        | Prior Authorization-IL and MN Plans Only |

| Product<br>Name | Generic Name   | GPI            | Brand/Generic |
|-----------------|--|----------------|---------------|
| XERMELO         | TELOTRISTAT ETHYL TAB 250 MG (AS TELOTRISTAT ETIPRATE) | 52570075100330 | Brand         |

# **Approval Criteria**

1 - Diagnosis of diarrhea secondary to carcinoid syndrome

2 - Age greater than or equal to 18 years

#### **AND**

**3** - 3-month trial and failure (≥ 4 bowel movements per day) with a somatostatin analog such as octreotide, lanreotide, or pasireotide.

#### **AND**

4 - Used in combination with a somatostatin analog

| Product Na                    | me: Xermel |  |                |               |
|-------------------------------|------------|--|----------------|---------------|
| Approval Length Therapy Stage |            | 12 month(s)                              |                |               |
|                               |            | Reauthorization                          |                |               |
| Guideline Type                |            | Prior Authorization-IL and MN Plans Only |                |               |
| Product Generic Na<br>Name    |            | nme                                      | GPI            | Brand/Generic |
| XERMELO TELOTRISTA            |            | T ETHYL TAB 250 MG (AS TELOTRISTAT       | 52570075100330 | Brand         |

### **Approval Criteria**

ETIPRATE)

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug.

| Product Na                 | me: Xermel | 0  |     |               |
|----------------------------|------------|--|-----|---------------|
| Approval Length            |            | 12/31/2039                                     |     |               |
| Guideline Type             |            | Prior Authorization-All plans except IL and MN |     |               |
| Product Generic Na<br>Name |            | nme  | GPI | Brand/Generic |

| XERMELO TELOTRISTAT ETHYL TAB 250 MG (AS TELOTRISTAT ETIPRATE) | 52570075100330 | Brand |
|--|----------------|-------|
|--|----------------|-------|

1 - Diagnosis of diarrhea secondary to carcinoid syndrome

AND

2 - Age greater than or equal to 18 years

**AND** 

**3** - 3-month trial and failure (≥ 4 bowel movements per day) with a somatostatin analog such as octreotide, lanreotide, or pasireotide.

**AND** 

4 - Used in combination with a somatostatin analog

# 2. Revision History

| Date       | Notes       |
|------------|-------------|
| 10/31/2023 | New program |

| Xolair (Omalizumab)  |
|--|
| The State Stranger commission for the State State Council, council, a state like State Sta |
|  |

# **Prior Authorization Guideline**

| Guideline ID          | GL-139376           |  |
|-----------------------|---------------------|--|
| <b>Guideline Name</b> | Xolair (Omalizumab) |  |
| Formulary             | Quartz              |  |

# **Guideline Note:**

| Effective Date: | 1/26/2024 |
|-----------------|-----------|
|-----------------|-----------|

### Note:

Member new to the plan (as evidenced by coverage effective date of less than or equal to 90 days) who initiated therapy using a manufacturer-sponsored free drug program, provider samples, and/or vouchers will go through initial criteria, otherwise for continuation of therapy for new to plan, reauthorization criteria applies

## 1. Criteria

| Product Name: Xolair |  |  |                |               |
|----------------------|--|--|----------------|---------------|
| Diagnosis            |  | Asthma                                     |                |               |
| Approval Length      |  | 12 month(s)                                |                |               |
| Therapy Stage        |  | Initial Authorization                      |                |               |
| Guideline Type       |  | Prior Authorization - IL and MN Plans Only |                |               |
| Product<br>Name      |  |  | GPI            | Brand/Generic |
| XOLAIR OMALIZUMAI    |  | B SUBCUTANEOUS SOLN PREFILLED              | 4460306000E510 | Brand         |

|        | SYRINGE 75 MG/0.5ML                                      |                |       |
|--------|--|----------------|-------|
| XOLAIR | OMALIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 150 MG/ML | 4460306000E520 | Brand |

**1** - Diagnosis of moderate-to-severe persistent allergic asthma as defined by Global Initiative for Asthma (GINA) Global Strategy for Asthma Management and Prevention Guidelines (Step 5)

**AND** 

2 - Member is 6 years or older

**AND** 

3 - Serum IgE level ≥ 30 international units/mL

**AND** 

**4** - Positive skin tests or in vitro reactivity to common aeroallergens (e.g. dust mites, pet dander, cockroaches)

AND

**5** - Member is a non-smoker or smoking cessation therapy has been recommended

**AND** 

- 6 One of the following:
- **6.1** Member has not well controlled or poorly controlled asthma despite episodic use of systemic corticosteroids or at least 3 months of medium to high-dose inhaled corticosteroids (ICS) in combination with long acting beta2 agonist (LABA) or leukotriene modifiers

#### OR

- **6.2** Member has one of the following adverse effects from medium to high dose ICS or long-term risks of adverse effects from high dose ICS or oral corticosteroids:
  - Cataracts in patients greater than 40 years of age
  - Glaucoma
  - Recurrent Thrush
  - Dysphonia
  - Growth inhibition, after evaluation by Endocrine Consult
  - Diagnosis of osteoporosis, treatment resistant to FDA approved osteoporosis treatment

