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

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

BadgerCare Plus members must call the Wisconsin Department of Health and Family Services at (800) 362-3002 or visit www.forwardhealth.wi.gov for information about your prescription drug benefits.
Agalsidase Beta (Fabrazyme®)
Prior Authorization Criteria

FORMULARY STATUS: Medical Benefit-Restricted (Infusion)

APPROVAL LIMITS: None

QUANTITY LIMITS: 1mg/kg IV infusion every two weeks

CRITERIA FOR COVERAGE:
• Prescribed by or in consultation of an expert in the treatment of Fabry’s Disease
  AND
• Diagnosis of Fabry’s Disease
  AND
• Will not be used in combination with migalastat
**Alglucosidase alfa (Myozyme/Lumizyme)**  
Prior Authorization Criteria

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Drug Status</th>
<th>Quantity Limits</th>
<th>Approval Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alglucosidase alfa</td>
<td>Medical Benefit-Restricted</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>(Lumizyme, Myozyme)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**CRITERIA FOR COVERAGE:**

- Covered for persons with a diagnosis of Pompe disease
**Alosetron**

**Prior Authorization Criteria**

**FORMULARY STATUS:** Nonpreferred-Restricted

**APPROVAL LIMITS:** None

**QUANTITY LIMITS:**
- 0.5mg- #90/30 days,
- 1mg- #60/30 days

**CRITERIA FOR COVERAGE:**
- Person with diarrhea- predominant irritable bowel syndrome (IBS)  
  **AND**  
- Prescribed by physician certified in the alosetron REMS Program  
  **AND**  
- Failed one-month trial of conventional therapy (such as loperamide or diphenoxylate/atropine)

**CRITERIA FOR COVERAGE OF QUANTITY EXCEPTIONS:**
- Therapeutic failure or intolerance to use of the commercially available dose forms within the quantity limits and the prescriber provides an evidence-based clinical rationale or use of a dose outside of the quantity limit

**CONTINUATION OF COVERAGE CRITERIA:**
- Persons new to coverage 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.
- Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.
Alpha-1 Proteinase Inhibitors (Aralast NP, Glassia, Prolastin-C, Zemaira)
Prior Authorization Criteria

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Drug Status</th>
<th>Quantity Limits</th>
<th>Approval Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alpha-1 Proteinase inhibitor (Aralast NP, Glassia, Prolastin-C, Zemaria)</td>
<td>Medical Benefit-Restricted</td>
<td>None</td>
<td>None</td>
</tr>
</tbody>
</table>

**CRITERIA FOR COVERAGE:**
- Alpha-1 proteinase deficient (< 11 mcmol/L)
- Person is no longer smoking
- Evidence of COPD (FEV₁ 25% to 80% predicted) attributable to emphysema
- Maximized COPD therapy based on GOLD guidelines
Amifampridine (Firdapse, Ruzurgi)
Prior Authorization Criteria

FORMULARY STATUS: Nonpreferred-Restricted

APPROVAL LIMITS: 12 Months

QUANTITY LIMITS:
- Amifampridine (Firdapse) - Eight tablets per day (#240)
- Amifampridine (Ruzurgi) - <45kg Five tablets per day OR ≥45kg Ten tablets per day

CRITERIA FOR COVERAGE:
- Prescriber is an expert in the treatment of neuromuscular disorders
- Person has a diagnosis of Lambert-Eaton myasthenic syndrome (LEMS) confirmed by neurophysiology studies or a positive anti-P/Q type voltage-gated calcium channel antibody test

CRITERIA FOR QUANTITY EXCEPTIONS:
- The prescriber provides an evidence-based clinical reason for using a dose outside of the quantity limits

CRITERIA FOR CONTINUATION OF COVERAGE:
- Documentation from the previous 12 months of therapy indicating improvement or stabilization in muscle weakness compared to baseline.
- For members new to plan, the prescriber must provide clinical documentation from the previous 12 months regarding the member's response to therapy with improvement or stabilization in muscle weakness compared to baseline.
- Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.

FOR BADGERCARE COVERAGE (Firdapse Only):
- Medication must be billed to ForwardHealth under the pharmacy benefit. Refer to the ForwardHealth policy “Select High Cost, Orphan, and Accelerated Approval Drugs” for additional information.
Amikacin Inhaled (Arikayce)
Prior Authorization Criteria

**FORMULARY STATUS:** Nonpreferred-Restricted

**APPROVAL LIMITS:**
- Initial: 6 months
- Renewal: 12 months x 1

**QUANTITY LIMITS:** One neb/day (#30)

**CRITERIA FOR COVERAGE:**
- Prescribed by, or in consultation with, an Infectious Disease expert
- Covered for adults with Mycobacterium avium complex (MAC) lung disease
- Documentation of positive sputum cultures despite at least 6 months of multidrug background guideline-based therapy
- Used in combination with guideline-based therapy

**CRITERIA FOR QUANTITY EXCEPTIONS:**
- Prescriber provides an evidence-based clinical rationale for using a dose outside of the quantity limit

**CRITERIA FOR CONTINUATION/RENEWAL:**
- Initial criteria were met
- Person achieves and/or maintains negative sputum culture status by month 6
<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Drug Status</th>
<th>Quantity Limits/Day</th>
<th>Approval Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anakinra (Kineret)</td>
<td>Nonpreferred-Restricted</td>
<td>1</td>
<td>None</td>
</tr>
</tbody>
</table>

**CRITERIA FOR COVERAGE (prescription benefit):**
- Prescribed by a Rheumatologist
- Medication must be self-administered
AND
1. **A diagnosis of** moderate to severely active rheumatoid arthritis (RA), reactive arthritis, juvenile idiopathic arthritis (JIA) and failure of two other biologic DMARD therapies such as etanercept, adalimumab, certolizumab, golimumab or infliximab.
OR
2. **A diagnosis of** cryopyrin associated periodic syndromes (CAPS) including Muckle Wells, neonatal-onset multisystemic inflammatory disorder, familial cold autoinflammatory syndrome, or other periodic syndromes.
OR
3. **A diagnosis of** systemic juvenile arthritis or adult-onset Still’s disease and failure, intolerance, or contraindication to an adequate trial of a scheduled prescription dosed NSAID and glucocorticoids

**CRITERIA FOR COVERAGE OF QUANTITY EXCEPTIONS:**
- Therapeutic failure or intolerance to one dose unit per day for available strengths and the prescriber provides an evidence-based clinical rationale for using a dose outside of the quantity limit.

**CRITERIA FOR CONTINUATION OF THERAPY (rheumatological diagnoses only):**
- Prescriber provides clinical documentation from the previous 12 months that describes the person’s response as stable disease or improvement seen on therapy.
- Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.

**IMPORTANT INFORMATION:**
Although anakinra is FDA-labeled for use in moderate to severely active RA, it is not the preferred choice for this diagnosis as other therapies are better tolerated and have greater efficacy for this indication.
### Antifibrotic Agents

#### Prior Authorization Criteria

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Formulary Status</th>
<th>Quantity Limits/Day</th>
<th>Approval Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pirfenidone (Esbriet)</td>
<td>Preferred-Restricted</td>
<td>267 mg capsules - 9/day, 801 mg tablets - 3/day</td>
<td>None</td>
</tr>
<tr>
<td>Nintedanib (Ofev)</td>
<td>Preferred-Restricted</td>
<td>2</td>
<td>None</td>
</tr>
</tbody>
</table>

**CRITERIA FOR COVERAGE:**

- Age ≥ 18
- Prescribed by a Pulmonologist
- Medications are included in the Specialty Medications Outcomes Management program. Drug must be obtained from one of the Specialty Pharmacies. Please refer to the Pharmacy Benefits section of the website.

**AND**

1) **For pirfenidone (Esbriet):**
   - General criteria met
   - Diagnosed with idiopathic pulmonary fibrosis (IPF) confirmed by high-resolution computed tomography or other FDA labeled indications.

2) **For nintedanib (Ofev):**
   - General criteria met
   - Diagnosed with idiopathic pulmonary fibrosis (IPF) confirmed by high-resolution computed tomography, **OR** Diagnosed with systemic sclerosis associated lung disease (SSc-ILD)
   - Failure, intolerance or contraindication to cyclophosphamide
   **OR**
   - Diagnosed with other FDA labeled indications.

**IMPORTANT INFORMATION**

- Combination pirfenidone and nintedanib therapy or other indications must be submitted with peer reviewed medical literature to support the proven efficacy and safety of the requested use along with the clinical rationale to support medical necessity for use.
### Restricted Antipsychotics

#### Prior Authorization Criteria

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Drug Status</th>
<th>Quantity Limits/Day</th>
<th>Approval Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aripiprazole (Abilify Discmelt equiv.)</td>
<td>Nonpreferred-Restricted</td>
<td>1</td>
<td>None</td>
</tr>
<tr>
<td>Asenapine (Saphris)</td>
<td>Nonpreferred-Restricted</td>
<td>2</td>
<td>None</td>
</tr>
<tr>
<td>Cariprazine (Vraylar)</td>
<td>Nonpreferred-Restricted</td>
<td>1</td>
<td>None</td>
</tr>
<tr>
<td>Iloperidone (Fanapt)</td>
<td>Nonpreferred-Restricted</td>
<td></td>
<td>None</td>
</tr>
<tr>
<td>Lurasidone (Latuda)</td>
<td>Nonpreferred-Restricted</td>
<td>1</td>
<td>None</td>
</tr>
</tbody>
</table>

#### CRITERIA FOR COVERAGE (asenapine, cariprazine, iloperidone, lurasidone):
- Therapeutic failure after an adequate trial with, or development of a clinically significant intolerance to, at least one preferred second-generation antipsychotic (aripiprazole, olanzapine, risperidone, quetiapine, or ziprasidone).

#### CRITERIA FOR COVERAGE (Abilify discmelt generic equivalent):
- Person is established on an equivalent aripiprazole dose with objective clinical documentation of response to therapy.
- Person has breakthrough symptoms due to documented poor adherence (a medication possession ratio (MPR ≤ 60% based on the previous 6 months of claims) despite interventions from a pharmacist and other health care providers.
- At least one additional generic second-generation antipsychotic did not control symptoms or caused side effects.

#### CONTINUATION OF COVERAGE CRITERIA:
- Persons new to the plan (see below for members with MN plans) who are being treated for depression or other mood disorders and are established on therapy will have coverage under their drug benefit with documentation of symptom improvement or disease stability.
- Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.

#### CRITERIA FOR QUANTITY EXCEPTIONS:
• Failure or intolerance to use of the commercially available dose forms within the quantity limit and the prescriber provides an evidence-based clinical rationale for using a dose outside of the quantity limits.

MINNESOTA PLANS ONLY:
• When prescribed for emotional disturbance or mental illness, approve if prescriber provides written documentation that all equivalent drugs in the formulary were considered and it has been determined that the drug prescribed will best treat the patient's condition.
• For continuation of care: (i.e. formulary changes or new member) approve if the drug was working, as long as:
  o The person has been treated with the drug for 90 days prior to the change AND
  o Prescriber provides written documentation that the drug prescribed will best treat the patient's condition.
Asfotase alfa (Strengiq)
Prior Authorization Criteria

FORMULARY STATUS: Nonpreferred-Restricted

APPROVAL LIMITS: 12 months

QUANTITY LIMITS: None

CRITERIA FOR COVERAGE:
• Initiated by an Endocrinologist
AND
• Covered for persons with a diagnosis of perinatal, infantile, or juvenile-onset hypophosphatasia (HPP) with symptom onset by age 6 months
AND
• documented hypophosphatasia-related skeletal disease

CONTINUATION OF COVERAGE CRITERIA:
• The prescriber provides clinical documentation from the previous 12 months demonstrating objective improvements in skeletal quality from baseline
Thrombopoietin Receptor Agonists For Liver Failure
Prior Authorization Criteria

FORMULARY STATUS:
Apatrombopag - Nonpreferred-Restricted
Lusutrombopag - Nonpreferred-Restricted

APPROVAL LIMITS:
Apatrombopag - Surgery: 5 days (1 fill)
cITP: initial 6 months, renewal 12 Months
Lusutrombopag - Surgery: Three tablets per day
    cITP: Two tablets per day
    7 days (1 fill)

QUANTITY LIMITS:
Apatrombopag - Surgery: Three tablets per day
    cITP: Two tablets per day
    One tablet per day (#7)
Lusutrombopag - One tablet per day (#7)

CRITERIA FOR COVERAGE:
• Prescribed by Hematology
AND
• Platelet count < 50,000/mL due to liver cirrhosis
AND
• Scheduled procedure with moderate to high bleeding risk scheduled in the next 14 days
OR
• Treatment of thrombocytopenia in adult patients with chronic immune thrombocytopenia (cITP) who had an insufficient response to previous therapies
  • Failure or intolerance to steroids and IVIG AND
  • Inadequate response to splenectomy OR rituximab

CRITERIA FOR COVERAGE OF QUANTITY EXCEPTIONS:
• The prescriber provides an evidence-based rationale for using a dose outside of the quantity limit.

CRITERIA FOR DURATION EXCEPTIONS:
• The prescriber provides published evidence to support a duration of treatment greater than 14 days.

CONTINUATION CRITERIA:
• Documentation of clinical response with increase in platelet count (ex: above 50,000 per microliter)

DEFINITION
Chronic platelet count defined as at least two separate readings
Azelaic acid (Azelex, Finacea)
Prior Authorization Criteria

**FORMULARY STATUS:**
Azelaic acid 20% (Azelex): Nonpreferred-Restricted
Azelaic acid 15% (Finacea equivalent): Nonpreferred-Restricted

**APPROVAL LIMITS:**
None

**QUANTITY LIMITS:**
None

**CRITERIA FOR COVERAGE:**
1. For azelaic acid 15% (Finacea)
   - Diagnosis of rosacea
   OR
   - Diagnosis of acne AND failure/intolerance of tretinoin and adapalene

2. For azelaic acid 20% (Azelex)
   - Diagnosis of acne
   AND
   - Failure/intolerance of tretinoin and adapalene
Aztreonam Inhalation Solution (Cayston)
Prior Authorization Criteria

**FORMULARY STATUS:** Preferred-Restricted

**APPROVAL LIMITS:** None

**QUANTITY LIMITS:** Three doses per day (#84 doses/28 days)

**CRITERIA FOR COVERAGE:**
- Person with a diagnosis of cystic fibrosis
  
  **AND**
  
  - History of recurrent *Pseudomonas aeruginosa* lung infections
    
    **AND**
    
    - For inhalation only
      
      **AND**
      
      - Recurrence despite prior use of tobramycin inhalation solution or documented tobramycin resistance

**CRITERIA FOR COVERAGE OF QUANTITY EXCEPTIONS:**
- Therapeutic failure to three times daily dosing and the prescriber provides an evidence-based clinical rationale for using a dose outside of the quantity limit.

**IMPORTANT INFORMATION:**
For chronic suppressive therapy, dosing regimen is 28 days on, 28 days off repeating.
Belimumab (Benlysta)
Prior Authorization Criteria

FORMULARY STATUS: Nonpreferred-Restricted (Subcutaneous Injection)
Medical Benefit-Restricted (Infusion)

APPROVAL LIMITS: 12 months

QUANTITY LIMITS: One injection per week (#4 per fill)

CRITERIA FOR COVERAGE:
• Prescribed by a Rheumatologist or other expert in the treatment of systemic lupus erythematosus (SLE)
   AND
• Diagnosis of auto-antibody positive moderate to severe SLE but not severe active lupus nephritis or severe active central nervous system lupus
   AND
• Symptoms persist despite treatment with hydroxychloroquine, nonsteroidal anti-inflammatories (NSAIDS such as ibuprofen, naproxen, etc.), a steroid-sparing immunosuppressive such as azathioprine or methotrexate, and a short course of oral steroids.
   AND
• Prescription benefit medications are included in the Specialty Pharmaceuticals Program. Medications except where noted must be obtained from one of the participating pharmacies. Contact 1-866-894-3784 or 877.208.1096 for more details.
   AND
• Prescription benefit medications must be self-administered

CRITERIA FOR COVERAGE (For infusion):
• Inability to self-administer weekly injection despite adequate teaching and interventions from a pharmacist and other health care providers

CRITERIA FOR COVERAGE OF QUANTITY EXCEPTIONS:
• Symptoms persist despite treatment with one injection per week and the prescriber provides an evidence-based clinical rationale for use of a dose outside of the quantity limit

CRITERIA FOR CONTINUATION OF COVERAGE:
• Clinical documentation from the previous 12 months demonstrating benefits from therapy
• (Infusion) Inability to self-administer weekly injection despite adequate teaching and interventions from a pharmacist and other health care providers
• Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers

IMPORTANT INFORMATION:
Should not be used in combination with other biologics or IV cyclophosphamide
Bezlotoxumab (Zinplava®)
Prior Authorization Criteria

FORMULARY STATUS: Medical benefit-Restricted

APPROVAL LIMITS: One dose

QUANTITY LIMITS: None

CRITERIA FOR COVERAGE:
• Person is 18 years or older
AND
• Prescribed by, or in consultation with, an Infectious Disease specialist
AND
• Has a confirmed diagnosis of current C diff infection and a positive stool test for toxigenic C difficile from a recent stool sample
AND
• Has recurrent/refractory C diff infection
AND
• Must be currently on standard of care antibiotics for C diff (vancomycin, fidaxomicin)
AND
• Person has had a therapeutic failure, intolerance, or contraindication to fecal microbiota transplantation (FMT)

Important information: Use of bezlotoxumab has only been evaluated as a one-time infusion; coverage for additional infusions is considered experimental and will not be covered.
Biologic Therapy for Dermatology
Prior Authorization Criteria

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Drug Status</th>
<th>Quantity Limits (maintenance/28 days) based on indication</th>
<th>Approval Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>First Line Agents:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adalimumab (Humira)</td>
<td>Preferred Restricted</td>
<td>#2 #4 for HS indication</td>
<td>12 months</td>
</tr>
<tr>
<td>Apremilast (Otezla)-considered biologic DMARD</td>
<td>Preferred Restricted</td>
<td>#60</td>
<td>12 months</td>
</tr>
<tr>
<td>Etanercept (Enbrel)</td>
<td>Preferred Restricted</td>
<td>25 mg #8 50 mg #4</td>
<td>12 months</td>
</tr>
<tr>
<td>Infliximab-biosimilar (Inflectra, Renflexis)</td>
<td>Medical Benefit Restricted</td>
<td>N/A</td>
<td>12 months</td>
</tr>
<tr>
<td>Risankizumab (Skyrizi)</td>
<td>Preferred Restricted</td>
<td>#2</td>
<td>12 months</td>
</tr>
<tr>
<td>Secukinumab (Cosentyx)</td>
<td>Preferred Restricted</td>
<td>#2 (150 mg)</td>
<td>12 months</td>
</tr>
<tr>
<td><strong>Second Line Agents:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Certolizumab (Cimzia)</td>
<td>Nonpreferred Restricted</td>
<td>#1kit</td>
<td>12 months</td>
</tr>
<tr>
<td>Guselkumab (Tremfya)</td>
<td>Nonpreferred Restricted</td>
<td>#1 every 8 weeks</td>
<td>12 months</td>
</tr>
<tr>
<td>Tildrakizumab (Ilumya)</td>
<td>Medical Benefit Restricted</td>
<td>#1 every 12 weeks</td>
<td>12 months</td>
</tr>
<tr>
<td>Ustekinumab (Stelara)</td>
<td>Nonpreferred Restricted</td>
<td>#1 every 12 weeks</td>
<td>12 months</td>
</tr>
<tr>
<td>Ustekinumab (Stelara)</td>
<td>Medical Benefit Restricted</td>
<td>N/A</td>
<td>12 months</td>
</tr>
<tr>
<td><strong>Third Line Agents</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Infliximab-brand (Remicade)</td>
<td>Not Covered Medical Benefit</td>
<td>N/A</td>
<td>12 months</td>
</tr>
</tbody>
</table>

*Induction therapy is covered if criteria met for specific indication and starter kits for loading doses where applicable are used.*

**PSORIASIS GENERAL CRITERIA FOR COVERAGE:**
1. Prescribed by a Dermatologist

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2. Prescription benefit medications must be self-administered and are included in the Specialty Pharmaceuticals Program. Medications must be obtained from one of the Specialty Pharmacies.
   a. Contact 1-866-894-3784 or 877-208-1096 for more details.
   b. Specialty Pharmaceuticals Program Information.

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

4. Diagnosis of severe plaque psoriasis with significant functional disability BSA involvement (>30%) AND Clinical failure/intolerance to at least one prior therapy. Details including medication, dose, potency, duration must be provided for each therapy. Include details of topical therapies, oral therapies and type of phototherapy used in past.

OR

5. Diagnosis of moderate to severe plaque psoriasis with significant functional disability:
   a. BSA involvement (>10%) OR debilitating palmar/plantar psoriasis or other vulnerable areas that are difficult to treat such as nails, hairy/scalp areas, genitals or intertriginous areas
   b. Clinical failure of prior therapy or contraindication to: Details including medication, dose, potency, duration must be provided for each therapy.
      i. Topical: (e.g. topical corticosteroids, calcipotriene, retinoids) AND
      ii. Oral Therapy: (e.g. methotrexate) {DOES NOT include apremilast} AND
      iii. Phototherapy: (e.g. broad band UVB, narrow band UVB, PUVA, excimer)
         1. If clinic-based phototherapy - record of phototherapy episodes provided.
            Adherence defined as 3 times per week for one month or if necessary, modified regimen based on required adjustments for tolerability
         2. If home-based phototherapy - provision of data log recording use and dose adjustments as need for tolerability

Failure is defined as the inability to achieve a clinically significant reduction in plaque thickness and/or erythema and/or scaling and/or itching and lack of clinically significant reduction in the BSA despite adherence to prescribed regimen for a minimum of 12 weeks (topical, systemic) and 4 weeks at maintenance phototherapy. Inability to attend phototherapy sessions will not constitute failure.

Note: For psoriatic arthritis, refer to the Rheumatology Biologic Therapy criteria

**DRUG SPECIFIC CRITERIA FOR TREATMENT OF MODERATE to SEVERE PLAQUE PSORIASIS:**

For adalimumab
- General criteria met

For apremilast (Considered Biologic DMARD)
- General criteria met

For etanercept
- General criteria met

For infliximab biosimilar
- General criteria met

For risankizumab
- General criteria met

For secukinumab
- General criteria met
For certolizumab
- General criteria met
AND
- Failure/ intolerance to three preferred first-line RX benefit biologic DMARDs included in table OR in female patient with current pregnancy or intent for soon pregnancy (does not cross placental barrier). Product choices should be from differing MOA)

For guselkumab:
- General criteria met
AND
- Failure/ intolerance to three preferred first-line RX benefit biologic DMARDs included in table (with at least one from same MOA)

For tildrakizumab:
- General criteria met
AND
- Failure/ intolerance to three preferred first-line RX benefit biologic included in table (with at least one from same MOA)

For ustekinumab
- General criteria met
AND
- For adolescent patients age 12-18, after failure of adequate trial of etanercept (Enbrel)
OR
- Failure/ intolerance to two preferred first-line RX benefit biologic DMARDs included in table AND
  Failure/intolerance to two second line RX benefit biologic DMARDs included in table.
- For clinic administration – documentation of inability to self-administer injections

HIDRADENITIS SUPPURATIVA (HS) CRITERIA FOR COVERAGE:
1. Prescribed by a Dermatologist
AND
2. Severe and/or refractory disease (Hurley II/Hurley III stage) with lesions despite previous treatment with topical antibiotics, systemic antibiotics, intralesional glucocorticoids, and/or surgical debridement

Therapy options:
- Adalimumab or infliximab biosimilar

CRITERIA FOR QUANTITY EXCEPTIONS
Adalimumab/Enanercept:
- Requires concomitant methotrexate (unless contraindicated)
AND
- Failure of an adherent 3-month trial of standard maintenance dosing with concomitant methotrexate (unless contraindicated)

For other requests:
- Regimen based on published literature supporting the dose and/or frequency being requested after failure of an adequate trial of standardized dosing
CRITERIA FOR CONTINUATION OF THERAPY: (12-month renewal or persons new to the plan)

- The prescriber must provide clinical documentation from the previous 12 months of the person’s response to therapy (e.g. improvement in PASI, PGA, TBSA affected, etc.)
- Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.
<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Benefit</th>
<th>Coverage Status</th>
<th>Quantity per month: maintenance therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adalimumab (Humira)</td>
<td>Rx</td>
<td>Preferred Restricted</td>
<td>#2-40mg injections</td>
</tr>
<tr>
<td>Infliximab (Remicade, Inflectra, Renflexis)</td>
<td>Medical</td>
<td>Restricted</td>
<td>na</td>
</tr>
<tr>
<td>Certolizumab (Cimzia)</td>
<td>RX</td>
<td>Non-preferred Restricted</td>
<td>#1-400mg syringe kit</td>
</tr>
<tr>
<td>Tofacitinib (Xeljanz)</td>
<td>RX</td>
<td>Non-preferred Restricted</td>
<td># 60</td>
</tr>
<tr>
<td>Vedolizumab (Entyvio)</td>
<td>Medical</td>
<td>Restricted</td>
<td>na</td>
</tr>
<tr>
<td>Natalizumab (Tysabri)</td>
<td>Medical</td>
<td>Restricted</td>
<td>na</td>
</tr>
<tr>
<td>Ustekinunumab (Stelara)</td>
<td>Medical</td>
<td>Restricted</td>
<td>single dose only</td>
</tr>
<tr>
<td></td>
<td>RX</td>
<td>Non-preferred Restricted</td>
<td>#1 per 8 weeks</td>
</tr>
</tbody>
</table>

Quantity Limits: quantity limits apply for each drug as is recommended for each specific indication loading doses as listed in label

**Induction therapy:**  
adalimumab  #160mg x1; 80mg x1 for first month  
certolizumab  #3 injection kits for first month  
ustekinumab  weight-based infusion X1

**Maintenance therapy:**  
As listed in the table

**Approval Limits:**  
None

**CRITERIA FOR COVERAGE:**  
- Prescribed by a Gastroenterologist  
- Prescription benefit medications are included in the Specialty Pharmaceuticals Program. Medications must be obtained from an authorized network specialty pharmacy. Contact 1-866-894-3784 or 1-877-208-1096 for more details.  
- Biologic therapies are not used in combination with other biologic DMARD therapies. Previously authorized biologic therapies will no longer be authorized when a new biologic therapy authorization is approved.  
- Diagnosis of inflammatory bowel disease as described below.

**Diagnosis of moderate to severely active Crohn’s disease AND**
In a low-risk individual: intolerance/contraindication to 2 conventional therapies OR inadequate disease control or inability to achieve remission after an adequate trial of 3 months with 2 conventional therapies OR demonstrated steroid dependence.

Therapy options
- Adalimumab OR Infliximab
- Certolizumab if failure/intolerance to adalimumab
- Ustekinumab in adults if failure/intolerance of 2 anti-TNF trial OR contraindication to anti-TNF therapy
- Vedolizumab in adults if failure/intolerance of 2 anti-TNF trial, OR contraindication to anti-TNF therapy
- Tofacitinib in adults if failure/intolerance to 2 anti-TNF trial and vedolizumab

In a high-risk individual with moderate to severely active Crohn’s disease

Therapy options
- Adalimumab OR Infliximab
- Certolizumab if prior failure/intolerance of adalimumab
- Ustekinumab in adults if prior failure/intolerance of 2 anti-TNF trials OR contraindication to anti-TNF therapy
- Vedolizumab if failure/intolerance of 2 anti-TNF trials OR contraindication to anti-TNF therapy
- Tofacitinib in adults if failure/intolerance to 2 anti-TNF trial and vendolizumab

In a hospitalized patient with acute flare of severely active Crohn’s disease with a lack of response to IV corticosteroids (dose equivalents of 60mg methylprednisolone) after 3-5 days in attempt to avoid surgical intervention with documentation of inflammatory component

Therapy options
- Adalimumab OR Infliximab
- Vedolizumab if contraindication to anti-TNF therapy OR failure/intolerance to two anti-TNF in attempt to avoid surgical intervention
- Ustekinumab- in adults IF failure/intolerance of 2 preferred first line agents

For natalizumab
- General criteria met for diagnosis of moderate to severely active Crohn’s disease in adults AND
- Failure of two preferred anti-TNF therapies or a contraindication to anti-TNF therapy exists AND failure/intolerance to vedolizumab or ustekinumab
- Must be used as monotherapy (without immunomodulatory therapy)

For use of Tysabri (natalizumab) for Crohn's disease, patients and prescriber must be enrolled in the manufacturer TOUCH Risk-Management Program. Refer to [touchprogram.com](http://touchprogram.com) for details

Diagnosis of moderate to severely active ulcerative colitis AND
In a high-risk individual

Therapy options (after short course of corticosteroids unless contraindicated)
- Adalimumab OR Infliximab
- Vedolizumab IF adult patients with a failure of anti-TNF trial or contraindication to anti-TNF therapy
- Tofacitinib IF adult patients with a failure/intolerance of 2 preferred first line agents
In a **hospitalized patient with acute flare of** severely active ulcerative colitis with lack of response to IV corticosteroids (dose equivalents of 60mg methylprednisolone) after 3-5 days in attempt to avoid surgical intervention with documentation of inflammatory component.

**Therapy options**
- Adalimumab OR Infliximab
- Vedolizumab (failure of anti-TNF trial or contraindication to anti-TNF therapy)
- Tofacitinib IF adult patients with a failure/intolerance of 2 preferred first line agents
- Ustekinumab in adults if prior failure/intolerance of 2 anti-TNF trials (contraindication to anti-TNF therapy) AND vedolizumab and tofacitinib.

**CRITERIA FOR COVERAGE OF QUANTITY EXCEPTIONS (listed drugs only):**

**For weekly dosing of adalimumab**
- Failure of a two-month trial of every other week therapy after completion of induction dosing regimen
- Based on subtherapeutic drug concentrations and absence (or low levels) of drug antibodies.

**For reduced interval or increased dose for ustekinumab** (dose other than 90mg, interval less than every 8 weeks)
- Failure of a two-month trial of every 8-week therapy after completion of induction dosing regimen
- Based on subtherapeutic drug concentrations and absence (or low levels) of drug antibodies.
- Provision of published literature supporting dose increase and/or frequency
- Failure of evidence-based first line alternatives

**CRITERIA FOR CONTINUATION OF THERAPY:**
- For persons new to the plan: must have a clinical assessment provided by the gastroenterologist (or other specialist if co-managed by Rheumatology) within previous 12 months and prescriber documents individual response to therapy, including individual improvement in functional status related to therapeutic response. Provision of recent labs, current symptoms and change in status should be provided to review for improvement and demonstrate effectiveness. Examples of documentation include laboratory assessment (i.e. CRP, hemoglobin, ESR, WBC, albumin, etc), symptom assessment (i.e. bleeding, stooling pattern, abdominal pain, extraintestinal complaints, fatigue, fever, etc) or recent endoscopy results.
- Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.

**CRITERIA FOR COVERAGE ON THE MEDICAL BENEFIT for CLINIC ADMINISTRATION instead of as take-home medication on the PRESCRIPTION BENEFIT (Humira, Simponi)**
- Requests for coverage on the medical benefit will be assessed for Medical Necessity

**IMPORTANT INFORMATION:**
- While the anti-TNF agents are category B in pregnancy, certolizumab does not appear to cross the placenta and therefore, it may pose less risk to a fetus. For pregnant women established on anti-TNF therapy, therapy interruptions prior to delivery are recommended with infliximab (8-10 weeks prior) and adalimumab (4-5 weeks prior). For pregnant women established on anti-TNF therapy and requiring an adjustment to anti-TNF therapy, consideration will be given to use of certolizumab.

**DEFINITIONS OF TERMS:**

**Inadequate Disease Control:**
Worsening of baseline symptoms (i.e. bowel frequency, presence of blood, abdominal pain or tenderness, fever, ), extraintestinal manifestations (i.e. fatigue, joint pain, skin rash, and ocular symptoms), laboratory assessment (i.e. C-reactive protein (CRP), hemoglobin, ESR white blood count (WBC), albumin, platelets, fecal calprotectin, etc.) and/or recent endoscopy results demonstrating ongoing inflammation.

High Risk in Ulcerative Colitis:
- Patient with extensive colitis, deep ulcers, age<40 years, High CRP and ESR, steroid-requiring disease, history of hospitalization, C difficile infection, CMV infection
  OR
- Low risk patient (with limited anatomic disease or mild endoscopic disease) AND inability to achieve remission on induction and maintenance therapy with conventional agents OR achieved remission on induction and maintenance therapy but has relapsed after steroid taper (primary non-response or secondary loss of response)

High Risk in Crohn’s Disease:
- Age<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.)

Induction and Maintenance Therapy with Conventional Agents:
Conventional therapy with immunomodulator therapy such as azathioprine, balsalazide, corticosteroids, mesalamine, mercaptopurine, methotrexate, sulfasalazine

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: Signs/Symptoms/Labs/Endoscopy 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 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 or elevated ESR or CRP

Primary non-response to anti-TNF therapy:
Lack of response to therapy as assessed after induction regimen, (i.e. approximately 12 weeks into therapy) and the inability to achieve steroid-free complete remission, despite dose optimization. This can be managed by evaluation of inflammation (is there evidence of inflammatory activity causing lack of perceived response or something else?), dose escalation, addition of immunomodulator or by changing to a different drug.

Secondary loss of response to anti-TNF therapy:
Re-emerging symptoms appear where they were previously controlled and are due to inflammation and not other causes (i.e. irritable bowel disease, infection, non-inflammatory component of IBD, etc.). The inability to maintain steroid-free complete remission after achieving symptomatic response. This can be managed by assessment of drug concentrations and antibody levels to determine if dose increase or therapy change.

**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

**References:**
<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Drug Status</th>
<th>Quantity Limit (maintenance/28 days) based on indication</th>
<th>Approval Limits</th>
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<tbody>
<tr>
<td><strong>First Line Agents:</strong></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Adalimumab (Humira)</td>
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<td>Apremilast (Otezla) considered biologic DMARD</td>
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<tr>
<td>Etanercept (Enbrel)</td>
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<td>25 mg - #8 50 mg - #4</td>
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<tr>
<td>Infliximab Biosimilar infusion (Inflectra, Renflexis)</td>
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<tr>
<td>Secukinumab (Cosentyx)</td>
<td>Preferred Restricted</td>
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<tr>
<td>Upadacitinib (Rinvoq) RX</td>
<td>Preferred Restricted</td>
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<td>12 months</td>
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<td><strong>Second Line Agents:</strong></td>
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<td>Abatacept (Orencia)</td>
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<td>Abatacept infusion (Orencia)</td>
<td>Medical Benefit Restricted</td>
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<td>12 months</td>
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<tr>
<td>Certolizumab (Cimzia)</td>
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<td>12 months</td>
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<td>Tocilizumab infusion (Actemra)</td>
<td>Medical Benefit Restricted</td>
<td></td>
<td>12 months</td>
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<td>Tocilizumab (Actemra)</td>
<td>Nonpreferred Restricted</td>
<td>#2</td>
<td>12 months</td>
</tr>
<tr>
<td>Tofacitinib (Xeljanz)</td>
<td>Nonpreferred Restricted</td>
<td>#60</td>
<td>12 months</td>
</tr>
<tr>
<td>Tofacitinib ER (Xeljanz XR)</td>
<td>Nonpreferred Restricted</td>
<td>#30</td>
<td>12 months</td>
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Third Line Agents:

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<th>Coverage</th>
<th>Benefit</th>
<th>Duration</th>
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</thead>
<tbody>
<tr>
<td>Infliximab BRAND infusion (Remicade)</td>
<td>Not Covered - Medical Benefit</td>
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<tr>
<td>Ustekinumab (Stelara)</td>
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<td>12 months</td>
</tr>
<tr>
<td>Ustekinumab (Stelara)</td>
<td>Medical Benefit Restricted</td>
<td>N/A</td>
<td>12 months</td>
</tr>
</tbody>
</table>

*Rituximab is a Medical Benefit therapeutic option. It does not require prior authorization and is not restricted.*

Induction therapy is covered if criteria met for specific indication and *starter kits for loading doses where applicable are used*.

RHEUMATOLOGY INDICATION GENERAL CRITERIA FOR COVERAGE:

- Prescribed by a Rheumatologist
- Prescription benefit medications are included in the Specialty Pharmaceuticals Program. Medications except where noted must be obtained from one of the participating pharmacies. Contact 1-866-894-3784 or 877-208-1096 for more details. Prescription benefit medications must be self-administered
- Biologic therapies are not used in combination with other biologic DMARD therapies. Previously authorized therapies will be no longer authorized when new biologic therapy authorization is approved.
- Diagnosis as listed with prerequisite therapy

1. **Rheumatoid arthritis (RA):** moderate to severely active established (disease duration of greater than 6 months), reactive arthritis, or juvenile idiopathic arthritis (JIA)
   - Documented failure with a 3-month trial of methotrexate at therapeutic doses unless contraindicated
   OR
   - Persons intolerant to, or with a contraindication to MTX therapy should fail an adequate trial (3 months) with another disease modifying anti-rheumatic drugs such as hydroxychloroquine, sulfasalazine, leflunomide or minocycline

2. **Early RA** (less than 6 months disease duration) with feature of poor prognosis (at least one item) 1. Functional limitations (based on HAQ or similar tool) 2. Extraarticular disease (e.g. presence of rheumatoid nodules, RA vasculitis or Felty’s syndrome (rheumatoid arthritis with splenomegaly and neutropenia) 3. positive rheumatoid factor or anti-cyclic citrullinated peptide antibodies (anti-CCP antibodies) 4. bony erosions on X-ray.

3. **Ankylosing spondylitis (AS)** not controlled by a 2-month trial of scheduled prescription doses of two different NSAIDs (such as naproxen, nabumetone, diclofenac, etc.)

4. **Moderate to severely active psoriatic arthritis (PsA)** and documented failure/intolerance to adequate trial (minimum 3 months) of methotrexate therapy (unless contraindication).

5. **Non-infectious uveitis** verified by an ophthalmologist or other eye specialist and ongoing symptoms despite an adequate trial with BOTH topical glucocorticoids and at least one systemic immunomodulator (e.g. oral corticosteroids, methotrexate, azathioprine, mycophenolate, or cyclosporine)
6. **Behcet’s disease** with oral ulcers/mucocutaneous involvement – consider after topical steroids, colchicine (EULAR 2018)

7. **Systemic juvenile idiopathic arthritis (SJIA)** or adult-onset Still’s disease **AND** Failure of an adequate trial (3 months) of corticosteroids and methotrexate

8. **Giant cell arteritis** which has relapsed despite use of corticosteroids or methotrexate **OR** Contraindication to methotrexate and steroids **OR** Inability to taper corticosteroids

**DRUG-SPECIFIC CRITERIA FOR COVERAGE:**

- **For adalimumab**
  - General criteria met **AND** diagnosis of RA, reactive arthritis, JIA, AS, PsA or uveitis

- **For apremilast: (Considered Biologic DMARD)**
  - General criteria met **AND** diagnosis of PsA or Behcet’s disease

- **For etanercept**
  - General criteria met **AND** diagnosis of RA, reactive arthritis, JIA, AS, PsA

- **For infliximab biosimilar**
  - General criteria met **AND** diagnosis of RA, AS, reactive arthritis, PsA, SJIA

- **For secukinumab:**
  - General criteria met **AND** diagnosis of PsA or AS

- **For upadacitinib**
  - General criteria met **AND** for diagnosis of RA

- **For abatacept**
  - General criteria met **AND** diagnosis of RA, JIA, PsA
  - Failure/intolerance of two preferred first line Rx benefit biologic DMARD included in table **OR** Contraindication to anti-TNF therapy
  - **For INFUSION only:** Failure of adequate trial of abatacept self-injection or inability to self-administer abatacept injection

- **For certolizumab**
  - General criteria met **AND** diagnosis of RA, PsA, or AS
  - Failure/intolerance of two preferred first line Rx benefit biologic DMARD included in table **OR** in female patient with current pregnancy or intent for soon pregnancy (does not cross placental barrier)

- **For tofacitinib/tofacitinib ER**
  - General criteria met **AND** Diagnosis of RA or PsA
  - Failure/intolerance to three preferred first line Rx benefit biologic DMARD included in table (including first-line of same MOA)

- **For tocilizumab**
  - General criteria met **AND** Diagnosis of RA **AND**
  - Failure/intolerance to two preferred first line Rx benefit biologic DMARD included in table **OR**
Contraindication to anti-TNF therapy

**OR**

- For Diagnosis of giant cell arteritis or SJIA
- **For INFUSION only:** Failure of adequate trial of tocilizumab self-injection or inability to self-administer tocilizumab injection. **OR** Approval of therapy for chimeric antigen receptor (CAR) T-cell to treat T-cell – induced severe or life-threatening cytokine release syndrome (CRS) in patients two years of age or older

**For ustekinumab**

- General criteria met AND Diagnosis of PsA
- Failure/intolerance to two preferred first line Rx benefit biologic DMARD included in table OR Contraindications to anti-TNF therapy AND
- Failure/intolerance to two second line Rx benefit biologic DMARD included in table
- **FOR CLINIC ADMINISTRATION** - documentation of inability to complete self-injection at home.
  