#### **AND**

**7** - Prescriber attestation that the initial six (6) months of therapy must be done in the clinic setting by a healthcare professional

| Product Name: Xolair |  |  |
|----------------------|--|--|
| Diagnosis            | Asthma   |  |
| Approval Length      | 12/31/2039                                       |  |
| Guideline Type       | Prior Authorization - All plans except IL and MN |  |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| XOLAIR          | OMALIZUMAB SUBCUTANEOUS SOLN PREFILLED<br>SYRINGE 75 MG/0.5ML | 4460306000E510 | Brand         |
| XOLAIR          | OMALIZUMAB SUBCUTANEOUS SOLN PREFILLED<br>SYRINGE 150 MG/ML   | 4460306000E520 | Brand         |

#### **Approval Criteria**

1 - Diagnosis of moderate-to-severe persistent allergic asthma as defined by Global Initiative for Asthma (GINA) Global Strategy for Asthma Management and Prevention Guidelines (Step 5)

#### **AND**

2 - Member is 6 years or older

| AND  |
|--|
| 3 - Serum IgE level ≥ 30 international units/mL  |
| AND  |
| AND  |
| <b>4</b> - Positive skin tests or in vitro reactivity to common aeroallergens (e.g. dust mites, pet dander, cockroaches)   |
| AND  |
| 5 - Member is a non-smoker or smoking cessation therapy has been recommended   |
| AND  |
| 6 - One of the following:  |
| <b>6.1</b> Member has not well controlled or poorly controlled asthma despite episodic use of systemic corticosteroids or at least 3 months of medium to high-dose inhaled corticosteroids (ICS) in combination with long acting beta2 agonist (LABA) or leukotriene modifiers |
| OR   |
| <b>6.2</b> Member has one of the following adverse effects from medium to high dose ICS or long-term risks of adverse effects from high dose ICS or oral corticosteroids:  |
| <ul> <li>Cataracts in patients greater than 40 years of age</li> <li>Glaucoma</li> <li>Recurrent Thrush</li> </ul>   |
| <ul> <li>Recurrent Thrush</li> <li>Dysphonia</li> <li>Growth inhibition, after evaluation by Endocrine Consult</li> <li>Diagnosis of osteoporosis, treatment resistant to FDA approved osteoporosis treatment</li> </ul>   |
| AND  |
| 7 - Prescriber attestation that the initial six (6) months of therapy must be done in the clinic   |

### setting by a healthcare professional

| Product Name: Xolair |  |  |
|----------------------|--|--|
| Diagnosis            | Urticaria                                  |  |
| Approval Length      | 12 month(s)                                |  |
| Therapy Stage        | Initial Authorization                      |  |
| Guideline Type       | Prior Authorization - IL and MN Plans Only |  |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| XOLAIR          | OMALIZUMAB SUBCUTANEOUS SOLN PREFILLED<br>SYRINGE 75 MG/0.5ML | 4460306000E510 | Brand         |
| XOLAIR          | OMALIZUMAB SUBCUTANEOUS SOLN PREFILLED<br>SYRINGE 150 MG/ML   | 4460306000E520 | Brand         |

### **Approval Criteria**

1 - Diagnosis of chronic (at least 3 months), refractory urticaria

#### **AND**

- 2 Member has tried and failed both of the following:
  - Scheduled, high dose non-sedating antihistamines
  - at least one short course of corticosteroids

### **AND**

 $\bf 3$  - Prescriber attestation that the initial six (6) months of therapy must be done in the clinic setting by a healthcare professional

| Product Name: Xolair |  |  |
|----------------------|--|--|
| Diagnosis            | Urticaria  |  |
| Approval Length      | 12/31/2039                                       |  |
| Guideline Type       | Prior Authorization - All plans except IL and MN |  |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| XOLAIR          | OMALIZUMAB SUBCUTANEOUS SOLN PREFILLED<br>SYRINGE 75 MG/0.5ML | 4460306000E510 | Brand         |
| XOLAIR          | OMALIZUMAB SUBCUTANEOUS SOLN PREFILLED SYRINGE 150 MG/ML      | 4460306000E520 | Brand         |

1 - Diagnosis of chronic (at least 3 months), refractory urticaria

#### AND

- 2 Member has tried and failed both of the following:
  - Scheduled, high dose non-sedating antihistamines at least one short course of corticosteroids

#### **AND**

3 - Prescriber attestation that the initial six (6) months of therapy must be done in the clinic setting by a healthcare professional

| Product Name: Xolair               |             |  |
|------------------------------------|-------------|--|
| Diagnosis Immunotherapy            |             |  |
| Approval Length                    | 12 month(s) |  |
| Guideline Type Prior Authorization |             |  |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| XOLAIR          | OMALIZUMAB SUBCUTANEOUS SOLN PREFILLED<br>SYRINGE 75 MG/0.5ML | 4460306000E510 | Brand         |
| XOLAIR          | OMALIZUMAB SUBCUTANEOUS SOLN PREFILLED<br>SYRINGE 150 MG/ML   | 4460306000E520 | Brand         |