  Note: infusion is only indicated for inflammatory bowel disease

**CRITERIA FOR COVERAGE OF QUANTITY EXCEPTIONS:**

**For adalimumab (Weekly dosing)**

- Failure of a three-month trial of every other week therapy with concomitant methotrexate (unless contraindicated or not appropriate for indication being requested)

**For etanercept (50mg twice weekly)**

- Failure of a three-month trial of 50mg per week (either as 25mg twice weekly or 50mg once weekly) with concomitant methotrexate (unless contraindicated or not appropriate for indication being requested)

**For tocilizumab (SQ) (#4 per month)**

- Weight > 100 kg or failure of a three-month trial of every other week therapy with concomitant methotrexate (unless contraindicated).
- For patients converting from IV 8mg/kg dose to SQ therapy.

**For apremilast/tofacitinib:**

- Therapeutic failure or intolerance of two tablets per day dosing or prescriber presents rationale or clinical reason for utilizing a dosing regimen that is not possible within the quantity limits.

**For tofacitinib ER/upadacitinib**

- Therapeutic failure or intolerance of two tablets per day dosing or prescriber presents rationale or clinical reason for utilizing a dosing regimen that is not possible within the quantity limits and that safety concerns with use of higher doses have been discussed with the patient.

**For all other biologic therapies not specifically listed above:**

- Symptoms not controlled on a “standard regimen” and rationale provided why alternate regimen would be expected to be effective (e.g. published literature, drug levels, etc.) or a change in therapy would not be clinically appropriate.

**CRITERIA FOR CONTINUATION OF THERAPY (12-month renewal or persons new to the plan):**

- Prescriber provides clinical documentation from the previous 12 months that describes response as stable disease or improvement seen on therapy. Examples of improvement include: laboratory
assessment (i.e. C-reactive protein, ESR, anemia improvement), symptomatic improvements (i.e. fatigue, function, HAQ score if available, joint pain).

- Restrictions to specific network pharmacies and participation in medication management programs may apply.
- Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.
- For therapies that have BOTH infusion and self-injection, use of self-injection first must have been completed before continuation or consideration of infusion therapy.
<table>
<thead>
<tr>
<th>Generic</th>
<th>Brand</th>
<th>HICL</th>
<th>GCN</th>
<th>Exception/Other</th>
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</thead>
<tbody>
<tr>
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<td>FREESTYLE INSULINX, FREESTYLE LITE, FREESTYLE</td>
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<td>02748</td>
<td>BRAND ≠ ONE TOUCH ULTRA BLUE, ONE TOUCH VERIO, ACCU-CHEK AVIVA, ACCU-CHEK AVIVA PLUS, ACCU-CHEK GUIDE, ACCU-CHEK SMARTVIEW, ACCU-CHEK COMPACT PLUS</td>
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Preferred Blood Glucose Test Strips Quantity Limit Exception
Prior Authorization Criteria

FORMULARY STATUS:

Abbott Products
FreeStyle, FreeStyle Lite, Insulinx, Precision Neo, Precision Xtra, Precision PCX, Precision Point of Care, Precision QID Preferred

Bayer Products
Breeze 2, Contour, Contour Next- Preferred

APPROVAL LIMITS: None

QUANTITY LIMITS: #200 per 30 days

CRITERIA FOR COVERAGE OF QUANTITY EXCEPTIONS:
- Person requires more than 200 strips per 30 days based on how often they are checking their blood sugar (documentation of directions and frequency of blood sugar checks is required).
Botulinum toxin (Botox, Dysport, Myobloc, Xeomin)
Prior Authorization Criteria

FORMULARY STATUS: Medical Benefit-Restricted

APPROVAL LIMITS:
- For use in migraine headaches: yearly renewals to document efficacy
- Other indications: indefinite

QUANTITY LIMITS:
- 4 treatments per 12 month period for migraine headaches

CRITERIA FOR COVERAGE:
The clinician must rule out other causes of the condition and address (if appropriate) prior to submitting a request for coverage of botulinum toxin.

- Cervical Dystonia (Spasmodic Torticollis)-defined by clonic and/or tonic involuntary contractions of multiple neck muscles with sustained head torsion and/or tilt and limited range of motion in the neck that has endured for six months or longer.
- Hemifacial Spasm
- Esophageal Achalasia: In persons who are considered high-risk (due to age or other co-morbidities) for standard treatments including pneumatic balloon dilation and myotomy, or those who have failed previous treatment (e.g. CCB, nitrates) or as a temporizing measure prior to surgical intervention or as an alternative to surgical intervention
- Laryngeal spasm (spasmodic dysphonia/tremor)
- Cricopharyngeal spasm
- Strabismus
- Blepharospasm
- Chronic anal fissure unresponsive (e.g. nocturnal bleeding, pain) to an adequate trial of conservative therapeutic measures
- Gustatory hyperhidrosis (Frey’s syndrome) following parotid surgery

The following conditions being treated must result in functional impairment (interference with joint function/mobility, interference with activities of daily living)

- Spasticity
  - Cerebral Palsy: in addition to physical/occupational therapy, conventional therapies (i.e. baclofen), or splinting
  - Upper and lower extremity spasticity (resulting from a stroke, traumatic or non-traumatic spinal cord injury, multiple sclerosis or other demyelinating disease of the central nervous system, traumatic brain injury or other central process) as a component of a rehabilitation and strengthening program
- Torsion dystonia: Oral therapies failed or were not tolerated
- Congenital muscular torticollis: Conservative treatment including physical therapy or stretching failed
- Focal hand dystonia
- Orofacial dyskinesia from TMJ disorder after trial of oral splints or failure of medication therapy
- Sialorrhea: When alternative treatments (e.g., anticholinergics or radiation to involved glands) failed or were not tolerated
- Urinary incontinence
  - Detrusor sphincter dyssynergia – Persons with neurologic etiologies such as spinal cord injury or demyelinating diseases who have failed or cannot tolerate oral agents such as alpha-antagonists or anti-spasmodics.
Neurogenic detrusor overactivity – Persons using clean intermittent self-catheterization who have incontinence and are unable to tolerate anticholinergics.

Overactive bladder- in persons who are refractory to behavioral modification, intolerant to anticholinergic therapies, and must be able to undergo post-void residual evaluation and self-catheterization.

- Facial dyskinesis due to aberrant nerve regeneration.
- Hyperhidrosis- when causing persistent or chronic cutaneous conditions (e.g., skin maceration, dermatitis, fungal infections)

**AND**

- Primary axillary-After failure of at least two other treatment options including: topical treatments (e.g. aluminum salts) and oral agents (e.g. anticholinergics)
- Palmar/plantar: After failure of at least two other treatments including: topical treatments (e.g., aluminum salts), oral agents (e.g., anticholinergics) or iontophoresis

**Migraine Headache**

- Suffers from chronic daily headaches (at least 15 days/month) that are not rebound due to medication overuse
- Has failed trials of at least three preventative medications (i.e. beta blockers, anticonvulsants, TCAs, calcium channel blockers, etc.)
- Has been disabled by the headaches (e.g. unable to work/attend school, unable to participate in ADLs, supported by headache diary, etc.). This can be described as moderate to severe disability by Migraine Disability Assessment (MIDAS test)
- Person is seen, and BoNT therapy has been approved by, a prescriber specializing in the medical management of migraine as part of a complete headache treatment plan (i.e. lifestyle modification)

- Other indications not listed must be submitted with peer-reviewed medical literature to support the proven efficacy and safety of the requested use along with the clinical rationale to support medical necessity for use

**CRITERIA FOR REAPPROVAL/CONTINUATION OF THERAPY:**

**For MIGRAINE HEADACHES:**

- Provider provides clinical documents from the previous 12 months detailing individual response to therapy (specific details provided regarding symptom improvement, decreased frequency and severity of headaches, improved ability to participate in therapies/ADLs, improved MIDAS score, less medication use, fewer ER/UC visits, ability to return to work, etc.).

**For all Other Diagnoses:**

For members new to the plan: must have a listed diagnosis above and the prescriber must provide clinical documentation from the previous 12 months verifying the person is established on therapy

- Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.

**CRITERIA FOR COVERAGE OF QUANTITY EXCEPTIONS FOR MIGRAINE HEADACHES:**

- Provider must document positive response to therapy (see above) and evidence of consistent (at least two successive occurrences) “wearing off” of therapeutic effect prior to the expected 3 month duration.

**FOR BADGERCARE COVERAGE:**

See the Forward Health Diagnosis Code-Restricted Physician-Administered Drug List (Table 1)
**IMPORTANT INFORMATION**

- Prabotulinumtoxina-xvfs excluded from coverage as only FDA indication is cosmetic

**TABLE 1**
For BadgerCare+ members only-

Claims are covered for the following diagnosis codes:

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<thead>
<tr>
<th>Code</th>
<th>Diagnosis</th>
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<td>G114</td>
<td>HEREDITARY SPASTIC PARAPLEGIA</td>
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<tr>
<td>G2402</td>
<td>DRUG INDUCED ACUTE DYSTONIA</td>
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<tr>
<td>G2409</td>
<td>OTHER DRUG INDUCED DYSTONIA</td>
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<tr>
<td>G241</td>
<td>GENETIC TORSION DYSTONIA</td>
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<td>Generic</td>
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<tr>
<td>SODIUM PICOSULFATE/ MAG OXIDE/ CITRIC ACID</td>
<td>PREPOPIK, CLENPIQ</td>
</tr>
<tr>
<td>SODIUM, POTASSIUM AND MAG SULFATES</td>
<td>SUPREP</td>
</tr>
<tr>
<td>NAPHOS M-B M-H/NA PHOS, DI-BA</td>
<td>OSMOPREP</td>
</tr>
<tr>
<td>BISAC/NACL/NAHCO3/ KCL/PEG 3350</td>
<td>GAVILYTE-H AND BISACODYL; PEG-PREP KIT</td>
</tr>
<tr>
<td>PEG3350/SOD SUL/NACL/KCL/ASB/C</td>
<td>PLENVU</td>
</tr>
</tbody>
</table>

Nonpreferred Bowel Preparations
Prior Authorization Criteria

**FORMULARY STATUS:** Non-preferred Restricted

**APPROVAL LIMITS:** None

**QUANTITY LIMITS:** One prep per 30 days

**CRITERIA FOR COVERAGE:**
- Person had an inadequate colon cleansing/bowel prep with a preferred bowel preparation

**CRITERIA FOR QUANTITY EXCEPTIONS:**
- Therapeutic failure or intolerance of one prep per 30 days dosing and the prescriber presents an evidence-based clinical rationale for utilizing a dosing regimen that is not possible within the quantity limits.
Positive Allosteric Modulators of GABA<sub>A</sub> Receptors
Prior Authorization Criteria

FORMULARY STATUS:
Brexanolone (Zulresso) Medical Benefit - Restricted

APPROVAL LIMITS: 3 days (One infusion per year)

CRITERIA FOR COVERAGE (all of the following must be met):
- Medication is prescribed by or in consultation with a psychiatrist AND
- Person is 18 years or older and ≤ 9 months postpartum AND
- Symptoms began within the third trimester and/or no later than 12 weeks after delivery AND
- Has a diagnosis of moderate or severe postpartum depression AND
- Does not have active or current problems with substance abuse AND
- Does not have active psychosis or bipolar, schizophrenia or schizoaffective disorder AND
- Person is enrolled in the Zulresso REMS Program

AND

- Person meets ONE of the following:
  - Documentation shows potential risk of harm to self or others.
  - Documentation shows severe impairment of activities of daily living (e.g. inability to care for self, requires supervision, impairments in social or occupational functioning) and/or impairing care of the infant due to depression.

CRITERIA FOR COVERAGE OF QUANTITY EXCEPTIONS:
- Provider must provide a clinical reason and evidence-based clinical rationale for use of a dose outside of the quantity limit.

IMPORTANT INFORMATION:
- Inpatient Hospital Claims: brexanolone does not require prior authorization.
- Outpatient Infusion Claims: brexanolone does require a prior authorization.
- The person, provider, facility and pharmacy must be enrolled in the Zulresso Risk Evaluation Mitigation Strategy (REMS) Program
- Coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers
- GABA<sub>A</sub> = gamma aminobutyric acid (GABA) is a major inhibitory neurotransmitter in the brain.
- Hamilton Rating Scale for Depression (HAM-D) Score Severe ≥ 20, Moderate ≥ 17-25
- Edinburgh Post Natal Depression Score (EPDS) Severe ≥ 19, Moderate ≥ 15-18
- Patient Health Questionnaire (PHQ-9) Depression Score Severe ≥ 15, Moderate ≥ 10-14
Brivaracetam (Briviact)
Prior Authorization Criteria

FORMULARY STATUS: Nonpreferred-Restricted

APPROVAL LIMITS: None

QUANTITY LIMITS: Two tablets per day (#60)

CRITERIA FOR COVERAGE:
- Covered for persons with partial-onset seizures
- Initiated by, or in consultation with, a Neurologist
- The person has experienced a side effect, or therapeutic failure, despite an adequate trial (both in dose and duration) of levetiracetam

CRITERIA FOR QUANTITY EXCEPTIONS:
Therapeutic failure or intolerance to twice daily dosing for available strengths and the prescriber provides an evidence-based clinical rationale for using a dose outside of the quantity limit
<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Formulary Status</th>
<th>Quantity Limits</th>
<th>Approval Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Isavuconazonium sulfate (Cresemba)</td>
<td>Preferred-Restricted</td>
<td>None</td>
<td>12 months</td>
</tr>
<tr>
<td>Posaconazole tab (Noxafil)</td>
<td>Preferred-Restricted</td>
<td>None</td>
<td>12 months</td>
</tr>
<tr>
<td>Voriconazole</td>
<td>Preferred-Restricted</td>
<td>None</td>
<td>12 months</td>
</tr>
<tr>
<td>Posaconazole susp. (Noxafil)</td>
<td>Non-Preferred-Restricted</td>
<td>None</td>
<td>12 months</td>
</tr>
</tbody>
</table>

**CRITERIA FOR COVERAGE:**

- Prescribed by, or in consultation with, an Infectious Disease specialist
- Suspected or confirmed serious fungal infection with probable resistance to other preferred antifungals or the other antifungals are not tolerated, or other significant drug-drug interactions exist with the other antifungals
- Prophylaxis of serious fungal infections in patients with hematologic malignancies with severely compromised immunity (posaconazole only)
- Continuation of hospital therapy
- **(Minnesota plans only)** – person with stage four metastatic cancer and the requested drug is being used to prevent or treat cancer-related fungal infections

**CONTINUATION OF COVERAGE CRITERIA:**

- Persons new to coverage 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.
- Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.
Budesonide Nasal (Rx Only)
Prior Authorization Criteria

FORMULARY STATUS: Preferred-Restricted

APPROVAL LIMITS: 15 months if approved for use in pregnancy; none for other approvals

QUANTITY LIMITS: None

CRITERIA FOR COVERAGE:

- Person is pregnant
- OR
- Person had therapeutic failure with, or could not tolerate, both fluticasone propionate (generic Flonase OTC) AND triamcinolone (Nasacort OTC) nasal spray.

CRITERIA FOR COVERAGE OF DURATION EXCEPTIONS:

- Duration of authorization can be extended or changed to indefinite if the person has met criteria 2 prior to pregnancy
CRITERIA FOR COVERAGE:
- Age ≥ 1 year
- Diagnosis of X-linked hypophosphatemia
- Low serum phosphate levels (age appropriate) despite at least six months of maximally tolerated oral phosphate and vitamin D supplementation
- Clinical documentation demonstrating evidence of rickets (children) or osteomalacia-associated bone disease (adults)

CONTINUATION OF COVERAGE CRITERIA:
- Age ≥ 1 year and a diagnosis of X-linked hypophosphatemia.
- Clinical documentation from the previous 12 months demonstrating objective improvements in skeletal quality from baseline.
- Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.

FOR BADGERCARE COVERAGE:
- Medication must be billed to ForwardHealth under the pharmacy benefit. Refer to the ForwardHealth policy “Select High Cost, Orphan, and Accelerated Approval Drugs” for additional information.
Complement Protein C5 Inhibitors
Prior Authorization Criteria

FORMULARY STATUS:
Eculizumab- (Soliris)  Medical Benefit Restricted
Ravulizumab- (Ultomiris) Medical Benefit Restricted

APPROVAL LIMITS:
PNH/aHUS: Initial approval 12 months,
PNH/aHUS: Continuation indefinite
M. Gravis: 12 months
NMOSD: 12 months

QUANTITY LIMITS:
None

INITIAL CRITERIA FOR COVERAGE of ravulizumab or eculizumab for the treatment of paroxysmal nocturnal hemoglobinuria (PNH):
- Confirmed diagnosis of PNH by flow cytometry
  - Prescribed by Hematologist or Oncologist AND
  - Document baseline hemoglobin (≤ 9 mg/dL with symptoms of anemia), lactate dehydrogenase level (LDH ≥ 1.5 X ULN) and/or number of transfusions in last year AND
  - Documentation of the clinical manifestations of disease (e.g. major vascular event, transfusion dependence, renal insufficiency, disabling fatigue and/or other end organ manifestations)
  - Documentation of receipt of both (meningococcal groups A/C/Y and W-135 diphtheria vaccine and meningococcal group B vaccine) meningococcal vaccinations (at least two weeks prior to therapy initiation) or as required by REMS program.

INITIAL CRITERIA FOR COVERAGE of eculizumab for the treatment of atypical hemolytic uremic syndrome (aHUS) or myasthenia gravis:
- Diagnosis of atypical hemolytic uremic syndrome (aHUS)
  - Prescribed by a Hematologist, Nephrologist or Oncologist AND
  - Document baseline level of one or more values (e.g. lactate dehydrogenase, serum creatinine/eGFR, platelet count and/or plasma exchange (PLEX)/infusion requirements) AND
  - Documentation states that Thrombotic Thrombocytopenic Purpura (TTP) and Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS) has been ruled out. The secondary cause of aHUS is stated if known. (eculizumab is not indicated for STEC-HUS).
  - Documentation of receipt of both (meningococcal groups A/C/Y and W-135 diphtheria vaccine and meningococcal group B vaccine) meningococcal vaccinations (at least two weeks prior to therapy initiation) or as required by REMS program.
- Diagnosis of Myasthenia Gravis Foundation of America (MGFA) class II to IV disease
  - Prescribed by a Neurologist AND
  - Positive serologic test for anti-acetylcholine receptor (AChR) antibodies AND
  - Baseline Myasthenia Gravis Activities of Daily Living (MG-ADL) total score ≥ 6 AND document a baseline level of one or more values (e.g. number of Myasthenia Gravis exacerbations/hospitalizations in the past year, number of PLEX or intravenous immune globulin (IVIG) infusions in the past year and/or Quantitative Myasthenia Gravis (QMG) score) AND
  - Failure of two immunosuppressive therapies for at least 6 months with a baseline refill pattern of at least 80% adherence. If intolerance occurs, one other immunosuppressive agent must be tried.
    - Immunosuppressive therapies include: prednisone, azathioprine, cyclophosphamide, cyclosporine, mycophenolate, tacrolimus or rituximab.

OR

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If all immunosuppressive agents are contraindicated or not clinically appropriate, justification must be documented, and the requirement *may be waived.* AND

- Failure of at least one of the following treatments:
  - Failure, intolerance, or contraindication to at least 3 months of therapeutic doses of IVIG OR
  - Failure, intolerance or contraindication to PLEX given at least four times per year without symptom control.