# **Approval Criteria**

**1** - Prescribed by an allergist

#### **AND**

**2** - Prescriber attestation that the initial six (6) months of therapy must be done in the clinic setting by a healthcare professional

| Product Name: Xolair |                                       |  |
|----------------------|---------------------------------------|--|
| Diagnosis            | Polyps                                |  |
| Approval Length      | 12 month(s)                           |  |
| Therapy Stage        | Initial Authorization                 |  |
| Guideline Type       | Prior Authorization - IL and MN Plans |  |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| XOLAIR          | OMALIZUMAB SUBCUTANEOUS SOLN PREFILLED<br>SYRINGE 75 MG/0.5ML | 4460306000E510 | Brand         |
| XOLAIR          | OMALIZUMAB SUBCUTANEOUS SOLN PREFILLED<br>SYRINGE 150 MG/ML   | 4460306000E520 | Brand         |

### **Approval Criteria**

**1** - Diagnosis of chronic rhinosinusitis with nasal polyposis

#### AND

- 2 All of the following:
  - At least eight weeks of moderate to severe nasal congestion/blockage/obstruction OR diminished sense of smell or rhinorrhea
  - Submission of medical records (e.g., chart notes) Documented nasal polyps by direct exam, endoscopy, or sinus CT scan (i.e., nasal polyp score five out of eight)
  - No chronic or acute infection requiring systemic treatment within two weeks before therapy initiation

#### AND

**3** - Prescribed by, or in consultation with, a specialist experienced in the treatment of nasal polyps (e.g., Otolaryngologist, Allergist)

#### **AND**

- **4** Trial and failure, contraindication, or intolerance to one of the following:
  - Greater than or equal to 2 nasal steroid sprays (i.e. failed two nasal sprays)
  - IM injections for polyps with one previous nasal spray

#### **AND**

- **5** Trial and failure, contraindication, or intolerance to one of the following:
  - Oral corticosteroids for nasal polyps
  - Prior surgery for nasal polyps greater than six months ago

#### **AND**

**6** - Requested medication will be used in combination with a nasal corticosteroid medication

#### **AND**

**7** - Requested medication will not used in combination with other biologic therapies (e.g. benralizumab, dupilumab, mepolizumab)

#### AND

**8** - Prescriber attestation that the initial six (6) months of therapy must be done in the clinic setting by a healthcare professional

| Product Name: Xolair |  |  |
|----------------------|--|--|
| Diagnosis            | Polyps   |  |
| Approval Length      | 12/31/2039                                       |  |
| Guideline Type       | Prior Authorization - All plans except IL and MN |  |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| XOLAIR          | OMALIZUMAB SUBCUTANEOUS SOLN PREFILLED<br>SYRINGE 75 MG/0.5ML | 4460306000E510 | Brand         |
| XOLAIR          | OMALIZUMAB SUBCUTANEOUS SOLN PREFILLED<br>SYRINGE 150 MG/ML   | 4460306000E520 | Brand         |

1 - Diagnosis of chronic rhinosinusitis with nasal polyposis

#### AND

- 2 All of the following:
  - At least eight weeks of moderate to severe nasal congestion/blockage/obstruction OR diminished sense of smell or rhinorrhea
  - Submission of medical records (e.g., chart notes) Documented nasal polyps by direct exam, endoscopy, or sinus CT scan (i.e., nasal polyp score five out of eight)
  - No chronic or acute infection requiring systemic treatment within two weeks before therapy initiation

#### **AND**

**3** - Prescribed by, or in consultation with, a specialist experienced in the treatment of nasal polyps (e.g., Otolaryngologist, Allergist)

#### **AND**

- **4** Trial and failure, contraindication, or intolerance to one of the following:
  - Greater than or equal to 2 nasal steroid sprays (i.e. failed two nasal sprays)
  - IM injections for polyps with one previous nasal spray

#### **AND**

**5** - Trial and failure, contraindication, or intolerance to one of the following:

- Oral corticosteroids for nasal polyps
- Prior surgery for nasal polyps greater than six months ago

6 - Requested medication will be used in combination with a nasal corticosteroid medication

#### **AND**

**7** - Requested medication will not used in combination with other biologic therapies (e.g. benralizumab, dupilumab, mepolizumab)

#### **AND**

**8** - Prescriber attestation that the initial six (6) months of therapy must be done in the clinic setting by a healthcare professional

| Product Name: Xolair |  |  |
|----------------------|--|--|
| Diagnosis            | All Indications                            |  |
| Approval Length      | 12 month(s)                                |  |
| Therapy Stage        | erapy Stage Reauthorization                |  |
| Guideline Type       | Prior Authorization - IL and MN Plans Only |  |

| Product<br>Name | Generic Name  | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| XOLAIR          | OMALIZUMAB SUBCUTANEOUS SOLN PREFILLED<br>SYRINGE 75 MG/0.5ML | 4460306000E510 | Brand         |
| XOLAIR          | OMALIZUMAB SUBCUTANEOUS SOLN PREFILLED<br>SYRINGE 150 MG/ML   | 4460306000E520 | Brand         |

### **Approval Criteria**

**1** - Submission of medial records documenting a positive clinical response to therapy and improvement in disease state from previous 12 months

- **2** Submission of medical records (e.g., chart notes) documenting from the previous 12 months in improvement to one of the following:
  - Decreased frequency of corticosteroid use to treat or prevent an exacerbation
  - Reductions in symptom exacerbation frequency or intensity
  - Decreased frequency of unscheduled clinic, urgent care or emergency department visits due to asthma
  - Increase in percent predicted FEV1 from pre-treatment baseline
  - Increase in percent predicted FEV1 from pre-treatment baseline
  - Reduction use of ICS, leukotriene or beta agonist therapy
  - Improvement in nasal polyposis score