- Documentation of receipt of both (meningococcal groups A/C/Y and W-135 diphtheria vaccine and meningococcal group B vaccine) meningococcal vaccinations (at least two weeks prior to therapy initiation) or as required by REMS program.

*Failure to M. Gravis therapy is defined as a substantial increase in pretreatment clinical manifestations of the disease such as physical function (e.g. breathing, speaking, swallowing, chewing, muscle weakness of the neck), mobility/ambulation (muscle weakness of hands and limbs) and/or fatigue despite 80% adherence to prescribed regimen.*

**INITIAL CRITERIA OF COVERAGE of eculizumab for the treatment of neuromyelitis optica spectrum disorder (NMOSD)**

- Prescribed by neurologist or in consultation with a specialist in the treatment of NMOSD AND
- 18 years or older AND
- Diagnosis of Neuromyelitis Optica Spectrum Disorder confirmed by positive serologic test for anti-aquaporin-4 (AQP4) receptor antibody AND
- At least one core clinical characteristic of NMOSD (e.g. longitudinally extensive transverse myelitis [LETM], optic neuritis, intractable nausea/vomiting/hiccups, etc.) AND
- Not used in combination with rituximab and no rituximab within the past 90 days AND
- No IVIG within the past three weeks AND
- No mitoxantrone within the previous 90 days AND
- Failure or intolerance to mycophenolate, rituximab, IVIG, or plasma exchange
- Documentation of completion of the full series of meningococcal vaccinations or as required by REMS program

**CRITERIA FOR CONTINUATION OF COVERAGE**

- Diagnosis of paroxysmal nocturnal hemoglobinuria (PNH).
  - Initiation criteria met AND
  - Documentation of improvement or clinical stability, (e.g. improvement in hemoglobin, lactate dehydrogenase level, haptoglobin level and/or number of transfusions in the last year).

OR

- Diagnosis of atypical hemolytic uremic syndrome (aHUS)
  - Initiation criteria met AND
  - Documentation of improvement or clinical stability for renewal (e.g. improvement in lactate dehydrogenase, serum creatinine/eGFR, platelet count and/or plasma exchange (PLEX) infusion requirements).

OR

- Diagnosis of Myasthenia Gravis Foundation of America (MGFA) class II to IV disease
  - Initiation criteria met AND
  - MG ADL score must improve with at least a 3-point reduction from baseline AND
  - Documentation of improvement or clinical stability for renewal (e.g. number of myasthenia gravis exacerbations/hospitalizations in the past year, number of PLEX/IVIG infusions in the past year and/or QMG score)
• Diagnosis of Neuromyelitis optica spectrum disorder
  o Initial criteria met **AND**
  o Documentation of improvement or clinical stability for renewal (e.g. number of relapses; improved in the past year, number of PLEX/IVIG infusions in the past year and/or vision, strength in arms/legs, reduced pain, vomiting/hiccups, bowel motility, etc.)

• For members new to the plan, the prescriber must provide clinical documentation from the previous 12 months of the person’s response to therapy (e.g. clinical manifestation stability/improvement based upon the continuation criteria above).
• Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.

**OTHER INFORMATION:**
Eculizumab is only available through a restricted program: Risk Evaluation Mitigation Strategy (REMS) and prescribers must be enrolled in the program 1-888-765-4747.

**Myasthenia Gravis Foundation of America (MGFA) Abbreviated Classifications:**

<table>
<thead>
<tr>
<th>Class</th>
<th>Clinical Signs</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Any ocular muscle weakness. All other muscle strength normal.</td>
</tr>
<tr>
<td>II</td>
<td>Mild muscle weakness with or without ocular muscle weakness</td>
</tr>
<tr>
<td>III</td>
<td>Moderate muscle weakness with or without ocular muscle weakness</td>
</tr>
<tr>
<td>IV</td>
<td>Severe muscle weakness with or without ocular muscle weakness. Use of feeding tube.</td>
</tr>
<tr>
<td>V</td>
<td>Intubation, with or without mechanical ventilation; except for routine postoperative care.</td>
</tr>
</tbody>
</table>

MGFA scoring tools are available here:
www.myasthenia.org/HealthProfessionals/EducationalMaterials.aspx

**American Academy of Neurology 2015 Core Clinical Characteristics for NMOSD**

<table>
<thead>
<tr>
<th>Optic neuritis</th>
<th>Acute brainstem syndrome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute myelitis</td>
<td>Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions</td>
</tr>
<tr>
<td>Area postrema syndrome: Episode of otherwise unexplained hiccups or nausea and vomiting</td>
<td>Symptomatic cerebral syndrome with NMOSD-typical brain lesions</td>
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Calcitonin gene-related peptide (CGRP) inhibitors

Prior Authorization Criteria

<table>
<thead>
<tr>
<th>Generic</th>
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<th>HICL</th>
<th>GCN</th>
<th>Exception/Other</th>
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<tr>
<td>FREMANEZUMAB</td>
<td>AJOVY</td>
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<td>GALCANEZUMAB</td>
<td>EMGALITY</td>
<td>40418,</td>
<td>40419, 46397</td>
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</table>

**FORMULARY STATUS:**
- Erenumab (Aimovig) Preferred Restricted
- Galcanezumab (Emgality) Preferred-Restricted
- Fremanezumab (Ajovy) Nonpreferred-Restricted

**APPROVAL LIMITS:**
- Initial: 12 months
- Renewal: Indefinite

**QUANTITY LIMITS:**
- Erenumab (Aimovig) 70 mg or 140 mg autoinjector monthly
- Fremanezumab (Ajovy) 225 mg monthly, 675 mg every 3 months
- Galcanezumab (Emgality) For Migraine: 240 mg loading dose, then 120 mg monthly
- Galcanezumab (Emgality) For Cluster Headache: 300mg (3—100mg Syringes) per month

**INITIAL CRITERIA FOR COVERAGE for migraines for a preferred CGRP product** (all of the following must be met):
- Age 18 or older
- Subcutaneous medications must be self-administered
- Prescribed by or consult with a provider experienced in the medical management of migraine.
- Person has at least 4 migraine days per month as supported by documentation.
- Person has had a treatment failure with at least 2 generic preventive migraine medications (e.g. anti-hypertensives, antiepileptics, antidepressants, botulinum toxin [chronic migraine only]). Failure is defined as a therapeutic failure of least a 6-week trial of each generic preventive medication or person is intolerant to the medication.
- Person is disabled by the headaches (e.g. unable to work/attend school, unable to participate in activities of daily living [ADLs], moderate to severe MIDAS score)
- Combination therapy of two CGRP monoclonal antibody inhibitors will not be covered.

**INITIAL CRITERIA FOR COVERAGE for migraines for all nonpreferred CGRP products:**
- Above criteria met AND
- Failure*/intolerance to both preferred agents

**INITIAL CRITERIA FOR COVERAGE for episodic cluster headaches for galcanezumab only:**
- Age 18 or older
- Subcutaneous medications must be self-administered
- Prescribed by or in consultation with a provider experienced in the medical management of episodic cluster headaches
- Diagnosis of cluster headaches that are not rebound headaches due to medication overuse
CONTINUATION CRITERIA FOR REAPPROVAL/CONTINUATION OF THERAPY:

- Initial criteria met AND
- **For Migraine:** Clinical documents from the previous 12 months provided (e.g. clinic note) showing person maintains a response to therapy (specific details regarding symptom improvement, decreased frequency of at least 2 days per month or 50% from baseline, decreased severity of headaches, improved ability to participate in therapies/ADLs, improved MIDAS score, less medication use, fewer ER/UC visits for migraine, ability to return to work/school, etc)
- **For Episodic Cluster Headaches (galcanezumab only):** Clinical documentation from the previous 12 months provided (e.g. clinic note) showing reduction in cluster headache frequency in comparison to baseline.
- Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.
- Combination therapy of two CGRP monoclonal antibody inhibitors will not be covered.

CRITERIA FOR COVERAGE OF QUANTITY EXCEPTIONS:

- Provider must provide a clinical reason and evidence-based clinical rationale for use of a dose outside of the quantity limit.

IMPORTANT INFORMATION:

- *Failure to a CGRP inhibitor is defined as an adequate 3-month trial of a monthly dosed CGRP inhibitor or a 6-month trial of a quarterly dosed CGRP inhibitor and the person did not experience:
  - reduced frequency of at least 2 fewer migraines per month or 50% reduction from baseline, OR
  - reduced severity of headaches, less acute medication use, improvement in MIDAS score, OR
  - improvement in the ability to participate in therapies/ADLs/work/school or fewer ER/UC visits, despite 80% adherence to the prescribed preventive regimen.
- Galcanezumab is the only CGRP inhibitor approved for the use of episodic cluster headaches.
Canakinumab (Ilaris)
Prior Authorization Criteria

FORMULARY STATUS: Medical Benefit-Restricted

APPROVAL LIMITS: None

QUANTITY LIMITS: None

CRITERIA FOR COVERAGE:
1. Diagnosis of Cryopyrin-associated Periodic Syndromes (CAPS) in adults and children over 4 years of age, Familial Cold Autoinflammatory Syndrome (FCAS), Muckle-Wells Syndrome (MWS), Familial Mediterranean Fever, tumor necrosis factor receptor-associated periodic syndrome or other periodic syndromes AND
   a. Failure or intolerance to anakinra (Kineret)
OR
2. Systemic juvenile idiopathic arthritis (SJIA): AND
   • Failure or intolerance to prior therapies such as glucocorticoids or NSAIDs AND
   • Failure or intolerance to anakinra (Kineret)

CRITERIA FOR CONTINUATION OF THERAPY (SJIA only):
• Person is new to the plan and the prescriber provides clinical documentation from the previous 12 months showing a response to therapy (improvement or stable disease)
• Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.

IMPORTANT INFORMATION:
Per product labeling, healthcare providers should administer Canakinumab to the patient.
Candesartan (HCTZ)
Prior Authorization Criteria

**FORMULARY STATUS:**
- Candesartan: Preferred-Restricted
- Candesartan/HCTZ: Preferred-Restricted

**APPROVAL LIMITS:**
- None

**QUANTITY LIMITS:**
- None

**CRITERIA FOR COVERAGE:**
- Diagnosis of heart failure
Caplacizumab-yhdp (Cablivi)
Prior Authorization Criteria

**FORMULARY STATUS:**
Prescription Benefit: Nonpreferred-Restricted
Medical Benefit: Medical Benefit-Restricted

**APPROVAL LIMITS:**
Prescription Benefit: 1 month (30 days)
Medical Benefit: Duration of outpatient plasma exchange

**QUANTITY LIMITS:**
One vial (11mg) per day

**CRITERIA FOR COVERAGE (Medical Benefit):**
All of the following must be met:
- Person is 18 years or older
- Has a diagnosis of severe acquired thrombotic thrombocytopenic purpura (aTTP) with at least one ADAMST13 level below 20 percent
- Person has been receiving plasma exchange (PEX) and caplacizumab as an inpatient
- PEX will be continued on an outpatient basis

**CRITERIA FOR COVERAGE (Prescription Benefit):**
All of the following must be met:
- Person is 18 years or older
- Has a diagnosis of severe aTTP with at least one ADAMST13 level below 20 percent
- Person has been receiving PEX and caplacizumab (either as an inpatient or in an outpatient clinic setting)
- Plasma exchange has been discontinued and caplacizumab therapy will continue in combination with immunosuppressive therapy (e.g. systemic corticosteroids or rituximab)
- The person has not had > 2 recurrences of aTTP while on caplacizumab therapy
- Caplacizumab injections will be self-administered
- Drug is included in the Quartz Specialty Pharmacy Network

**CRITERIA FOR DURATION EXCEPTIONS (Maximum additional 28 days):**
All of the following must be met:
- Person has completed an initial 30-day course of caplacizumab therapy after discontinuation of PEX
- ADAMTS13 activity is below 20 percent
<table>
<thead>
<tr>
<th>Generic</th>
<th>Brand</th>
<th>HICL</th>
<th>GCN</th>
<th>Exception/Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>CARBIDOPA/LEVODOPA</td>
<td>RYTARY</td>
<td></td>
<td>37693, 37694, 37695, 37696</td>
<td></td>
</tr>
</tbody>
</table>

**Carbidopa/levodopa ER capsules (Rytary)**

**Prior Authorization Criteria**

**FORMULARY STATUS:** Nonpreferred-Restricted

**APPROVAL LIMITS:** None

**QUANTITY LIMITS:** None

**CRITERIA FOR COVERAGE:**
- Prescribed by a Neurologist
- AND
- Have experienced breakthrough symptoms despite titrated treatment with CONCURRENT immediate-release and extended-release carbidopa/levodopa generics
- AND
- Have a diagnosis of Parkinson’s disease, post-encephalitic parkinsonism, or parkinsonism following intoxication from carbon monoxide or manganese

**CONTINUATION OF COVERAGE CRITERIA:**
- Persons new to the plan 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.
- Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.
Cenegermin (Oxervate)
Prior Authorization Criteria

FORMULATORY STATUS: Nonpreferred-Restricted

APPROVAL LIMITS: 8 weeks

QUANTITY LIMITS: One vial per day per affected eye
(#28 per for one eye OR #56 for two eyes per 28 days)

CRITERIA FOR COVERAGE:
• Prescribed by an Ophthalmologist
AND
• Confirmed diagnosis of Stage 2* or Stage 3* Neurotrophic Keratitis
AND
• Documentation of decreased or loss of corneal sensitivity and corneal epithelium changes
AND
• Documentation of treatment of underlying conditions if appropriate (i.e. herpetic eye disease, diabetes, dry eye, multiple sclerosis, etc.)
AND
• Failure to improve with conservative management after an adequate trial of:
  o Ocular lubricants or artificial tears for at least two weeks
AND
• Discontinuation of ophthalmic steroids or avoidance of ophthalmic preservatives

CRITERIA FOR QUANTITY EXCEPTIONS:
• Prescriber provides an evidence-based clinical rationale for using a dose outside of the quantity limit.

CRITERIA FOR DURATION EXCEPTIONS:
• Prescriber provides an evidence-based clinical rationale for using a treatment duration beyond the limit.

*IMPORTANT INFORMATION:
• Stage 2 (Moderate) = NK exhibits nonhealing persistent epithelial defect (PED)
• Stage 3 (Severe) = NK exhibits corneal ulceration involving subepithelial (stromal) tissue which may progress to corneal perforation

FOR BADGERCARE COVERAGE:
Medication must be billed to ForwardHealth under the pharmacy benefit. Refer to the ForwardHealth policy “Select High Cost, Orphan, and Accelerated Approval Drugs” for additional information.
Cerliponase Alfa (Brineura)
Prior Authorization Criteria

FORMULARY STATUS: Medical Benefit - Restricted

APPROVAL LIMITS: 12 months

QUANTITY LIMITS: None

CRITERIA FOR COVERAGE OF INITIAL USE:
• Diagnosis of late infantile neuronal ceroid lipofuscinosis type 2 (CLN2)
  AND
• Age 3 years or older
  AND
• Combined score of at least 3 on the CLN2 Clinical Rating Score

CRITERIA FOR CONTINUATION OF THERAPY/COVERAGE:
• Diagnosis of late infantile neuronal ceroid lipofuscinosis type 2 (CLN2)
  AND
• Age 3 years or older
  AND
• Individual is ambulatory (score of 1 or higher on the motor domain), which can include with assistance.

Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.
Chronic Constipation Medications
Prior Authorization Criteria

<table>
<thead>
<tr>
<th>Generic</th>
<th>Brand</th>
<th>HICL</th>
<th>GCN</th>
<th>Exception/Other</th>
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<tr>
<td>LUBIPROSTONE</td>
<td>AMITIZA</td>
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<tr>
<td>LINACLOTIDE</td>
<td>LINZESS</td>
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<td>NALOXEGOL</td>
<td>MOVANTIK</td>
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<td>PLECANATIDE</td>
<td>TRULANCE</td>
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<td>NALDEMEDINE</td>
<td>SYMPROIC</td>
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<tr>
<td>PRUCALOPRIDE</td>
<td>MOTEGRITY</td>
<td>36920</td>
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</tbody>
</table>

**FORMULARY STATUS:**
Linaclotide (Linzess)- Preferred-restricted
Lubiprostone (Amitiza)- Nonpreferred-restricted
Naldemedine (Symproic) Nonpreferred-restricted
Naloxegol (Movantik) Preferred-restricted
Plecanatide (Trulance) Nonpreferred-restricted
Prucalopride (Motegrity) Nonpreferred-restricted

**APPROVAL LIMITS:**
None

**QUANTITY LIMITS:**
Linaclotide- One capsule per day (#30)
Lubiprostone- Two capsules per day (#60)
Naldemedine- One tablet per day (#30)
Naloxegol- One tablet per day (#30)
Plecanatide- One tablet per day (#30)
Prucalopride- One tablet per day (#30)

**CRITERIA FOR COVERAGE:**
Person is age 18 or older, AND one of the following:

1. **Diagnosis is Chronic Constipation (linaclotide, lubiprostone, plecanatide, prucalopride):**
   - Two first line therapies were not tolerated or failed after an adequate trial (e.g. Miralax, stimulants, fiber supplements, stool softeners)

   OR

2. **Diagnosis is Irritable Bowel Syndrome-Constipation (linaclotide, lubiprostone, plecanatide)**
   - Failure or intolerance of an adequate trial of at least two alternatives therapies (e.g. Miralax, fiber, stimulants, dicyclomine, hyoscyamine, tricyclic or SSRI antidepressants)

   OR

3. **Diagnosis is Opioid Induced Constipation (naloxegol):**
   - Person on chronic opioid therapy and experiencing opioid induced constipation **AND**
   - Failure to alleviate opioid induced constipation with an adequate trial of a combination of a stimulant (ex. senna) and an osmotic laxative (ex. Miralax)

   OR

4. **Diagnosis is Opioid-Induced Constipation (lubiprostone, naldemedine):**
   - Person on chronic opioid therapy and experiencing opioid induced constipation, **AND**
   - Failure to alleviate opioid induced constipation with an adequate trial of a combination of a stimulant (ex. senna) and an osmotic laxative (ex. Miralax), **AND**
   - Failure to alleviate constipation with an adequate trial of or intolerance to naloxegol
CRITERIA FOR COVERAGE MINNESOTA PLANS ONLY:
- Diagnosis is Opioid-Induced Constipation, **AND**
- The person has stage four metastatic cancer, **AND**
- Person is taking opioids to treat cancer-related pain

CRITERIA FOR COVERAGE OF QUANTITY EXCEPTIONS:
- Prescriber provides an evidence-based clinical rationale for using a dosing regimen outside of the quantity limits

CONTINUATION OF COVERAGE CRITERIA:
- Persons new to coverage 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.
- Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.
Clindamycin topical products
Prior Authorization Criteria

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Drug Status</th>
<th>Quantity Limits</th>
<th>Approval Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clindamycin 1% gel (Clindagel equiv.)</td>
<td>Nonpreferred-Restricted</td>
<td>None</td>
<td>None</td>
</tr>
</tbody>
</table>

CRITERIA FOR COVERAGE:
- Diagnosis of acne
AND
- Failure/intolerance to preferred generic clindamycin 1% gel (Cleocin-T equiv.)
AND
- Prescriber provides an evidence-based clinical rationale why a different clindamycin product would produce different results from the previous trial based on specific drug characteristics
Clobazam film (Sympazan)
Prior Authorization Criteria

FORMULARY STATUS: Nonpreferred-Restricted

APPROVAL LIMITS: None

QUANTITY LIMITS: None

CRITERIA FOR COVERAGE:
- Person with a diagnosis of Lennox-Gastaut syndrome with continued seizure activity despite adequate trials of at least two preferred antiepileptic drugs (e.g. levetiracetam, lamotrigine)
AND
- A trial of generic clobazam (tablets and solution) was not tolerated due to physical inability to swallow
Clomipramine (Anafranil)
Prior Authorization Criteria

<table>
<thead>
<tr>
<th>Drug</th>
<th>Drug Status</th>
<th>Quantity Limits</th>
<th>Approval Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clomipramine (Anafranil generic equivalent)</td>
<td>Preferred-Restricted</td>
<td>None</td>
<td>None</td>
</tr>
</tbody>
</table>

CRITERIA FOR COVERAGE for obsessive compulsive disorder:
- Lack of efficacy with an adequate trial of, or intolerance to, two preferred antidepressants within the Serotonin Selective Reuptake Inhibitor (SSRI) category

CRITERIA FOR COVERAGE for other mood or anxiety disorders:
- Lack of efficacy with an adequate trial of, or intolerance to, two preferred antidepressants within the Serotonin Selective Reuptake Inhibitor (SSRI) or Selective Norepinephrine Reuptake Inhibitor (SNRI) categories

CONTINUATION OF COVERAGE CRITERIA:
- Persons new to the plan who are being treated for obsessive compulsive disorder (OCD) and are established on therapy will have coverage under their drug benefit with documentation of symptom improvement or disease stability.
- Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.

IMPORTANT INFORMATION:
Preferred SSRI include citalopram, escitalopram, fluoxetine, paroxetine, and sertraline. Preferred TCAs include amitriptyline, desipramine, imipramine, nortriptyline, and protriptyline.
<table>
<thead>
<tr>
<th>Generic</th>
<th>Brand</th>
<th>HICL</th>
<th>GCN</th>
<th>Exception/Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>CODEINE PHOSPHATE/ GUAIFENESIN LIQUID</td>
<td>CODITUSSIN AC, VIRTUSSIN AC, CHERATUSSIN AC, ROBAFEN AC, IOPHEN-C NR, RELCOF C, MAR-COF CG, M-CLEAR, M-CLEAR WC, GUAIFENESIN AC, GUAIFENESIN-CODEINE, GUIATUSS AC, TRYMINE CG, NINJACOF-XG, GUAIATUSSIN AC, G TUSSIN AC, ALLFEN CDX, CODEINE-GUAIFENESIN, CODAR GF, PRO-CLEAR CAPS, AMBITUSSIN AC, VIRTUSSIN AC, CODITUSSIN AC</td>
<td>00206</td>
<td>GCN NEQ 16247, 30682, 99747</td>
<td></td>
</tr>
<tr>
<td>PROMETHAZINE HCL/CODEINE SYRUP</td>
<td>PROMETHAZINE-CODEINE</td>
<td>00345</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CHLORPHENIRAMINE/CODEINE PHOS SUSP</td>
<td>ZODRYL AC SUSPENSION, TUXARIN ER</td>
<td>00347</td>
<td>GCN NEQ 16247, 30682, 99747</td>
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<tr>
<td>CODEINE POLI/CHLORPHENIR POLIS ER 12H</td>
<td>TUZISTRA XR</td>
<td>00348</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PROMETHAZINE/PHENYLEPH/CODEINE SYRUP</td>
<td>PROMETHAZINE VC-CODEINE</td>
<td>00420</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CODEINE/BUTALBITAL/ASA/CAFFEIN CAPSULE</td>
<td>FIORINAL-COD 30-50-325-40 CAP, ASCOMP WITH CODEINE</td>
<td>01699</td>
<td></td>
<td></td>
</tr>
<tr>
<td>BUTALBIT/ACETAMIN/CAFF/CODEINE CAPSULE</td>
<td>FIORICET-COD 50-300-40-30 CAP</td>
<td>01713</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ACETAMINOPHEN WITH CODEINE TABLET</td>
<td>TYLENOL WITH CODEINE</td>
<td>01717</td>
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<td></td>
</tr>
<tr>
<td>CARISOPRODOL/ASPIRIN/CODEINE TABLET</td>
<td>CARISOPRODOL COMPOUND-CODEINE</td>
<td>01720</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CODEINE SULFATE TABLET</td>
<td>CODEINE SULFATE</td>
<td>01722</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ACETAMINOPHEN/CAFF/DIHYDROCOD CAPSULE</td>
<td>TREZIX 16-320.5-30 MG CAPSULE</td>
<td>01739</td>
<td>GCN NEQ 43264</td>
<td></td>
</tr>
<tr>
<td>TRAMADOL HCL</td>
<td>ULTRAM, ULTRAM ER</td>
<td>08317</td>
<td>GCN NEQ 20524</td>
<td></td>
</tr>
<tr>
<td>CONZIP</td>
<td>TRAMADOL HCL/ACETAMINOPHEN TABLET</td>
<td>ULTRACET TABLET</td>
<td>22880</td>
<td></td>
</tr>
<tr>
<td>--------</td>
<td>----------------------------------</td>
<td>-----------------</td>
<td>-------</td>
<td></td>
</tr>
<tr>
<td></td>
<td>PSEUDOEPHED/CODEINE/ GUAIFEN SYRUP</td>
<td>ZODRYL DEC, LORTUSS EX, TUSNEL C, VIRTUSSIN DAC, CODITUSSIN DAC</td>
<td>35174</td>
<td>BRAND NEQ CHERATUSSIN DAC, GUAIFENESIN DAC, PHENYLHISTINE, MYTUSSIN DAC, GCN NEQ 29559, 30673</td>
</tr>
<tr>
<td></td>
<td>BROMPHENIRAMINE/P-EPH/ CODEINE LIQUID</td>
<td>M-END PE LIQUID</td>
<td>35361</td>
<td>GCN NEQ 99350, 36828</td>
</tr>
<tr>
<td></td>
<td>BROMPHENIRA/PSEUDOEPHED/ CODEIN LIQUID</td>
<td>RYDEX LIQUID</td>
<td>35501</td>
<td>BRAND NEQ MAR-COF BP, M-END WC, MESEHIST WC</td>
</tr>
<tr>
<td></td>
<td>DEXCHLORPHEN/PHENYLEPH/ CODEINE LIQUID</td>
<td>PRO-RED AC SYRUP</td>
<td>35645</td>
<td>GCN NEQ 99789</td>
</tr>
<tr>
<td></td>
<td>CHLORPHEN/PSEUDOEPHED/ CODEINE SUSP</td>
<td>ZODRYL DAC</td>
<td>36713</td>
<td>GCN NEQ 30702</td>
</tr>
<tr>
<td></td>
<td>CHLORPHENIRAMINE/PE/ CODEINE LIQUID</td>
<td>CAPCOF, MAXI-TUSS CD</td>
<td>37229</td>
<td></td>
</tr>
<tr>
<td></td>
<td>TRIPROLIDINE/PHENYLEPH/ CODEINE SYRUP</td>
<td>HISTEX-AC</td>
<td>42426</td>
<td></td>
</tr>
</tbody>
</table>

**Codeine and Tramadol-Containing Products**  
**Prior Authorization Criteria**

**FORMULARY STATUS:** Varies-Restricted  
**APPROVAL LIMITS:** None  
**QUANTITY LIMITS:** None  
**CRITERIA FOR COVERAGE:**  
- Age >11 years
Compounded Hormones
Prior Authorization Criteria

FORMULARY STATUS:
Estrogen Nonpreferred-Restricted
Progesterone Nonpreferred-Restricted
Testosterone Nonpreferred-Restricted

APPROVAL LIMITS:
For hormones for high-risk pregnancy:
1st trimester: 4 fills/4 months; 2nd trimester: 6 fills/6 months
Other hormone indications: 12 months

QUANTITY LIMITS: None

CRITERIA FOR COVERAGE:
1. For compounded progesterone to maintain pregnancy:
   Women in 1st trimester
   • Woman is currently pregnant AND
   • Progesterone needed to maintain pregnancy
   Women beyond 1st trimester
   • Woman has a preterm birth

2. For other hormones or indications (e.g., hormone replacement therapy):
   • Failed all preferred alternatives available on the formulary
   AND
   • Adequate published evidence submitted by the prescriber to support use of the specific drug/concentration/formulation for the patient’s specific use.
   AND
   • For testosterone, when used for a diagnosis of primary or secondary hypogonadism or mixed hypogonadism that clinically appropriate laboratory data demonstrate androgen deficiency* AND are symptomatic with symptoms other than sexual dysfunction.

3. (Illinois plans only) For compounded progesterone to treat infertility
   • Resident of the state of Illinois
   • Documentation of inability to conceive after 12 months of unprotected intercourse or inability to sustain a successful pregnancy OR

<table>
<thead>
<tr>
<th>Generic</th>
<th>Brand</th>
<th>HICL</th>
<th>GCN</th>
<th>Exception/Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>ESTROGEN</td>
<td></td>
<td>01422, 07315, 09627, 22707, 34395</td>
<td>93535, 10750, 51295</td>
<td>ROUTE = MISCELL.</td>
</tr>
<tr>
<td>PROGESTERONE</td>
<td></td>
<td>01440</td>
<td>26048, 11170</td>
<td>ROUTE = MISCELL.</td>
</tr>
<tr>
<td>TESTOSTERONE</td>
<td></td>
<td>01403, 01402, 40042, 22168</td>
<td>10150, 29858</td>
<td>ROUTE = MISCELL.</td>
</tr>
</tbody>
</table>
• Documentation of a medical condition that renders conception impossible through unprotected intercourse (e.g. congenital absence of the uterus or ovaries) **OR**
• Documentation that 12 months of medically supervised methods of conception (e.g. artificial insemination) have failed and will not likely lead to a successful pregnancy

**CRITERIA FOR COVERAGE OF DURATION EXCEPTIONS:**
• Above criteria are met
• Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage
• For non-pregnancy indications, prescriber provides clinical documentation from the previous 12 months that describes the person’s response as stable disease or improvement seen on therapy **OR**
• For pregnancy indication: prescriber provides clinical rationale for using an extended duration

**IMPORTANT INFORMATION:**
Medications will not be covered to improve libido, for sexual dysfunction, or for use in assisted-reproductive techniques (pre-pregnancy).
Medications that are administered in the clinic are not included in the pharmacy benefit. They are covered under the medical benefit.

* 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 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.
Compounded Prescriptions*
Prior Authorization Criteria

FORMULARY STATUS: Varies

APPROVAL LIMITS: 12 months

QUANTITY LIMITS: None

CRITERIA FOR COVERAGE:
These criteria will be applied only if a compound claim requires prior authorization (e.g. most expensive ingredient requires prior authorization)
• Medication is not commercially available in a formulation that is suitable for the patient.
• Adequate published evidence supports the use of the medication in the concentration prescribed and in the route that will be used for the patient’s condition.
• None of the products in the compound are otherwise excluded from coverage as defined by the person’s benefit.
• None of the products in the compound are experimental or limited by the FDA to investigational use only.

*See separate prior authorization criteria for compounded hormones

CRITERIA FOR COVERAGE OF DURATION EXCEPTIONS:
• Above criteria are met AND
• Prescriber provides clinical documentation from the previous 12 months that describes the person’s response as stable disease or improvement seen on therapy.
• Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage.
**Standalone Personal Continuous Glucose Monitors (CGM)**

**FORMULARY STATUS:**
Dexcom G6 CGM system (meter, transmitters and sensors) Non-Preferred

**Quantity Limits:**
- Dexcom System meter (HICL 36756): 1 meter per 12 months
- Dexcom G6 Transmitter (NDC 08627001601): 1 transmitter per 90 days
- Dexcom G6 Sensor (NDC 08627005303): 3 sensors (1 kit) per 30 days

**Approval Limits:**
12 months

**CRITERIA FOR COVERAGE:**
- The ordered device is FDA approved for use by the age group of the patient, **AND**
- Prescribed by endocrinologist or diabetes specialist with expertise in the management of CGM systems, **AND one of the following:**
  A. **Diagnosis of Type 1 diabetes, AND**
     - Current use of an insulin pump, **AND**
     - Documented compliance with blood glucose testing at least three times per day, **AND**
       - Unable to achieve optimum glycemic control (i.e. HbA1c<7%), **OR**
       - Documentation of at least two severe hypoglycemic events (less than 50 mg/dL) within the past 30 days
  OR
  B. **Diagnosis of Type 1 diabetes, AND**
     - 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 six months **AND**
     - Compliance with a diabetic education program including documented blood glucose testing at least three times per day for a minimum of three months, **AND**
     - At least **ONE** of the following:
       - Hemoglobin A1C greater than 7.0%, **OR**
       - Documentation of at least two severe hypoglycemic events (less than 50 mg/dL) within the past 30 days, **OR**
       - Dawn phenomenon with fasting blood sugars frequently exceeding 200mg/dl, **OR**
       - History of severe glycemic excursions, **OR**
       - Recurrent nocturnal hypoglycemia, **OR**
       - Extreme sensitivity to insulin, **OR**
       - Wide fluctuations in blood glucose before mealtimes
  OR
  C. **Diagnosis of Type 2 diabetes, AND**
• 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 six months, AND
• Documentation of at least two severe hypoglycemic events (less than 50 mg/dL) within the past 30 days despite appropriate modifications in insulin therapy, AND
• Documented compliance with blood glucose testing at least three times per day, AND
• Unable to achieve optimum glycemic control (i.e. HbA1c<7%)

CRITERIA OF CONTINUATION/RENEWAL OF COVERAGE:
• Initial criteria met AND
• Person has been evaluated within the past 12 months by an Endocrinologist or Diabetes specialist, AND
• Documentation is supplied to show use of the device an average of at least 5 days per week during the month prior to the request
• Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.

THE FOLLOWING ARE NOT COVERED BENEFITS:
• Additional CGM software or hardware
• Other combination home blood glucose monitor devices
• Remote glucose monitoring devices
• CGMs that are not FDA approved for use by the age group of the patient
• Other related diabetic supplies unless listed on the Quartz formulary
**Generic**

<table>
<thead>
<tr>
<th>Generic</th>
<th>Brand</th>
<th>HICL</th>
<th>GCN</th>
<th>Other/Exception</th>
</tr>
</thead>
<tbody>
<tr>
<td>BUDESONIDE</td>
<td>PULMICORT</td>
<td></td>
<td>98025, 98024</td>
<td></td>
</tr>
<tr>
<td></td>
<td>FLEXHALER</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Restricted Inhaled Corticosteroid**

Prior Authorization Criteria

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Drug Status</th>
<th>Quantity Limits/30 Days</th>
<th>Approval Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Budesonide (Pulmicort)</td>
<td>Nonpreferred-Restricted</td>
<td>2 inhalers</td>
<td>Pregnancy: 15 months Other diagnoses: None</td>
</tr>
</tbody>
</table>

**CRITERIA FOR COVERAGE:**

- Failure (documented by the doctor as an objective change in symptom control such as Asthma Control Test score, nocturnal awakenings, increased rescue inhaler use, etc. that is not due to an acute exacerbation such as viral illness) at an equipotent dose (see Table 1 on the second page of these criteria), intolerance, or contraindication to BOTH a preferred fluticasone and a mometasone-containing alternative.

OR

- Use as an add-on 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. (A copy of the patient’s asthma treatment plan demonstrating a preferred alternative as the patient’s primary maintenance inhaler must be included.

OR

- Person is currently pregnant

**PREFERRED ALTERNATIVES:**

- Fluticasone (Flovent)
- Fluticasone/salmeterol (Advair)
- Fluticasone/vilanterol (Breo Ellipta)
- Mometasone (Asmanex)
- Mometasone/formoterol (Dulera)

**Table 1. ICS equivalent dosing chart.**

<table>
<thead>
<tr>
<th>Children 5 years and younger - Low, medium and High doses of ICS</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

**Children 6-11 years - Low, medium and High doses of ICS**

<table>
<thead>
<tr>
<th></th>
<th>Low (mcg)</th>
<th>Medium (mcg)</th>
<th>High (mcg)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
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<tr>
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</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Low (mcg)</td>
<td>Medium (mcg)</td>
<td>High (mcg)</td>
</tr>
<tr>
<td>----------------</td>
<td>-----------</td>
<td>--------------</td>
<td>------------</td>
</tr>
<tr>
<td>Beclomethasone</td>
<td>100-200</td>
<td>&gt;200-400</td>
<td>&gt;400</td>
</tr>
<tr>
<td>Budesonide DPI</td>
<td>200-400</td>
<td>&gt;400-800</td>
<td>&gt;800</td>
</tr>
<tr>
<td>Budesonide (nebules)</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Ciclesonide HFA</td>
<td>80-160</td>
<td>&gt;160-320</td>
<td>&gt;320</td>
</tr>
<tr>
<td>Fluticasone furoate (DPI)</td>
<td>100</td>
<td>N/A</td>
<td>200</td>
</tr>
<tr>
<td>Fluticasone propionate</td>
<td>100-250</td>
<td>&gt;250-500</td>
<td>&gt;500</td>
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<tr>
<td>Fluticasone propionate</td>
<td>100-250</td>
<td>&gt;250-500</td>
<td>&gt;500</td>
</tr>
<tr>
<td>Mometasone furoate</td>
<td>110-220</td>
<td>&gt;220-440</td>
<td>&gt;440</td>
</tr>
<tr>
<td>Triamcinolone acetonide</td>
<td>400-1000</td>
<td>&gt;1000-2000</td>
<td>&gt;2000</td>
</tr>
</tbody>
</table>
Corticotropin Gel (HP Acthar)
Prior Authorization Criteria

FORMULARY STATUS:
Prescription Benefit: Nonpreferred-Restricted
Medical Benefit: Restricted

APPROVAL LIMITS: 3 months with partial fill (max 15 days/prescription)

CRITERIA FOR COVERAGE:
• Age ≤ 1 year
• Diagnosis of infantile spasm by a Neurologist with electroencephalogram pattern consistent with hypsarrhythmia

CRITERIA FOR RE-APPROVAL/CONTINUATION OF THERAPY:
• Provider provides an evidence-based rationale for use beyond 3 months and submits clinical documentation of evidence of patient response to therapy from the previous 3 month period.
• Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.

IMPORTANT INFORMATION:
Vigabatrin (Sabril) is an alternative treatment option for infantile spasm.

Data exists for use of corticotropin gel in multiple other indications: however, as noted in the package label: “Acthar gel has limited therapeutic value in those conditions responsive to corticosteroid therapy; in such cases, corticosteroid therapy is considered the treatment of choice.”

Corticotropin gel is a limited distribution medication. Please see www.acthar.com for more information regarding availability.
CRISABOROLE | EUCRISA | 43999

Crisaborole (Eucrisa)
Prior Authorization Criteria

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Drug Status</th>
<th>Quantity Limit</th>
<th>Approval Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Crisaborole (Eucrisa)</td>
<td>Nonpreferred-Restricted</td>
<td>None</td>
<td>None</td>
</tr>
</tbody>
</table>

CRITERIA FOR COVERAGE:
- Persons aged ≥2 years
- Diagnosis of mild to moderate atopic dermatitis
- Failure after an adequate (1 month) trial of, or intolerance to:
  - Low or medium potency topical corticosteroids – dependent on which is clinically appropriate (ex. triamcinolone or betamethasone valerate)
  - Topical calcineurin inhibitors (ex. tacrolimus, pimecrolimus)
- Contraindication to topical corticosteroids and topical calcineurin inhibitors
**Generic** | **Brand** | **HICL** | **GCN** | **Exception/Other**
--- | --- | --- | --- | ---
IVACAFTOR | KALYDECO | 38461 | | |
IVACAFTOR/LUMACAFTOR | ORKAMBI | 42235 | | |
TEZACAFTOR/IVACAFTOR | SYMDEKO | 44771 | | |

### Cystic Fibrosis Transmembrane Receptor (CFTR) Modifiers

**Prior Authorization Criteria**

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Drug Status</th>
<th>Quantity Limit/Day</th>
<th>Approval Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ivacaftor (Kalydeco)</td>
<td>Nonpreferred-Restricted</td>
<td>2</td>
<td>12 months</td>
</tr>
<tr>
<td>Lumacaftor/ivacaftor (Orkambi)</td>
<td>Nonpreferred-Restricted</td>
<td>Tablets - 4, Packets - 2</td>
<td>12 months</td>
</tr>
<tr>
<td>Tezacaftor/ivacaftor (Symdeko)</td>
<td>Nonpreferred-Restricted</td>
<td>2</td>
<td>12 months</td>
</tr>
</tbody>
</table>

**CRITERIA FOR COVERAGE:**

- Person with chronic sinopulmonary, gastrointestinal or nutritional abnormalities related to cystic fibrosis (CF) requiring medical treatment.
- Prescribing provider specializing in management of CF
- Confirmed diagnosis of CF with documented evidence of mutations in the CF transmembrane conductance regulator (CFTR) gene in one of the following three categories:
  1. For persons with **homozygous F508del** CFTR mutation:
     a. For Orkambi – age ≥ 2 years
     b. For Symdeko – age ≥ 6 years and intolerance, significant drug interactions, or failure after an adequate six-month trial of Orkambi
  2. For persons with **heterozygous** CFTR gene mutation that is responsive to tezacaftor/ivacaftor (Symdeko), as noted in the package label:
     a. For Kalydeco – age 2-5 years OR person ≥ 6 years old and intolerance or failure after an adequate six-month trial of Symdeko
     b. For Symdeko – age ≥ 6 years
  3. For persons with CFTR mutations only responsive to ivacaftor (Kalydeco), noted in the package label:
     a. For Kalydeco – age ≥ 6 months

**CRITERIA FOR CONTINUATION OF COVERAGE (new to plan/12-month):**

- Clinical documentation from the previous 12 months demonstrating a response to therapy such as:
  a. FEV1 stabilization or improvement from baseline
  b. Reduction in the number of pulmonary exacerbations that require antibiotics in the past year
  c. Improvement in BMI from baseline
  d. Person-specific description of benefit
- Person is using the Quartz first-line drug for their age-mutation combination as outlined in the initial criteria
  OR
- There is clinical documentation supporting failure or intolerance to the Quartz first-line drug for their age-mutation combination

**Note:**

Revised: 02/12/2020
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Continuation of therapy criteria will not be applied to persons who are not new to the plan who were not previously approved for coverage of their current therapy (such as those who initiate therapy through provider samples or manufacturer-sponsored free drug programs).