# 2. Background

| Outcome Measure values for uncontrolled asthma                          |                                   |                                  |  |  |  |
|---|-----------------------------------|----------------------------------|--|--|--|
| Measure   | Not Well Controlled               | Very Poorly Controlled           |  |  |  |
| Baseline symptoms (outside of exacerbation)                             | > 2 days/week                     | Throughout the day               |  |  |  |
| Nighttime awakening   | 1-3 times/week                    | ≥ 4 times/week                   |  |  |  |
| Interference with normal activity                                       | Some limitation                   | Extremely limited                |  |  |  |
| Short acting beta agonist use for symptom control                       | > 2 days/week                     | Several times per day            |  |  |  |
| FEV1  | 60-80% predicted or personal best | < 60% predicted or personal best |  |  |  |
| Asthma exacerbations requiring oral steroids ≥ 2 times in the past year | Yes                               | Yes                              |  |  |  |
| Asthma Control Test (ACT)   | 16-19                             | ≤ 15                             |  |  |  |

# 3. Revision History

| Date      | Notes       |
|-----------|-------------|
| 1/26/2024 | New Program |

| Xuriden (Uridine triacetate)  |  |  |
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| Guideline ID GL-131951 |                              |
|------------------------|------------------------------|
| Guideline Name         | Xuriden (Uridine triacetate) |
| Formulary              | Quartz                       |

# **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

# 1. Criteria

| Product Name: Xuriden |  |
|-----------------------|--|
| Approval Length       | 12 month(s)                              |
| Therapy Stage         | Initial Authorization                    |
| Guideline Type        | Prior Authorization-IL and MN Plans Only |

| Product<br>Name | Generic Name                                    | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| XURIDEN         | URIDINE TRIACETATE ORAL GRANULES PACKET 2<br>GM | 30903875203020 | Brand         |

# **Approval Criteria**

1 - Diagnosis of hereditary orotic aciduria

| Product Name: Xuriden |  |
|-----------------------|--|
| Approval Length       | 12 month(s)                              |
| Therapy Stage         | Reauthorization                          |
| Guideline Type        | Prior Authorization-IL and MN Plans Only |

| Product<br>Name | Generic Name                                    | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| XURIDEN         | URIDINE TRIACETATE ORAL GRANULES PACKET 2<br>GM | 30903875203020 | Brand         |

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug and that there has been a response to therapy (improvement in hematologic counts and urine orotic acid levels).

| Product Name: Xuriden |  |  |
|-----------------------|--|--|
| Approval Length       | 3 month(s)                                     |  |
| Therapy Stage         | Initial Authorization                          |  |
| Guideline Type        | Prior Authorization-All plans except IL and MN |  |

| Product<br>Name | Generic Name                                    | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| XURIDEN         | URIDINE TRIACETATE ORAL GRANULES PACKET 2<br>GM | 30903875203020 | Brand         |

## **Approval Criteria**

1 - Diagnosis of hereditary orotic aciduria

| Product Name: Xuriden   |                       |     |               |
|---|-----------------------|-----|---------------|
| Approval Length 12/31/2039                                    |                       |     |               |
| Therapy St  | Stage Reauthorization |     |               |
| Guideline Type Prior Authorization-All plans except IL and MN |                       |     |               |
| Product Generic Name<br>Name                                  |                       | GPI | Brand/Generic |

| XURIDEN | URIDINE TRIACETATE ORAL GRANULES PACKET 2<br>GM | 30903875203020 | Brand |
|---------|---|----------------|-------|
|---------|---|----------------|-------|

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug and that there has been a response to therapy (improvement in hematologic counts and urine orotic acid levels).

| Date       | Notes       |
|------------|-------------|
| 10/31/2023 | New program |

| Xyrem (sodium oxybate)   |  |  |
|--|--|--|
| State Company and the State of State Company and the State S |  |  |

| Guideline ID                          | GL-131921 |
|---------------------------------------|-----------|
| Guideline Name Xyrem (sodium oxybate) |           |
| Formulary                             | Quartz    |

# **Guideline Note:**

| Effective Date: |
|-----------------|
|-----------------|

# 1. Criteria

| Product Name: Generic Sodium oxybate                    |                                     |  |
|---|-------------------------------------|--|
| Approval Length 12 month(s)                             |                                     |  |
| Therapy Stage   | Therapy Stage Initial Authorization |  |
| Guideline Type Prior Authorization-IL and MN Plans Only |                                     |  |

| Product<br>Name   | Generic Name                           | GPI            | Brand/Generic |
|-------------------|--|----------------|---------------|
| SODIUM<br>OXYBATE | SODIUM OXYBATE ORAL SOLUTION 500 MG/ML | 62450060202020 | Generic       |

# **Approval Criteria**

1 - Diagnosis of cataplexy in narcolepsy or excessive daytime sleepiness in narcolepsy