IMPORTANT INFORMATION:
Ivacaftor monotherapy is not effective in persons with CF who are homozygous for the F508del mutation in the CFTR gene.
Dalfampridine (Ampyra equivalent)  
Prior Authorization Criteria

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Drug Status</th>
<th>Quantity Limits/Day</th>
<th>Approval Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dalfampridine (Ampyra equiv.)</td>
<td>Nonpreferred - Restricted</td>
<td>2</td>
<td>Initial - 3 months Renewal - 12 months</td>
</tr>
</tbody>
</table>

**CRITERIA FOR INITIAL COVERAGE:**
- Person with multiple sclerosis and has an Expanded Disability Status Scale (EDSS) score of 4 or greater
- Person is ambulatory with or without assistance

**CRITERIA FOR QUANTITY EXCEPTIONS:**
- Prescriber provides an evidence-based rationale for using a dose outside of the quantity limits

**CRITERIA FOR CONTINUATION OF COVERAGE (3 month):**
- Initial criteria met
- Prescriber provides clinical documentation from the previous 3 months that the person demonstrated response to dalfampridine (at least 20% improvement from baseline in walking speed in timed 25-foot walk test).

**CRITERIA FOR CONTINUATION OF COVERAGE (12 month):**
- 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).
- Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.
Dapsone (Aczone)
Prior Authorization Criteria

FORMULARY STATUS:
Dapsone (Aczone 7.5%, generic 5%): Preferred-Restricted

APPROVAL LIMITS:
None

QUANTITY LIMITS:
None

CRITERIA FOR COVERAGE (5%):
• Diagnosis of acne
AND
• Failure/intolerance of 2 prior therapies for acne (can include oral antibiotics, topical adapalene (RX/OTC), topical antimicrobial therapy, topical tretinoin, topical azelaic acid, topical benzoyl peroxide (RX/OTC), and topical salicylic acid (RX/OTC))

CRITERIA FOR COVERAGE (7.5%):
• Criteria for coverage of the 5% formulation met
AND
• Failure of dapsone 5% gel
Delafloxacin (Baxdela)
Prior Authorization Criteria

FORMULARY STATUS: Nonpreferred-Restricted

APPROVAL LIMITS: Approve for the duration of treatment-usually 6-14 days (1 fill)

QUANTITY LIMITS: None

CRITERIA FOR COVERAGE:
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 documented consultation with, an Infectious Disease Specialist.

AND
• Report of cultures and susceptibilities documenting resistance to preferred alternatives needs to be provided for approval.

CRITERIA FOR COVERAGE OF DURATION EXCEPTIONS:
• Prescriber provides an evidence-based clinical rationale for use of an extended duration.

CONTINUATION OF COVERAGE CRITERIA:
• Persons new to the plan 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.
• Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.
**Denosumab (Prolia, Xgeva)**

**Prior Authorization Criteria**

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Drug Status</th>
<th>Quantity Limits</th>
<th>Approval Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Denosumab (Prolia, Xgeva)</td>
<td>Medical Benefit-</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td></td>
<td>Restricted</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**CRITERIA FOR COVERAGE (Prolia):**

A. For the treatment of postmenopausal women or men 50 years and older who have:
   - had a low trauma (fragility) fracture of hip or spine **OR**
   - T-score is less than or equal to -2.5 at the femoral neck, total hip, lumbar spine, or 33% (one-third) radius **OR**
   - low bone mass (T-score between -1.0 and -2.5 at femoral neck or lumbar spine) **AND**
     - 10 year probability of a hip fracture of at least 3% **OR**
     - 10 year probability of a major osteoporosis-related fracture of at least 20% **OR**
     - Fragility fracture of proximal humerus, pelvis, or distal forearm **OR**
   - For persons who have no prior fragility fracture or low/moderate fracture risk, *documentation of failure of an adequate trial (reduce BMD on therapy, fracture on therapy), intolerance to, or contraindication to oral bisphosphonate therapy is required*  
   - For persons with prior fragility fractures or have high fracture risk, no prior oral bisphosphonate trial is required

**OR**

B. To increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer **AND** oral bisphosphonate therapy failed, was not tolerated, or is contraindicated.

**OR**

C. To increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer, **AND** oral bisphosphonate therapy failed, was not tolerated, or is contraindicated.

*fracture risk to be assessed with FRAX score, number of osteoporosis related fractures, increased fall risk; indicators of higher fracture risk include: advanced age, glucocorticosteroids, very low T score, increased fall risk (many of these factors will reflect in the FRAX score; however, some risk factors are not incorporated, like number of fractures, time of fracture (recent), increased fall risk)

**CRITERIA FOR COVERAGE (Xgeva):**

A. Prevention of skeletal-related events in patients with bone metastases from solid tumors **OR** multiple myeloma **OR** treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy

**AND**

B. Documented intolerance to use of zoledronic acid **OR** Renal deterioration (an increase in serum creatinine > 0.5 mg/dL over baseline in patients within 3 months following use of zoledronic acid), or a calculated CrCl < 30 ml/min **OR** Contraindication to zoledronic acid **OR** Person at high risk of toxicity related to use of zoledronic acid including baseline renal function impairment (CrCl between 45-60 ml/min) **OR** diagnosis of myeloma with elevated light chains

**OR**

C. For the treatment of giant cell tumor of the bone that is unresectable or where surgical resection is likely to result in severe morbidity

**OR**

D. For a different FDA labeled indication that is not addressed above
E. (Minnesota plans only): person with stage four metastatic cancer and the requested drug is being used as supportive care for symptoms related to their cancer diagnosis

CONTINUATION OF CARE CRITERIA:

- Persons new to coverage who are established on therapy will have coverage under their medical benefit for the remainder of the current treatment course.
- Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.

Important information:
Medications administered in the clinic are not included in the pharmacy benefit. They are covered by the medical benefit and must be procured by the clinic that is administering the medication.
Deutetrabenazine (Austedo)
Prior Authorization Criteria

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Drug Status</th>
<th>Quantity Limit</th>
<th>Approval Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deutetrabenazine (Austedo)</td>
<td>Nonpreferred-Restricted</td>
<td>None</td>
<td>None</td>
</tr>
</tbody>
</table>

CRITERIA FOR COVERAGE:

- The drug is prescribed by, or in consultation with, a Neurologist or other expert in the treatment of Huntington’s disease or tardive dyskinesia/movement disorders

AND

- Person has a diagnosis of chorea associated with Huntington’s disease

OR

- Person has a diagnosis of tardive dyskinesia AND
  - Symptoms persist despite discontinuation of the offending dopamine receptor blocking drug OR
  - The prescriber provides an 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

- An adequate trial of clonazepam did not control symptoms or caused significant side effects.

AND (for patients whose primary symptomology is tardive dystonia)

- An adequate trial of trihexyphenidyl did not control symptoms, caused significant side effects, or is contraindicated
### Restricted Diclofenac
Prior Authorization Criteria

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Drug Status</th>
<th>Quantity Limits</th>
<th>Approval Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diclofenac powder pack (Cambia)</td>
<td>Nonpreferred - Restricted</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Diclofenac 1.5%, 2% topical</td>
<td>Nonpreferred - Restricted</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Diclofenac 3% gel (generics)</td>
<td>Nonpreferred - Restricted</td>
<td>None</td>
<td>3 months</td>
</tr>
<tr>
<td>Diclofenac (Zipsor)</td>
<td>Nonpreferred - Restricted</td>
<td>None</td>
<td>None</td>
</tr>
</tbody>
</table>

**CRITERIA FOR COVERAGE (Oral Formulations):**
- Covered for persons with a therapeutic failure of an adequate trial with maximized doses of preferred oral diclofenac or intolerance to preferred oral diclofenac
- Therapeutic failure of, or intolerance to, an adequate trial with maximized doses of another preferred oral NSAID

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

**CRITERIA FOR COVERAGE (Topical Diclofenacs):**
- Therapeutic failure of an adequate trial of maximized doses, intolerance, or contraindication to two preferred oral NSAIDs and
- Therapeutic failure of an adequate trial of maximized dosing of generic diclofenac 1% gel

**OR**
- Diclofenac 3% gel (only) used for short-term treatment of actinic keratosis

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

**IMPORTANT INFORMATION:**
Other preferred oral NSAIDS include celecoxib, diclofenac sodium, etodolac, ibuprofen, indomethacin, nabumetone, naproxen, piroxicam, and sulindac (please see the formulary on the website for a complete listing). Topical diclofenac has not been shown to be more effective than oral diclofenac.

Diclofenac topical kits are not covered.
CRITERIA FOR RE-APPROVAL/CONTINUATION OF THERAPY:

- Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.
- For diclofenac 3% gel, prescriber provides an evidence-based clinical rationale for extended duration and failure of other clinical alternatives.
Doxazosin ER (Cardura XL)
Prior Authorization Criteria

FORMULARY STATUS: Nonpreferred-Restricted

APPROVAL LIMITS: None

QUANTITY LIMITS: One tablet per day (#1)

CRITERIA FOR COVERAGE:
• Person with a failure of immediate-release doxazosin (unable to achieve symptom control due to therapy-limiting side effects)

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

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

CRITERIA FOR A QUANTITY EXCEPTION:
• Once daily dosing at the commercially available dose forms did not control symptoms or caused side effects and the prescriber provides an evidence-based rationale for using a dose outside of the quantity limit
Droxidopa (Northera)  
Prior Authorization Criteria

**FORMULARY STATUS:** Nonpreferred-Restricted

**APPROVAL LIMITS:** 2 months with partial fill (max 15 days/prescription)

**QUANTITY LIMITS:** None

**CRITERIA FOR COVERAGE:**
- 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, and non-diabetic autonomic neuropathy
  
  **AND**
  - Lack of effect with midodrine and fludrocortisone
  
  **AND**
  - Prescribed by Neurologist

**CRITERIA FOR RE-APPROVAL/CONTINUATION OF THERAPY:**
- Prescriber provides clinical documentation from the previous two months of demonstrated ongoing beneficial response to therapy.
  - Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.

**IMPORTANT INFORMATION:**
For the first two months of therapy when partial fills are required, the copay will be split in half. If continued efficacy is demonstrated after two months of partial fills, a one-month supply will be allowed.
Dupilumab (Duxpent)  
Prior Authorization Criteria

**FORMULARY STATUS:**
Prescription Benefit: Nonpreferred-Restricted  
Medical Benefit: Restricted

**APPROVAL LIMITS:**  
Initial: 6 months; after 6 months, 12 months

**QUANTITY LIMITS:**  
Loading dose: x 1  
Maintenance dose: Two injections per 28 days (#4 ml)

**CRITERIA FOR INITIAL COVERAGE:**

1. **Atopic Dermatitis**
   - Age ≥ 12 years **AND**
   - Diagnosis of moderate to severe atopic dermatitis based on body surface area (>10%), extent of disability, extent of pruritus, or impact on sleep, quality of life, current use of systemic immunomodulators **AND**
   - Clinical failure* or side effects from optimized topical treatment with either a moderate to high-potency topical steroid or a topical calcineurin inhibitor **AND**
   - Clinical failure* of phototherapy, unless not indicated based on area affected,  
     o If clinic-based phototherapy - record of phototherapy episodes provided. Adherence defined as 3 times per week for one month or if necessary, modified regimen based on required adjustments for tolerability  
     o If home-based phototherapy - provision of data log recording use and dose adjustments as needed for tolerability **AND**
   - Prescription benefit medication must be self-administered and is included in the Specialty Pharmaceuticals Program. Medications must be obtained from one of the Specialty Pharmacies. Contact 1.866.894.3784 or 877.208.1096 for more details.

*Failure is defined as the inability to achieve a clinically significant improvement in itching, sleep, disability, BSA, etc., despite adherence to prescribed regimen for a minimum of 4 weeks (topical) and 4 weeks at maintenance phototherapy. Inability to attend phototherapy sessions will not constitute failure

2. **Eosinophilic Asthma**
   - Prescribed by an asthma specialist (e.g. Allergist, Immunologist, Pulmonologist) **AND**
   - Age ≥ 12 years old **AND**
   - Has a diagnosis of eosinophilic asthma with a documented blood eosinophil count of ≥ 150 cells/mm³ (other causes of eosinophilia such as hypereosinophilic syndromes, neoplastic disease, or parasitic disease must be ruled out) **AND**
   - Symptoms are not well controlled or poorly controlled (Table 1) despite an adherent** ≥ 3 month trial of high-dose inhaled corticosteroids (Table 2) in combination with a long-acting bronchodilator or leukotriene modifier

**AND**

**Adherent treatment is defined as a medication possession ratio (MPR) ≥ 70% based on the previous 120 days of prescription claims (records will be required for approval)**
OR

- Patient has intolerance 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
  - 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

Prescription benefit medication must be self-administered and is included in the Specialty Pharmaceuticals Program. Medications must be obtained from one of the Specialty Pharmacies. Contact 1.866.894.3784 or 877.208.1096 for more details.

3. Nasal Polyps

- Prescribed by a specialist experienced in the treatment of nasal polyps (ex: Otolaryngologist, Allergist) AND
- Age ≥18 years old AND
- Diagnosis of chronic rhinosinusitis with nasal polyposis AND
- At least eight weeks of moderate to severe nasal congestion/blockage/obstruction OR diminished sense of smell or rhinorrhea AND
- Documented nasal polyps by direct exam, endoscopy, or sinus CT scan (ex: nasal polyp score five out of eight)
- Persistent or worsening of nasal polyps despite being on a daily nasal steroid and previous failure or intolerance to one other nasal steroid spray (i.e. failed two nasal sprays or IM injections for polyps with one previous nasal spray) AND
- Prior treatment or contraindication/intolerance to oral corticosteroids for nasal polyps OR prior surgery for nasal polyps greater than six months ago AND
- Will be used in combination with a nasal corticosteroid medication AND
- No chronic or acute infection requiring systemic treatment within two weeks before therapy initiation AND
- Not used in combination with other biologic therapies/systemic immunosuppressant therapies to treat inflammatory disease or autoimmune disease (e.g., rheumatoid arthritis, inflammatory bowel disease, asthma)

AND

Prescription benefit medication must be self-administered and is included in the Specialty Pharmaceuticals Program. Medications must be obtained from one of the Specialty Pharmacies. Contact 1.866.894.3784 or 877.208.1096 for more details.

CRITERIA FOR CONTINUATION/RENEWAL:

- Prescription benefit medication must be self-administered and is included in the Specialty Pharmaceuticals Program. Medications must be obtained from one of the Specialty Pharmacies. Contact 1.866.894.3784 or 877.208.1096 for more details.

AND

- DERMATITIS: Clinical documentation from the previous 6-12 months of improvement, e.g. body surface area, sleep, itching, other comorbidities, etc.
- ASTHMA: The prescriber must provide clinical documentation from an office visit in the preceding 12 months showing response to therapy such as:
- 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
- Sustained (at least six months) improvement in Asthma Control Test (ACT) scores

**NASAL POLYPS:** Clinical documentation from an office visit from the previous 6-12 months showing response to therapy (e.g. reduction in nasal congestion/obstruction, reduction in nasal polyposis score, etc.)

**AND**

- Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.

**CRITERIA FOR QUANTITY EXCEPTIONS:**
- Prescriber provides a clinical, evidence-based rationale for use of a dosing regimen outside of the quantity limit

**MEDICAL BENEFIT**
- Requests for coverage on the medical benefit will be assessed for Medical Necessity.

**IMPORTANT INFORMATION:**
- Use of dupilumab in combination with IL-5 inhibitors or omalizumab will only be considered on a case by case basis if each individual agent with combination high dose ICS/LABA did not control symptoms. (Note: Combination therapy for a diagnosis of Nasal Polyps has not been studied at this time and will not be allowed unless published evidence is submitted with the request.)
Edaravone (Radicava)
Prior Authorization Criteria

FORMULARY STATUS: Medical Benefit-Restricted

APPROVAL LIMITS: 12 months

QUANTITY LIMITS: None

CRITERIA FOR COVERAGE:

ALL OF THE FOLLOWING MUST BE MET:
• Prescribed by a Neurologist or other specialist in treating amyotrophic lateral sclerosis (ALS) AND
• Diagnosis of definite or probable ALS based on El Escorial revised Airlie House diagnostic criteria AND
• Independent living status (ie, Japan ALS Severity Classification Grade 1 or 2) AND
• Score of ≥ 2 on all 12 items of the ALS Functional Rating Scale (ALSFRS-R) (assessed and documented within the last 3 months) AND
• FVC % predicted ≥ 80% (assessed and documented within the last 3 months) AND
• Duration of disease from the first symptom of 2 years or less AND
• Age 20-75 AND
• Person is currently using riluzole or has a documented contraindication/intolerance/or lack of therapeutic effect of therapy

CRITERIA FOR CONTINUATION/RENEWAL
• 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 AND
• Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers
Elagolix (Orilissa)
Prior Authorization Criteria

FORMULARY STATUS: Nonpreferred-Restricted

APPROVAL LIMITS: None

QUANTITY LIMITS:
150 mg tablets - One tablet per day (#30)
200 mg tablets - Two tablets per day (#60)

CRITERIA FOR COVERAGE:
• Diagnosis of endometriosis and prescribed for the management of moderate to severe pain associated with endometriosis (pain symptoms other than dyspareunia)
AND
• Prescription is initiated by, or in consultation with, a specialist in gynecology
AND
• Significant pelvic pain symptoms continue despite an adequate trial (at least 3 months) of at least two different continuous hormonal contraceptives* used in combination with maximized prescription-strength NSAID

*Hormonal contraceptives include all formulations (oral combinations, oral single agents, injectable, implantable etc.)

CRITERIA FOR QUANTITY EXCEPTION:
• Prescriber provides an evidence-based rationale for using a dose outside of the quantity limit.
Elapegademase (Revcovi)
Prior Authorization Criteria

FORMULARY STATUS: Nonpreferred-Restricted
Medical Benefit-Restricted

APPROVAL LIMITS: 12 months

QUANTITY LIMITS: None

CRITERIA FOR COVERAGE:
• The drug is prescribed by an expert in the treatment of immune deficiencies
  AND
• Person has a diagnosis of adenosine deaminase severe combined immune deficiency (ADA-SCID)

CRITERIA FOR CONTINUATION/RENEWAL OF COVERAGE:
The prescriber provides recent clinical documentation (within 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
Elexacaftor/Tezacaftor/Ivacaftor (Trikafta)

Prior Authorization Criteria

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Drug Status</th>
<th>Quantity Limit/Day</th>
<th>Approval Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Elexacaftor/Tezacaftor/Ivacaftor (Trikafta)</td>
<td>Nonpreferred-Restricted</td>
<td>3</td>
<td>12 months</td>
</tr>
</tbody>
</table>

CRITERIA FOR COVERAGE:
- Diagnosis of cystic fibrosis (CF) with documented evidence of ≥ 1 F508del mutation in the cystic fibrosis transmembrane receptor (CFTR) gene
- Prescribed by a provider specializing in the treatment of CF
- Documented chronic sinopulmonary, gastrointestinal, or nutritional abnormalities related to CF requiring medical treatment
- Age 12 years or older

CRITERIA FOR COVERAGE OF QUANTITY EXCEPTIONS:
- The prescriber provides an evidence-based rationale for using a dose outside of the quantity limit.