**2** - Trial and failure, contraindication, or intolerance to one preferred narcolepsy medication (e.g. modafinil, armodafinil)

| Product Name: Generic Sodium oxybate                    |            |                 |     |               |
|---|------------|-----------------|-----|---------------|
| Approval Le   | ength      | 12 month(s)     |     |               |
| Therapy Sta   | age        | Reauthorization |     |               |
| Guideline Type Prior Authorization-IL and MN Plans Only |            |                 |     |               |
| Product   | Generic Na | me              | GPI | Brand/Generic |

| Product<br>Name   | Generic Name                           | GPI            | Brand/Generic |
|-------------------|--|----------------|---------------|
| SODIUM<br>OXYBATE | SODIUM OXYBATE ORAL SOLUTION 500 MG/ML | 62450060202020 | Generic       |

## **Approval Criteria**

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months documenting an improvement in sleepiness symptoms.

| Product Name: Generic Sodium oxybate                          |                                     |  |
|---|-------------------------------------|--|
| Approval Length 3 month(s)                                    |                                     |  |
| Therapy Stage   | Therapy Stage Initial Authorization |  |
| Guideline Type Prior Authorization-All plans except IL and MN |                                     |  |

| Product<br>Name   | Generic Name                           | GPI            | Brand/Generic |
|-------------------|--|----------------|---------------|
| SODIUM<br>OXYBATE | SODIUM OXYBATE ORAL SOLUTION 500 MG/ML | 62450060202020 | Generic       |

## **Approval Criteria**

1 - Diagnosis of cataplexy in narcolepsy or excessive daytime sleepiness in narcolepsy

**2** - Trial and failure, contraindication, or intolerance to one preferred narcolepsy medication (e.g. modafinil, armodafinil)

| Product Name: Generic Sodium oxybate |  |  |
|--------------------------------------|--|--|
| Approval Length 12/31/2039           |  |  |
| Therapy Stage                        | Reauthorization                                |  |
| Guideline Type                       | Prior Authorization-All plans except IL and MN |  |

| Product<br>Name   | Generic Name                           | GPI            | Brand/Generic |
|-------------------|--|----------------|---------------|
| SODIUM<br>OXYBATE | SODIUM OXYBATE ORAL SOLUTION 500 MG/ML | 62450060202020 | Generic       |

## **Approval Criteria**

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months documenting an improvement in sleepiness symptoms.

| Date       | Notes       |
|------------|-------------|
| 10/31/2023 | New program |

| Zep                  | osia (Oz   | animo   | d)   |  |
|----------------------|--|---|------|--|
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|                      |  |   |      |  |

| Guideline ID          | GL-143573          |
|-----------------------|--------------------|
| <b>Guideline Name</b> | Zeposia (Ozanimod) |
| Formulary             | Quartz             |

## **Guideline Note:**

| Effective Date:    | 4/1/2024  |
|--------------------|-----------|
| P&T Approval Date: | 1/17/2023 |
| P&T Revision Date: | 7/18/2023 |

### Note:

Member new to the plan (as evidenced by coverage effective date of less than or equal to 90 days) who initiated therapy using a manufacturer-sponsored free drug program, provider samples, and/or vouchers will go through initial criteria, otherwise for continuation of therapy for new to plan, reauthorization criteria applies

## 1. Criteria

| Product Name: Zeposia             |                 |   |     |               |
|-----------------------------------|-----------------|---|-----|---------------|
| Diagnosis Ulcerative colitis (UC) |                 |   |     |               |
| Approval Length                   |                 | 12/31/2039  |     |               |
| Guideline Type                    |                 | Prior Authorization - Applies to ALL plans except IL and MN |     |               |
| Product<br>Name                   | Generic Name GF |   | GPI | Brand/Generic |

| ZEPOSIA<br>7-DAY<br>STARTER<br>PACK | OZANIMOD CAP PACK 4 X 0.23 MG & 3 X 0.46 MG                | 6240705020B210 | Brand |
|-------------------------------------|--|----------------|-------|
| ZEPOSIA<br>STARTER<br>KIT           | OZANIMOD CAP PACK 4 X 0.23 MG & 3 X 0.46 MG & 21 X 0.92 MG | 6240705020B215 | Brand |
| ZEPOSIA                             | OZANIMOD HCL CAP 0.92 MG                                   | 62407050200120 | Brand |

1 - Diagnosis of moderate to severely active ulcerative colitis (UC)

### **AND**

2 - Prescribed by or in consultation with Gastroenterologist

### **AND**

- **3** One of the following:
- **3.1** All of the following:
- **3.1.1** Member is considered high risk based on at least ONE of the following characteristics:
  - Extensive colitis
  - Deep ulcers
  - Age less than 40 years
  - High CRP and ESR
  - Steroid-requiring disease
  - History of hospitalization (due to UC)
  - C. difficile infection
  - CMV infection

## **AND**

**3.1.2** Trial and failure, intolerance, or contraindication to a short course (2-4 weeks) of oral corticosteroids

### **AND**

- **3.1.3** Trial and failure, intolerance or contraindication to TWO of the following:
  - adalimumab
  - upadacitinib
  - golimumab
  - ustekinumab
  - tofacitinib/ER