CONTINUATION CRITERIA (new to plan/12-month renewal):
- Clinical documentation from the previous 12 months demonstrating a response to therapy such as:
  - 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
  - Person-specific description of benefit

Note:
Continuation of therapy criteria will not be applied to persons who are not new to the plan who were not previously approved for coverage of their current therapy (such as those who initiate therapy through provider samples or manufacturer-sponsored free drug programs).
Eluxadoline (Viberzi)
Prior Authorization Criteria

FORMULARY STATUS: Nonpreferred-Restricted

APPROVAL LIMITS: None

QUANTITY LIMITS: Two tablets per day (#60)

CRITERIA FOR COVERAGE:
• Covered for persons with diarrhea predominant irritable bowel syndrome (IBS)
  AND
• Have failed, or been intolerant to, a one month trial of conventional therapy (such as loperamide or diphenoxylate/atropine)

CONTINUATION OF COVERAGE CRITERIA:
• Persons new to the plan 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.
• Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.

CRITERIA FOR QUANTITY EXCEPTIONS:
• Therapeutic failure or intolerance to twice daily dosing for available strengths and the prescriber provides an evidence-based clinical rationale for use of a dose outside of the quantity limit
Emapalumab (Gamifant)
Prior Authorization Criteria

**FORMULARY STATUS:** Medical Benefit-Restricted

**APPROVAL LIMITS:** 3 months

**QUANTITY LIMITS:** None

**CRITERIA FOR COVERAGE:**
- Prescribed by a hematologist, oncologist or related specialty, AND
- Person is currently taking and will continue treatment with dexamethasone, AND
- Overall treatment plan includes a hematopoietic stem cell transplantation (HSCT) AND
- Person diagnosed with primary hemophagocytic lymphohistiocytosis (HLH) defined as either:
  - Familial HLH caused by a gene mutation, OR
  - HLH associated with an immunodeficiency syndrome (e.g. Griscelli syndrome), OR
  - Prescriber provides objective medical documentation and published evidence to support a clinical diagnosis of primary HLH AND
- Medical documentation is provided to show continued HLH signs and symptoms despite one of the following:
  - Prior treatment with at least two standard non-steroid HLH therapies (i.e. etoposide, alemtuzumab, antithymocyte globulin) in combination with a steroid medication, OR
  - Retreatment with a previously effective therapy, OR
  - Objective medical rationale for why first and second-line treatments cannot be used AND
- Evidence of active disease based on at least three of the following signs/symptoms:
  - Hemoglobin levels <90 g/L (in infants <4 weeks old, hemoglobin <100 g/L)
  - Platelets <100 × 10^9/L
  - Neutrophils <1.0 × 10^9/L
  - Elevated liver enzymes (i.e. 3-times the ULN for AST, ALT, GGT or LDH)
  - Fasting triglycerides ≥3.0 mmol/L or ≥265 mg/dL
  - Fibrinogen ≤1.5 g/L
  - Ferritin ≥500 mg/L
  - Elevated D-dimer
  - Splenomegaly and/or hepatomegaly
  - Neurologic symptoms (seizures, mental status changes, visual disturbances, ataxia)

**CONTINUATION OF COVERAGE CRITERIA:**
- For persons new to plan who are established on therapy, medical documentation must be provided to show that the initial criteria were met, AND
- Medical documentation from the past 6 months is provided to show both of the following: a 50% improvement in at least 3 signs/symptoms of active disease and treatment plan includes a HSCT or medical rationale is provided for why person is unable to undergo HSCT.
- Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.

**FOR BADGERCARE COVERAGE:**
- Medication must be billed to ForwardHealth under the pharmacy benefit. Refer to the ForwardHealth policy “Select High Cost, Orphan, and Accelerated Approval Drugs” for additional information.

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Page 93
Generic Name | Brand Name | HICL | GCN | Exception/Other
--- | --- | --- | --- | ---
EMICIZUMAB-KXWH | HEMLIBRA | 44640 | | |

**Emicizumab (Hemlibra)**

**Prior Authorization Criteria**

**FORMULARY STATUS:**
Prescription Benefit: Nonpreferred-Restricted

**APPROVAL LIMITS:** None

**QUANTITY LIMITS:** None

**CRITERIA FOR INITIAL COVERAGE:**
- Diagnosis of congenital hemophilia A
  - with inhibitors to Factor VIII and requiring prophylaxis to prevent or reduce bleeding episodes AND not used in combination with Immune Tolerance Induction (ITI) therapy OR is currently on bypassing agent (NovoSeven, FEIBA)
  - OR
  - without inhibitors and requiring prophylaxis to prevent or reduce bleeding episodes AND has poor venous access OR has failure to achieve adequate trough level on optimal dose/frequency of Factor VIII product
  - AND
- Person is followed by a plan approved bleeding disorders program
  - AND
- Included in the Specialty Pharmaceuticals Program. Medications must be obtained from one of the participating pharmacies. Contact 1-866-894-3784 or 877.208.1096 for more details.

**IMPORTANT INFORMATION:**
- Hemlibra is for subcutaneous administration and therefore does not require clinic-administration.
- Since Hemlibra dosing is weight-based, verify the most appropriate vial size is being requested.
### Drugs for Eosinophilic Conditions

#### Prior Authorization Criteria

**FORMULARY STATUS:**

- **Benralizumab (Fasenra):**
  - Pharmacy Benefit - Preferred Restricted
  - Medical Benefit - Restricted
- **Mepolizumab (Nucala):**
  - Medical Benefit - Restricted
  - Pharmacy Benefit - Non-Preferred Restricted
- **Reslizumab (Cinqair):**
  - Medical Benefit - Restricted

**APPROVAL LIMITS:**

- **Asthma:** 12 months
- **EGPA:** Initial 6 months, Subsequent 12 months

**QUANTITY LIMITS:**

- **Benralizumab AutoInjct/Syringe:**
  - Pharmacy Benefit 1 mL/56 days (maintenance), MB or Rx Allowed for Induction, if Rx then 1mL/28 days x 3mo
- **Mepolizumab Autoinjector/Syringe:**
  - Pharmacy Benefit Asthma Diagnosis 1 mL per month
  - EGPA Diagnosis 3 mL per month

**CRITERIA FOR COVERAGE FOR ALL DIAGNOSES (INITIAL or CONTINUATION):**

- Prescription benefit medication must be self-administered and is included in the Specialty Pharmaceuticals Program. Medications must be obtained from one of the Specialty Pharmacies. Contact 1.866.894.3784 or 877.208.1096 for more details.

**AND**

- Requests for coverage on the medical benefit will be assessed for Medical Necessity.
  - Induction will be allowed underneath the pharmacy benefit or medical benefit.

**AND**

- See indication specific criteria

**CRITERIA FOR COVERAGE of eosinophilic asthma:**

1. Prescribed by an asthma specialist (Allergist, Immunologist, Pulmonologist)
2. Age ≥ 6 years for mepolizumab, ≥ 12 years benralizumab; 18 years for reslizumab
3. Has a diagnosis of eosinophilic asthma with a documented blood eosinophil count of ≥ 150 cells/mm³
   *other causes of eosinophilia such as hypereosinophilic syndromes, neoplastic disease, or parasitic disease must be ruled out

**AND**

4. Symptoms are not well controlled or poorly controlled (Table 1) despite an adherent** ≥ 3 month trial of high-dose inhaled corticosteroids (Table 2) in combination with a long-acting bronchodilator or leukotriene modifier
   **Adherent treatment is defined as a medication possession ratio (MPR) ≥ 70% based on the previous 120 days of prescription claims (records will be required for approval)**
   **OR**
   - a. Patient has intolerance 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
  o Cataracts in patients > 40 years of age
  o Glaucoma
  o Recurrent thrush
  o Dysphonia
  o Growth inhibition, after evaluation by Endocrine Consult
  o Diagnosis of osteoporosis, treatment resistant to FDA approved osteoporosis treatment

AND

5. For mepolizumab and reslizumab: Failure or intolerance to benralizumab.
   Il-5 inhibitor in combination with omalizumab will only be considered on a case by case basis if each
   individual agent with combination high dose ICS/LABA did not control symptoms

CRITERIA FOR COVERAGE of mepolizumab (Nucala) for eosinophilic granulomatosis with
polyangiitis (EGPA) (formerly known as Churg-Strauss Syndrome):
1. Prescribed by a provider experienced in the treatment EGPA (i.e. allergist, pulmonologist or
   rheumatologist)
2. Age ≥ 18 years
3. Confirmed diagnosis of relapsed* or refractory† EGPA defined as:
   a. Blood eosinophil level of ≥ 10% or an absolute eosinophil count > 1000 cells/µL with other
      causes ruled out (i.e. hypereosinophilic syndromes, neoplastic disease, or parasitic disease)
      AND
   b. At least TWO of the following organ systems or features of EGPA disease:
      o Histopathological evidence of
        ▪ eosinophilic vasculitis (i.e. bleeding under skin, red rash, petechiae, fibrinoid
degeneration, blood clots) OR
        ▪ perivascular eosinophilic infiltration (i.e., inflammatory cells around blood vessels,
lichenoid infiltration) OR
        ▪ eosinophil-rich granulomatosis inflammation (i.e. nodules, thick aggregation of
histiocytes)
      o Neuropathy (i.e. mono or polyneuropathy, mononeuritis multiplex)
      o Pulmonary infiltrates (i.e. asthma, chronic pneumonia, hemoptysis, cough)
      o Sino-nasal abnormality (i.e. sinusitis, allergic rhinitis, polyposis)
      o Cardiomyopathy (i.e. heart failure, myocarditis, pericarditis, subendocardial fibrosis)
      o Glomerulonephritis (i.e. hematuria, red cell casts, proteinuria)
      o Alveolar hemorrhage (by bronchoalveolar lavage)
      o Palpable purpura (i.e. skin nodules, urticarial rash, digital ischemia)
      o Positive antineutrophil cytoplasmic antibody [ANCA]
4. Person has failed prednisone and failed‡ a therapeutic trial (3 months) or is intolerant to at least
   ONE immunosuppressive agent (i.e. cyclophosphamide, azathioprine, or methotrexate).
5. Baseline disease severity assessed with an objective measure/tool (i.e. chronic oral corticosteroid
dose, number of intermittent steroid bursts, Birmingham Vasculitis Activity Score BVAS, number of
   urgent care, emergency room visits or hospitalizations, etc.)

CRITERIA FOR CONTINUATION/RENEWAL for eosinophilic asthma:
1. The prescriber must provide clinical documentation from an office visit in the preceding 12 months
   showing response to therapy such as:
   a. Decreased frequency of use of, or ability to lower the chronic daily dose, of oral corticosteroids
      to treat/prevent exacerbations
   b. Decreased frequency of use of unscheduled emergency department/urgent care visits for
      exacerbations
c. Reduction in reported symptoms such as chest tightness, coughing, shortness of breath, or nocturnal awakenings

d. Sustained (at least six months) improvement in Asthma Control Test (ACT) scores

2. Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.

Continuation of case by case approved IgE inhibitor and IL-5 inhibitor combination therapy will only be considered if ICS/LABA therapy was also continued AND there was reduction in oral steroid dose, exacerbations or hospitalizations.

CRITERIA FOR CONTINUATION/RENEWAL of mepolizumab for EGPA:

1. The prescriber must provide clinical documentation from an office visit in the preceding 12 months showing a response to therapy based upon at least ONE objective measure such as:
   a. Birmingham Vasculitis Activity Score (BVAS version 3) improvement from baseline (i.e. a clinically significant score improvement for vasculitis is 16 units or greater)
   b. Reduction in the total daily dose of prednisolone/prednisone (50-75% reduction in dose from baseline) or reduction in intermittent steroid bursts
   c. Improvement in the duration of remission or improvement in rate of relapses, urgent care, emergency room visits or hospitalizations.

2. Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.

CRITERIA FOR COVERAGE OF QUANTITY EXCEPTIONS:

- Symptoms persist despite treatment with adherence to the medication within the quantity limits and prescriber provides evidence-based clinical rationale for use of a dose outside of the quantity limits.

IMPORTANT INFORMATION:

Requests for doses that are higher or more frequent than what is FDA approved and use for off-label indications will be considered experimental as defined in the Certificate of Coverage and are not covered.

*Definition of relapsing EGPA; at least one confirmed EGPA relapse while the person was on prednisolone dose of ≥ 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

†Definition of refractory EGPA: 1) failure to attain remission (BVAS = 0 and oral steroid dose ≤ 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 ≥ 7.5 mg/day prednisolone or equivalent.

‡Failure of an immunosuppressant is 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.)

Table 1. Outcome Measure values for uncontrolled asthma

<table>
<thead>
<tr>
<th>Measure</th>
<th>Not Well Controlled</th>
<th>Very Poorly Controlled</th>
</tr>
</thead>
</table>

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<table>
<thead>
<tr>
<th>Baseline symptoms (outside of exacerbation)</th>
<th>&gt; 2 days/week</th>
<th>Throughout the day</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nighttime awakening</td>
<td>1-3 times/week</td>
<td>≥ 4 times/week</td>
</tr>
<tr>
<td>Interference with normal activity</td>
<td>Some limitation</td>
<td>Extremely limited</td>
</tr>
<tr>
<td>Short acting beta agonist use for symptom control</td>
<td>&gt; 2 days/week</td>
<td>Several times per day</td>
</tr>
<tr>
<td>FEV1</td>
<td>60-80% predicted or personal best</td>
<td>&lt; 60% predicted or personal best</td>
</tr>
<tr>
<td>Asthma exacerbations requiring oral steroids ≥ 2 times in the past year</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Asthma Control Test (ACT)</td>
<td>16-19</td>
<td>≤ 15</td>
</tr>
</tbody>
</table>

Table 2. High Dose Corticosteroid

<table>
<thead>
<tr>
<th>Drug</th>
<th>High Daily Dose (Adult)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Beclohexasone HFA</strong></td>
<td></td>
</tr>
<tr>
<td>40 or 80 mcg/puff</td>
<td>&gt;400 mcg</td>
</tr>
<tr>
<td><strong>Budesonide DPI</strong></td>
<td></td>
</tr>
<tr>
<td>90, 180 or 200 mcg/inhalation</td>
<td>&gt;640 mcg</td>
</tr>
<tr>
<td><strong>Ciclesonide HFA</strong></td>
<td></td>
</tr>
<tr>
<td>80 or 160 mcg</td>
<td>&gt; 320 mcg</td>
</tr>
<tr>
<td><strong>Flunisolide HFA 80 mcg/puff</strong></td>
<td>&gt;640 mcg</td>
</tr>
<tr>
<td><strong>Fluticasone</strong></td>
<td></td>
</tr>
<tr>
<td>HFA/MDI: 44, 110 mcg/puff</td>
<td>&gt;500 mcg</td>
</tr>
<tr>
<td>DPI: 50, 100, 250 mcg/inhalation</td>
<td>&gt;500 mcg</td>
</tr>
<tr>
<td><strong>Mometasone DPI</strong></td>
<td></td>
</tr>
<tr>
<td>200 mcg/inhalation</td>
<td>&gt;440 mcg</td>
</tr>
<tr>
<td>Generic</td>
<td>Brand</td>
</tr>
<tr>
<td>------------------</td>
<td>-----------</td>
</tr>
<tr>
<td>EPOETIN ALFA</td>
<td>RETACRIT</td>
</tr>
<tr>
<td>DARBEPOETIN ALFA</td>
<td>ARANESP</td>
</tr>
<tr>
<td>METHOXY PEG-EPOETIN BETA</td>
<td>MIRCERA</td>
</tr>
</tbody>
</table>

**Erythropoiesis-Stimulating Agent**

**Prior Authorization Criteria**

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Drug Status</th>
<th>Quantity Limits/Day</th>
<th>Approval Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Erythropoietin (Retacrit)</td>
<td>Preferred-Restricted</td>
<td>None</td>
<td>12 months</td>
</tr>
<tr>
<td>Darbepoetin (Aranesp)</td>
<td>Preferred-Restricted</td>
<td>None</td>
<td>12 months</td>
</tr>
<tr>
<td>Methoxy PEG-epoetin beta (Mircera)</td>
<td>Preferred-Restricted</td>
<td>None</td>
<td>12 months</td>
</tr>
<tr>
<td>Erythropoietin (Epogen, Procrit)</td>
<td>Non-formulary-Not Covered (RX benefit)</td>
<td>Not Covered (Medical Benefit)</td>
<td></td>
</tr>
</tbody>
</table>

**CRITERIA FOR COVERAGE:**

- Person or family member administering medication
- Hemoglobin < 10 g/dL (HCT < 30%)

**CRITERIA FOR COVERAGE OF DURATION EXCEPTIONS:**

- Person continues to meet clinical criteria after initial 12 months of therapy

**IMPORTANT INFORMATION:**

People should have adequate iron stores with iron therapy as indicated to restore/maintain iron stores. Methoxy PEG-epoetin beta is not indicated for the treatment of anemia due to conditions other than chronic renal failure.