### OR

**3.2** Continuation of prior therapy with ozanimod, verified by paid claims or medical records (e.g. chart notes)

| Product Name: Zeposia |                                       |
|-----------------------|---------------------------------------|
| Diagnosis             | Ulcerative colitis (UC)               |
| Approval Length       | 12 month(s)                           |
| Guideline Type        | Prior Authorization - IL and MN Plans |

| Product<br>Name                     | Generic Name   | GPI            | Brand/Generic |
|-------------------------------------|--|----------------|---------------|
| ZEPOSIA<br>7-DAY<br>STARTER<br>PACK | OZANIMOD CAP PACK 4 X 0.23 MG & 3 X 0.46 MG                | 6240705020B210 | Brand         |
| ZEPOSIA<br>STARTER<br>KIT           | OZANIMOD CAP PACK 4 X 0.23 MG & 3 X 0.46 MG & 21 X 0.92 MG | 6240705020B215 | Brand         |
| ZEPOSIA                             | OZANIMOD HCL CAP 0.92 MG                                   | 62407050200120 | Brand         |

## **Approval Criteria**

1 - Diagnosis of moderate to severely active ulcerative colitis (UC)

### **AND**

2 - Prescribed by or in consultation with Gastroenterologist

- 3 One of the following:
- **3.1** All of the following:
- **3.1.1** Member is considered high risk based on at least ONE of the following characteristics:
  - Extensive colitis
  - Deep ulcers
  - Age less than 40 years
  - High CRP and ESR
  - Steroid-requiring disease
  - History of hospitalization (due to UC)
  - C. difficile infection
  - CMV infection

### AND

**3.1.2** Trial and failure, intolerance, or contraindication to a short course (2-4 weeks) of oral corticosteroids

### **AND**

- **3.1.3** Trial and failure, intolerance or contraindication to TWO of the following:
  - adalimumab
  - upadacitinib
  - golimumab
  - ustekinumab
  - tofacitinib/ER

### OR

**3.2** Continuation of prior therapy with ozanimod, verified by paid claims or medical records (e.g. chart notes)

| Product Name: Zeposia |                    |
|-----------------------|--------------------|
| Diagnosis             | Multiple Sclerosis |
| Approval Length       | 12 month(s)        |

| Guideline Type                      |  | Prior Authorization |                |               |
|-------------------------------------|--|---------------------|----------------|---------------|
| Product<br>Name                     | Generic Name   |                     | GPI            | Brand/Generic |
| ZEPOSIA<br>7-DAY<br>STARTER<br>PACK | OZANIMOD CAP PACK 4 X 0.23 MG & 3 X 0.46 MG                |                     | 6240705020B210 | Brand         |
| ZEPOSIA<br>STARTER<br>KIT           | OZANIMOD CAP PACK 4 X 0.23 MG & 3 X 0.46 MG & 21 X 0.92 MG |                     | 6240705020B215 | Brand         |
| ZEPOSIA                             | OZANIMOD HCL CAP 0.92 MG                                   |                     | 62407050200120 | Brand         |

1 - Diagnosis of a relapsing form of multiple sclerosis

**AND** 

2 - Prescribed by or in consultation with a Neurologist

**AND** 

- **3** One of the following:
- **3.1** Paid claims or submission of medical records (e.g. chart notes) show there have been adequate trials of ALL appropriate formulary therapeutic alternatives and there was (a) inadequate clinical response, (b) inappropriate clinical response, (c) intolerance or (d) allergy to those medications

OR

**3.2** An exception to the formulary may be considered when ALL appropriate formulary therapeutic alternatives have not been tried and there is submission of medical record documentation (e.g. chart notes) demonstrating that ALL appropriate formulary therapeutic alternatives will be (a) ineffective, (b) less effective or (c) will result in adverse effects

| Date      | Notes       |
|-----------|-------------|
| 2/29/2024 | New Program |

| Zokinvy (Lonafarnib)   |
|--|
| S hardway was halpen. Tolk as hardware was a stand and sell and halpen hardware. |

| Guideline ID   | GL-129641            |  |
|----------------|----------------------|--|
| Guideline Name | Zokinvy (Lonafarnib) |  |
| Formulary      | Quartz               |  |

# **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

# 1. Criteria

| Product Name: Zokinvy              |                       |
|------------------------------------|-----------------------|
| Approval Length                    | 12 month(s)           |
| Therapy Stage                      | Initial Authorization |
| Guideline Type Prior Authorization |                       |

| Product<br>Name | Generic Name         | GPI            | Brand/Generic |
|-----------------|----------------------|----------------|---------------|
| ZOKINVY         | LONAFARNIB CAP 50 MG | 99463045000120 | Brand         |
| ZOKINVY         | LONAFARNIB CAP 75 MG | 99463045000130 | Brand         |

## **Approval Criteria**

1 - Diagnosis of Hutchinson-Gilford progeria syndrome OR other FDA approved diagnosis

**2** - Prescribed by, or in consultation with, a specialist in the treatment of progeria or related-syndromes

| Product Name: Zokinvy              |                 |
|------------------------------------|-----------------|
| Approval Length                    | 12 month(s)     |
| Therapy Stage                      | Reauthorization |
| Guideline Type Prior Authorization |                 |

| Product<br>Name | Generic Name         | GPI            | Brand/Generic |
|-----------------|----------------------|----------------|---------------|
| ZOKINVY         | LONAFARNIB CAP 50 MG | 99463045000120 | Brand         |
| ZOKINVY         | LONAFARNIB CAP 75 MG | 99463045000130 | Brand         |

## **Approval Criteria**

**1** - The prescriber must provide clinical documentation from an office visit in the preceding 12 months that use of the drug has slowed the disease progression and function is improved relative to the expected natural course of the disease.

| Date      | Notes       |
|-----------|-------------|
| 10/6/2023 | New Program |

| Zontivity (vorapaxar)  |  |  |  |  |
|--|--|--|--|--|
| (g) the following mort indigent. To this as teacher most or most of last last last last last the most the most the most than the following the most than the most the most than the most the most than the most the most the most than the most the |  |  |  |  |
|  |  |  |  |  |

| Guideline ID          | GL-132750             |  |
|-----------------------|-----------------------|--|
| <b>Guideline Name</b> | Zontivity (vorapaxar) |  |
| Formulary             | Quartz                |  |

## **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

## Note:

Member new to the plan (as evidenced by coverage effective date of less than or equal to 90 days) who initiated therapy using a manufacturer-sponsored free drug program, provider samples, and/or vouchers will go through initial criteria, otherwise for continuation of therapy for new to plan, reauthorization criteria applies

## 1. Criteria

| Product Name: Zontivity |   |  |                |               |
|-------------------------|---|--|----------------|---------------|
| Approval Length         |   | 12/31/2039   |                |               |
| Guideline Type          |   | Prior Authorization - All plans except IL and MN Plans |                |               |
| Product<br>Name         | Generic Name  |  | GPI            | Brand/Generic |
| ZONTIVITY               | ZONTIVITY VORAPAXAR SULFATE TAB 2.08 MG (BASE EQUIVALENT) |  | 85155780300320 | Brand         |
|                         |   |  |                |               |

- **1** Diagnosis of one of the following:
  - Peripheral Arterial Disease (PAD)
  - History of myocardial infarction (MI)

### **AND**

2 - Prescribed by or in consultation with a Cardiologist

### AND

**3** - Submission of medical records (e.g., chart notes) documenting increased risk of thrombotic cardiovascular events despite being on combination therapy with BOTH aspirin and P2Y12 therapy (e.g., clopidogrel, ticagrelor, or prasugrel)

| Product Name: Zontivity                              |                       |
|--|-----------------------|
| Approval Length 12 month(s)                          |                       |
| Therapy Stage  | Initial Authorization |
| Guideline Type Prior Authorization - IL and MN Plans |                       |

| Product<br>Name | Generic Name                                    | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| ZONTIVITY       | VORAPAXAR SULFATE TAB 2.08 MG (BASE EQUIVALENT) | 85155780300320 | Brand         |

### **Approval Criteria**

- **1** Diagnosis of one of the following:
  - Peripheral Arterial Disease (PAD)
  - History of myocardial infarction (MI)

#### **AND**

2 - Prescribed by or in consultation with a Cardiologist

### **AND**

**3** - Submission of medical records (e.g., chart notes) documenting increased risk of thrombotic cardiovascular events despite being on combination therapy with BOTH aspirin and P2Y12 therapy (e.g., clopidogrel, ticagrelor, or prasugrel)

| Product Name: Zontivity |                                       |  |
|-------------------------|---------------------------------------|--|
| Approval Length         | 12 month(s)                           |  |
| Therapy Stage           | Reauthorization                       |  |
| Guideline Type          | Prior Authorization - IL and MN Plans |  |

| Product<br>Name | Generic Name                                    | GPI            | Brand/Generic |
|-----------------|---|----------------|---------------|
| ZONTIVITY       | VORAPAXAR SULFATE TAB 2.08 MG (BASE EQUIVALENT) | 85155780300320 | Brand         |

## **Approval Criteria**

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug

| Date     | Notes                   |
|----------|-------------------------|
| 9/7/2023 | 2024 New Implementation |

| Zory                                    | Zoryve (roflumilast cream)   |                   |  |
|---|--|-------------------|--|
| Ther hit and image contrast its oliquid | kyed. Turkh may hara hann manai, rawanii, or daladai iladiy dada hai yainen ha | avenille ad halas |  |

| Guideline ID          | GL-131913                  |
|-----------------------|----------------------------|
| <b>Guideline Name</b> | Zoryve (roflumilast cream) |
| Formulary             | Quartz                     |

# **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

# 1. Criteria

| Product Na                 | Product Name: Zoryve   |  |                |               |
|----------------------------|------------------------|--|----------------|---------------|
| Approval Length 12/31/2039 |                        |  |                |               |
| Guideline Type             |                        | Prior Authorization – All plans except IL and MN plans |                |               |
| Product<br>Name            |                        |  | GPI            | Brand/Generic |
| ZORYVE                     | ROFLUMILAST CREAM 0.3% |  | 90250045003720 | Brand         |

# **Approval Criteria**

1 - Diagnosis of psoriasis

|                                  |   | AND                                     |                      |               |
|----------------------------------|---|---|----------------------|---------------|
| <b>2</b> - 12 years              | s or older  |   |                      |               |
|                                  |   |   |                      |               |
|                                  |   | AND                                     |                      |               |
| <b>3</b> - Prescrib psoriasis    | ed by, or in  | consultation with a dermatologist, or o | ther specialist in t | he treatment  |
|                                  |   | AND                                     |                      |               |
| <b>4</b> - One of t              | he following  | :                                       |                      |               |
| pote<br>listir<br>• Pers<br>cont | <ul> <li>Trial and failure, contraindication, or intolerance to one preferred high or super-high potency topical corticosteroid (see the formulary at QuartzBenefits.com for a complete listing of options)</li> <li>Person has facial or other sensitive area involvement and a trial and failure, contraindication, or intolerance to one preferred non steroid therapy (e.g., calcipotriene, retinoids)</li> </ul> |   |                      |               |
|                                  |   |   |                      |               |
| Product Na                       | me: Zoryve  |   |                      |               |
| Approval Le                      | ength   | 12 month(s)                             |                      |               |
| Therapy Sta                      | age   | Initial Authorization                   |                      |               |
| Guideline T                      | уре   | Prior Authorization- II and MN plans    |                      |               |
| Product<br>Name                  | Generic Na  | me                                      | GPI                  | Brand/Generic |
| ZORYVE                           | ROFLUMILAS  | ST CREAM 0.3%                           | 90250045003720       | Brand         |
|                                  | Approval Criteria  1 - Diagnosis of psoriasis   |   |                      |               |
|                                  |   | AND                                     |                      |               |

2 - 12 years or older

#### **AND**

**3** - Prescribed by, or in consultation with a dermatologist, or other specialist in the treatment psoriasis

### **AND**

- **4** One of the following:
  - Trial and failure, contraindication, or intolerance to one preferred high or super-high potency topical corticosteroid (see the formulary at QuartzBenefits.com for a complete listing of options)
  - Person has facial or other sensitive area involvement and a trial and failure, contraindication, or intolerance to one preferred non steroid therapy (e.g., calcipotriene, retinoids)

| Product Name: Zoryve |                                      |  |
|----------------------|--------------------------------------|--|
| Approval Length      | 12/31/2039                           |  |
| Therapy Stage        | Reauthorization                      |  |
| Guideline Type       | Prior Authorization- II and MN plans |  |

| Product<br>Name | Generic Name           | GPI            | Brand/Generic |
|-----------------|------------------------|----------------|---------------|
| ZORYVE          | ROFLUMILAST CREAM 0.3% | 90250045003720 | Brand         |

## **Approval Criteria**

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug

| Date | Notes |
|------|-------|
|      |       |

| 10/31/2023 | New Program |
|------------|-------------|
|------------|-------------|

| Ztlido (Lidocaine Patch) |   |  |  |  |
|--------------------------|---|--|--|--|
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|                          |   |  |  |  |

| Guideline ID          | GL-129640                |
|-----------------------|--------------------------|
| <b>Guideline Name</b> | Ztlido (Lidocaine Patch) |
| Formulary             | Quartz                   |

# **Guideline Note:**

| Effective Date: | 1/1/2024 |
|-----------------|----------|
|-----------------|----------|

# 1. Criteria

| Product Name: Ztlido |                                       |
|----------------------|---------------------------------------|
| Approval Length      | 12 month(s)                           |
| Therapy Stage        | Initial Authorization                 |
| Guideline Type       | Prior Authorization - IL and MN Plans |

| Product<br>Name | Generic Name                 | GPI            | Brand/Generic |
|-----------------|------------------------------|----------------|---------------|
| ZTLIDO          | LIDOCAINE PATCH 1.8% (36 MG) | 90850060005910 | Brand         |

# **Approval Criteria**

**1** - Person with a diagnosis of post-herpetic neuralgia

**2** - Trial and failure, contraindication or intolerance of an equivalent dose of generic lidocaine 5% transdermal patches

### **AND**

**3** - Trial and failure, contraindication or intolerance to at least one other preferred drug with evidence for reducing symptoms of post-herpetic neuralgia symptoms

### **AND**

**4** - The prescriber provides an evidence-based clinical rationale for why different results from those seen with generic 5% lidocaine patches would be expected

### OR

**5** - (Minnesota plans only) – the person has stage four metastatic cancer and the requested drug is being used to treat cancer-related pain

| Product Name: Ztlido |                                       |
|----------------------|---------------------------------------|
| Approval Length      | 12 month(s)                           |
| Therapy Stage        | Reauthorization                       |
| Guideline Type       | Prior Authorization - IL and MN Plans |

| Product<br>Name | Generic Name                 | GPI            | Brand/Generic |
|-----------------|------------------------------|----------------|---------------|
| ZTLIDO          | LIDOCAINE PATCH 1.8% (36 MG) | 90850060005910 | Brand         |

### **Approval Criteria**

**1** - Submission of medical records (e.g., chart notes) documenting that within the past 12 months the member is continuing therapy with the requested drug.

Product Name: Ztlido

| Approval Length | 12/31/2039                                       |
|-----------------|--|
| Guideline Type  | Prior Authorization - All plans except IL and MN |

| Product<br>Name | Generic Name                 | GPI            | Brand/Generic |
|-----------------|------------------------------|----------------|---------------|
| ZTLIDO          | LIDOCAINE PATCH 1.8% (36 MG) | 90850060005910 | Brand         |

1 - Person with a diagnosis of post-herpetic neuralgia

### **AND**

**2** - Trial and failure, contraindication or intolerance of an equivalent dose of generic lidocaine 5% transdermal patches

#### **AND**

**3** - Trial and failure, contraindication or intolerance to at least one other preferred drug with evidence for reducing symptoms of post-herpetic neuralgia symptoms

### **AND**

**4** - The prescriber provides an evidence-based clinical rationale for why different results from those seen with generic 5% lidocaine patches would be expected

| Date      | Notes       |
|-----------|-------------|
| 10/6/2023 | New Program |