Retacrit, Aranesp and Mircera administered in a clinic or healthcare facility do not require prior authorization.
Esketamine Nasal Inhalation (Spravato)
Prior Authorization Criteria

FORMULARY STATUS: Medical Benefit - Restricted

APPROVAL LIMITS:
Initial: 3 months
Renewal: 12 months

CRITERIA FOR COVERAGE (all of the following must be met):
• Medication is prescribed by or in consultation with a psychiatrist, AND
• Nasal esketamine with be will used in combination with an antidepressant medication, AND
• Person is 18 years or older, AND
• Has a diagnosis of treatment-resistant depression, AND
• Does not have active or current problems with substance abuse, AND
• Person is enrolled in the Spravato REMS Program
  AND
• Treatment was initiated during an inpatient hospitalization
  OR
• Symptoms of depression continue despite an adequate trial (at or above minimum therapeutic dose for at least 4 weeks) with:
  o 4 antidepressants from the SSRI, SNRI, or bupropion classes OR
  o 3 antidepressants from the SSRI, SNRI, or bupropion classes and at least 1 adjunct medication (e.g. stimulants, aripiprazole)
  OR
• Symptoms of depression continue and there is medical documentation to show treatment limiting side effects with:
  o 4 antidepressants from the SSRI, SNRI, or bupropion classes OR
  o 3 antidepressants from the SSRI, SNRI, or bupropion classes and at least 1 adjunct medication (e.g. stimulants, aripiprazole)
  ▪ SSRI = selective serotonin reuptake inhibitors
  ▪ SNRI = serotonin-norepinephrine reuptake-inhibitors

CRITERIA FOR COVERAGE CONTINUATION after 3 months:
• Initial criteria met AND
• Clinical documentation from the previous 3 month to show treatment response.
• Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers

CRITERIA FOR CONTINUATION OF COVERAGE/REAPPROVAL after 12 months:
• Prescriber provides clinical documentation from the previous 12 month to show continued response and medical reasons to support treatment continuation.
• Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers

IMPORTANT INFORMATION:
• Each treatment with esketamine nasal Inhalation must be supplied by a certified treatment center, supervised by a health care provider and billed as part of the medical benefit.
• The patient, facility and pharmacy must be enrolled in the Spravato Risk Evaluation Mitigation Strategy (REMS) Program
Febuxostat (Uloric)
Prior Authorization Criteria

FORMULARY STATUS: Preferred-Restricted

APPROVAL LIMITS: None

QUANTITY LIMITS: None

CRITERIA FOR COVERAGE:
- Persons with allopurinol intolerance
- Inadequate serum urate levels on maximum clinically appropriate dose of allopurinol

PREFERRED FORMULARY ALTERNATIVES: allopurinol, colchicine, probenecid
<table>
<thead>
<tr>
<th>Generic</th>
<th>Brand</th>
<th>HICL</th>
<th>GCN</th>
<th>Exception/Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>FENTANYL</td>
<td>DURAGESIC</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FENTANYL CITRATE</td>
<td>ACTIQ</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Fentanyl**
Prior Authorization Criteria

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Drug Status</th>
<th>Quantity Limit per 30 Days</th>
<th>Approval Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fentanyl lollipop (Actiq equiv.)</td>
<td>Nonpreferred-Restricted</td>
<td>120</td>
<td>None</td>
</tr>
<tr>
<td>Fentanyl transdermal patches (Duragesic equiv., generics)</td>
<td>12, 25, 50, 75, 100 mcg/hr – Preferred-Restricted</td>
<td>10</td>
<td>None</td>
</tr>
<tr>
<td></td>
<td>37.5, 62.5, 87.5 mcg mcg/hr – Nonpreferred-Restricted</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**CRITERIA FOR COVERAGE of immediate release fentanyl:**

- Medication is limited to the treatment of breakthrough cancer pain
- Person is already tolerant to opioids, defined as:
  a) oral morphine 60mg daily for one week **or**
  b) transdermal fentanyl 25mcg/hr for one week **or**
  c) oxycodone 30mg daily for one week **or**
  d) oral hydromorphone 8mg daily for one week **or**
  e) equianalgesic dose of another opioid for at least one week
- Person has failed an adequate trial of:
  a) immediate release oxycodone **or**
  b) immediate release oral hydromorphone **or**
  c) immediate release morphine
- Prescriber is Oncologist or specialty in Pain Management

**OR**

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

**CRITERIA FOR COVERAGE of transdermal fentanyl patches:**

- The person had short-acting opioids for breakthrough pain management and the long-acting opioid dose was adjusted appropriately based on rescue medication use.
  - Person had a therapeutic failure of an adequate trial (both dose* and duration) of a long-acting oral opioid
OR
  o Person had an intolerance to at least 2 long acting opioid formulations
OR
  • (Minnesota plans only) – person has stage four metastatic cancer and the requested drug is being used to treat cancer-related pain
  * Adequate dose = dose of long acting oral opioid is close to or is the equivalent dose of transdermal fentanyl

CRITERIA FOR COVERAGE OF QUANTITY EXCEPTIONS:
Therapeutic failure of four dose units per day for available strengths of immediate release fentanyl or therapeutic failure of every 72-hour dosing of available strengths of transdermal fentanyl patch and the prescriber provides an evidence-based clinical rationale for using a dose outside of the quantity limit

CONTINUATION OF COVERAGE CRITERIA (for fentanyl transdermal patches ONLY):
• Members new to the plan who are established on therapy will have coverage under their drug benefit with documentation of symptom improvement or disease stability.
• Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.
Ferric Citrate (Auryxia)
Prior Authorization Criteria

FORMULARY STATUS:
Ferric Citrate (Auryxia): Nonpreferred-Restricted

APPROVAL LIMITS:
None

QUANTITY LIMITS:
None

CRITERIA FOR COVERAGE:
• Diagnosis of chronic kidney disease (CKD) requiring dialysis with hyperphosphatemia after failure of an adequate trial of, or intolerable side effects from, BOTH a sevelamer product (Renagel, Renvela) and lanthanum (Fosrenol)

OR
• Diagnosis of iron deficiency anemia in persons with chronic kidney disease (CKD) not on dialysis after failure of an adequate trial of, or intolerable side effects from, at least two forms of oral iron products (ferrous sulfate, polysaccharide complex, ferrous fumarate, ferrous gluconate)
Fidaxomicin (Dificid)  
Prior Authorization Criteria

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Drug Status</th>
<th>Quantity Limits</th>
<th>Fill</th>
<th>Approval Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fidaxomicin (Dificid)</td>
<td>Preferred-Restricted</td>
<td>20</td>
<td>1 Fill</td>
<td></td>
</tr>
</tbody>
</table>

CRITERIA FOR COVERAGE:
1. Outpatient initiation of treatment
   - Relapse or recurrence after a sufficient treatment course with vancomycin
   - Documentation (i.e. PCR positive, toxin assay, or colonoscopy) of recurrent \textit{C. difficile} infection
   OR
   - Person with documented low levels of neutralizing antibodies to \textit{C. difficile}

2. Continuation of hospital therapy
   - Person has been receiving as an inpatient during hospitalization and needs to complete the course of therapy as an outpatient

3. \textit{(Minnesota plans only)} – person with stage four metastatic cancer and the requested drug is being used to treat a cancer-related \textit{C. difficile} infection

CRITERIA FOR COVERAGE OF DURATION EXCEPTIONS:
- Prescriber presents rationale, clinical reason for utilizing a dosing regimen that is not possible within the quantity limits and utilizing an extended duration

IMPORTANT INFORMATION:
Persons that have relapsed within 4 weeks of treatment with fidaxomicin should not be candidates for retreatment with fidaxomicin. Persons who have relapsed within 4 weeks of treatment with fidaxomicin, received antibiotics within these 4 weeks and have recurrent \textit{C. difficile} infection could be considered for a repeat course of fidaxomicin.
Fluticasone-Salmeterol (generic, Wixela Inhub)  
Prior Authorization Criteria

FORMULARY STATUS: Nonpreferred-Restricted

APPROVAL LIMITS: None

QUANTITY LIMITS: 2 inhalers per 30 days (#2)

CRITERIA FOR COVERAGE:
- Person has tried an equivalent dose of brand Advair diskus and it failed to control symptoms or caused side effects
- Prescriber provides an evidence-based rationale for why the same result would not happen with the generic equivalent

CRITERIA FOR QUANTITY EXCEPTIONS:
- Failure to control symptoms using twice daily dosing of the commercially available dose forms and the prescriber provides an evidence-based rationale for using a dose outside of the quantity limit

IMPORTANT INFORMATION:
Advair diskus brand is preferred and will process at a tier 1 cost share for persons with a tiered cost share benefit
Fostamatinib (Tavalisse)
Prior Authorization Criteria

**FORMULARY STATUS:**
Fostamatinib (Tavalisse) Nonpreferred-Restricted

**APPROVAL LIMITS:**
None

**QUANTITY LIMITS:**
Two tablets per day (#60)

**CRITERIA FOR COVERAGE:**
- Prescribed by Hematology
- Diagnosis of chronic immune thrombocytopenia (ITP)
  - Platelet count < 50,000/mL
  - Failure of 2 prior ITP therapies (e.g. corticosteroids, rituximab, azathioprine, danazol, splenectomy, or eltrombopag)

**CRITERIA FOR QUANTITY EXCEPTIONS:**
- Failure of the commercially available dose forms within the quantity limit and the doctor provides an evidence-based rationale for use of a dose outside of the quantity limit.
Fluoxetine 10 mg Tablet
Prior Authorization Criteria

<table>
<thead>
<tr>
<th>Drug</th>
<th>Drug Status</th>
<th>Quantity limit/Day</th>
<th>Approval Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluoxetine 10 mg tablet</td>
<td>Nonpreferred-Restricted</td>
<td>1.5</td>
<td>None</td>
</tr>
</tbody>
</table>

CRITERIA FOR COVERAGE:
- Person requires a dose that cannot be met using the preferred fluoxetine capsule formulations (5 or 15 mg per day)
- An adequate trial of daily dosing at 10 mg and 20 mg did not control symptoms or caused intolerable side effects.

CRITERIA FOR COVERAGE OF QUANTITY EXCEPTIONS:
- Doses greater than 15 mg per day require use of the preferred fluoxetine capsule formulation

IMPORTANT INFORMATION:
- Preferred fluoxetine HCL 10 mg, 20 mg and 40 mg capsules and 20 mg/5 mL solution are available on the formulary without restriction.
### Enzyme Inhibitors for Gaucher Disease

**Prior Authorization Criteria**

<table>
<thead>
<tr>
<th>Generic</th>
<th>Brand</th>
<th>HICL</th>
<th>GCN</th>
<th>Exception/Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>ELIGLUSTAT TARTRATE</td>
<td>CERDELGA</td>
<td>41346</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MIGLUSTAT</td>
<td>ZAVESCA</td>
<td>25098</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**FORMULARY STATUS:**
- Eliglustat (Cerdelga) - Nonpreferred-Restricted
- Miglustat - Nonpreferred-Restricted

**APPROVAL LIMITS:**
- None

**QUANTITY LIMITS:**
- Eliglustat (Cerdelga) - Two capsules per day dosing (# 60)

**CRITERIA FOR COVERAGE:**
- Persons with type-1 Gaucher disease
  **AND**
- Enzyme replacement is not an option for the person (due to allergy, hypersensitivity, etc.)
  **AND (eliglustat only)**
- Have been determined to be CYP2D6 extensive, intermediate, or poor metabolizers by an FDA-approved test

**CRITERIA FOR COVERAGE OF QUANTITY EXCEPTIONS:**
- Reasonable clinical rationale for prescribed dosing regimen provided & regimen not possible within the quantity limits

**IMPORTANT INFORMATION:**
Patients who are CYP2D6 ultra-rapid metabolizers may not get therapeutic effects from eliglustat. Dose recommendations cannot be made for patients with indeterminate CYP2D6 metabolizing status.
### Mandatory Generic Substitution Policy Exception

**Prior Authorization Criteria**, **

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Drug Status**</th>
<th>Quantity Limits</th>
<th>Approval Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Varies</td>
<td>Nonpreferred-Restricted</td>
<td>Varies</td>
<td>Varies</td>
</tr>
</tbody>
</table>

*most brand drugs with an approved generic formulation are Nonformulary and not covered. Some benefits may cover select brand formulations if prior authorization criteria for coverage are met to meet specific state or Federal requirements

**If approved, branded drugs with an approved generic will be covered at the nonpreferred level

**CRITERIA FOR COVERAGE:**

- An adequate trial of the generic formulation has been tried at the same dose and in the same formulation as the requested brand drug*
- Objective documentation is provided of a clinically significant change in side effects or symptom control with use of the generic formulation including time frames and an evaluation of causation based on the pharmacokinetics/pharmacodynamics of the requested drug
  - Documentation that the recorded reaction was observed with more than one generic manufacturer if available is required
- An office visit note is provided from the time the reported reaction occurred which evaluates for, and rules out, potential non-drug causes for a reported reaction or change in symptom control
- An explanation is provided from the prescriber explaining how the reported reaction differs from the person’s previous disease history or the expected progression of the person’s disease over time
- Adequate trials of at least two clinically appropriate formulary alternatives did not control symptoms or caused side effects***
  - ***except for drugs on the MSE list or oral oncology drugs

**DEFINITIONS:**

**Adequate clinical trial:** a trial with duration and dose adjustments to a level shown to provide maximal therapeutic effect for a particular disease based on published clinical trials.
Glucagon-like Peptide 1 (GLP-1) Agonist
Prior Authorization Criteria

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Drug Status</th>
<th>Quantity Limit/30 Days</th>
<th>Approval Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exenatide (Byetta)</td>
<td>Preferred-Restricted</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Exenatide once weekly</td>
<td>Preferred-Restricted</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>(Bydureon (BCise))</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dulaglutide (Trulicity)</td>
<td>Preferred-Restricted</td>
<td>None</td>
<td>None</td>
</tr>
</tbody>
</table>

CRITERIA FOR COVERAGE for preferred products:
- Diagnosis of Diabetes mellitus
  AND
- Inadequate glucose control (e.g. A1C, fasting plasma glucose, postprandial glucose)
  AND
- Adequate trial (defined as maximum tolerated doses) of metformin for 3 months or until intolerable side effects occur OR metformin contraindicated
  OR
- Hemoglobin A1c ≥ 9.0 and being started/used in combination with metformin or another treatment for diabetes mellitus if metformin is contraindicated/not tolerated

CONTINUATION OF THERAPY:
- Persons new to coverage who are 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 persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.

CRITERIA FOR COVERAGE OF QUANTITY EXCEPTIONS:
- The prescriber provides an evidence-based clinical rationale for using a dosing regimen outside of the quantity limits
### GONADOTROPIN RELEASING HORMONE (GNRH) AGONIST

Prior Authorization Criteria

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Brand name</th>
<th>Benefit</th>
<th>Coverage Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leuprolide acetate solution (daily injection)</td>
<td>generic</td>
<td>Prescription</td>
<td>Nonpreferred Restricted (Excluded by some certificates)</td>
</tr>
<tr>
<td>Leuprolide acetate suspension IM injection</td>
<td>Lupron Depot, Lupron Depot-Ped</td>
<td>Medical (clinic administered)</td>
<td>Covered unless excluded by certificate</td>
</tr>
<tr>
<td>Leuprolide acetate suspension Sub Q injections</td>
<td>Eligard, Atrigel</td>
<td>Medical (clinic administered)</td>
<td>Covered unless excluded by certificate</td>
</tr>
<tr>
<td>Histrelin implant yearly</td>
<td>Supprelin LA, Vantas</td>
<td>Medical (clinic administered)</td>
<td>Covered unless excluded by certificate</td>
</tr>
</tbody>
</table>

**APPROVAL LIMITS:** Varies by benefit

**QUANTITY LIMITS:** None

**CRITERIA FOR COVERAGE:**

**Prescription benefit:**
- The injections will be self-administered for prescription benefit.
- Medications used for treatment of infertility are excluded from coverage unless specifically noted as covered in the certificate of coverage or included in specific state mandates.
- Medications used for the treatment of gender dysphoria are covered unless specifically excluded in the certificate of coverage.
- Medications used for all other diagnoses (ex. prostate cancer, endometriosis, dysmenorrhea, etc) are covered.
- **(Illinois plans only)** GNRH agonists to treat infertility (12 fills per 12 months)
  - Resident of the state of Illinois
  - Documentation of inability to conceive after 12 months of unprotected intercourse or inability to sustain a successful pregnancy OR
  - Documentation of a medical condition that renders conception impossible through unprotected intercourse (e.g. congenital absence of the uterus or ovaries) OR
  - Documentation that 12 months of medically supervised methods of conception (e.g. artificial insemination) have failed and will not likely lead to a successful pregnancy

**Medical Benefit:**
• If medication is being administered in a clinic setting by a health care provider, coverage on the pharmacy benefit is excluded. The drug must be obtained by the clinic and billed under person’s medical benefit.
• Medications used for treatment of infertility are excluded from coverage unless specifically noted as covered in the certificate of coverage or included in specific state mandates.
• Medications used for the treatment of gender dysphoria are covered unless specifically excluded in the certificate of coverage.
• Medications used for all other diagnoses (ex. prostate cancer, endometriosis, dysmenorrhea, etc) are covered and do not require prior authorization on the medical benefit.

The person’s current certificate of coverage, SBC, or any related documents will be verified to assess exclusions or mandates with each request.
Glycopyrronium topical (Qbrexza)
Prior Authorization Criteria

FORMULARY STATUS: Nonpreferred-Restricted

APPROVAL LIMITS: None

QUANTITY LIMITS: 1 towelette per day (#30)

CRITERIA FOR COVERAGE:
- Person with a 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)
- Failure of an adequate trial or intolerance to BOTH prescription strength topical aluminum antiperspirants and an oral anticholinergic drug such as glycopyrrolate or oxybutynin

CRITERIA FOR COVERAGE OF QUANTITY EXCEPTIONS:
- Prescriber provides an evidence-based clinical rationale for use of a quantity outside of the limit
Hemophilia Factor Products
Prior Authorization Criteria

Factor XIII Products: Corifact

Factor IX Products: Alphanine SD, Mononine, Bebulin VH, Profilnine SD, Benefix RT, Ixinity, Idelvion, Rixubis, Aprolix, Rebinyn

Factor VIII Products: Eloctate, Esperoct, Nuwiq, Afstyla, Adynovate, Recombinate, Kovaltry, Kogenate FS, Helixate FS, Advate, Koate, Hemofil, Monoclate-P, Xyntha, Novoeight, JIVI, Tretten, Obizur

von Willebrand Factor Products: Wilate, Alphanate, Humate-P, Vonvendi

Factor VII Products: NovoSeven RT

Factor X Products: Coagadex

Anti-Inhibitor Products: Feiba NF

FORMULARY STATUS: Medical Benefit - Restricted

APPROVAL LIMITS: None

QUANTITY LIMITS: None

CRITERIA FOR COVERAGE:
• Medication must be provided from a preferred provider
  o UW Health Specialty Pharmacy 1-866-894-3784

OTHER INFORMATION:
• For Hemlibra (emicizumab-kxwh), refer to the individual Prior Authorization criteria.
<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Formulary Status</th>
<th>Quantity Limit/Day</th>
<th>Approval Limits*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glecaprevir/pibrentasvir (Mavyret)</td>
<td>Preferred-Restricted</td>
<td>3</td>
<td>8-16 weeks</td>
</tr>
<tr>
<td>Ledipasvir/sofosbuvir (Harvoni brand)</td>
<td>Preferred-Restricted</td>
<td>1</td>
<td>8-24 weeks</td>
</tr>
<tr>
<td>Sofosbuvir/velpatasvir (Epclusa brand)</td>
<td>Preferred-Restricted</td>
<td>1</td>
<td>12 weeks</td>
</tr>
<tr>
<td>Sofosbuvir/velpatasvir/voxilaprevir (Vosevi)</td>
<td>Preferred-Restricted</td>
<td>1</td>
<td>12 weeks</td>
</tr>
<tr>
<td>Daclatasvir (Daklinza)</td>
<td>Nonpreferred-Restricted</td>
<td>1</td>
<td>12-24 weeks</td>
</tr>
<tr>
<td>Sofosbuvir (Sovaldi)</td>
<td>Nonpreferred-Restricted</td>
<td>1</td>
<td>12-48 weeks</td>
</tr>
<tr>
<td>Ombitasvir/paritaprevir/ritonavir (Technivie)</td>
<td>Nonpreferred-Restricted</td>
<td>2</td>
<td>12 weeks</td>
</tr>
<tr>
<td>Ombitasvir/paritaprevir/ritonavir/ dasabuvir (Viekira Pak)</td>
<td>Nonpreferred-Restricted</td>
<td>1 dose pack</td>
<td>12-24 weeks</td>
</tr>
<tr>
<td>Ombitasvir/paritaprevir/ritonavir/ dasabuvir (Viekira XR)</td>
<td>Nonpreferred-Restricted</td>
<td>3</td>
<td>12-24 weeks</td>
</tr>
<tr>
<td>Simeprevir (Olysio)</td>
<td>Nonpreferred-Restricted</td>
<td>1</td>
<td>12-24 weeks</td>
</tr>
<tr>
<td>Elbasvir/grazoprevir (Zepatier)</td>
<td>Nonpreferred-Restricted</td>
<td>1</td>
<td>12-16 weeks</td>
</tr>
</tbody>
</table>

*As indicated in package labeling or hcvguidelines.org based on specific criteria met below (the shortest recommended duration will be approved)

**CRITERIA FOR COVERAGE (preferred agents):**
Clinical documentation of all of the following must be provided:
- Diagnosis of chronic hepatitis C infection (infection of > 6 months)
• HCV genotype
• Viral RNA levels measured within the past 3 months prior to initiating therapy
• Patient age
• Past treatment regimens used or documented treatment naïve
• Extent of liver disease: non-cirrhotic, compensated cirrhosis (Child-Pugh A), decompensated cirrhosis (Child-Pugh B, C)
• Current renal function
• Prescriber (must be specialist in Gastroenterology, Hepatology, Infectious Disease or Transplant)
• NS5A RAS (if indicated to direct treatment)
• History of liver transplant
• History of kidney transplant
• HIV status and therapy

CRITERIA FOR COVERAGE (nonpreferred agents): Contraindication or intolerance to all preferred agents or use in a patient population that cannot be treated with a preferred agent.

Therapy will be approved based on FDA label and/or HCVguidelines.org approved regimens for the shortest duration that has shown to be effective and therapeutically appropriate for the indication.

ALL authorized medications (preferred and nonpreferred) are included in the Hepatitis C Medication Adherence Program. *Medications must be obtained from one of the Specialty Pharmacies. Please refer to the Pharmacy Benefits section of the website.
*Does not include simeprevir (Olysio) or ombitasvir/paritaprevir/ritonavir (Technivie).

CONTINUATION OF COVERAGE CRITERIA:
• Members new to the plan who are established on therapy will have coverage 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 programs may apply.
• Continuation of therapy/coverage criteria may not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.
<table>
<thead>
<tr>
<th>Generic</th>
<th>Brand</th>
<th>HICL</th>
<th>GCN</th>
<th>Exception/Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>C1 ESTERASE INHIBITOR</td>
<td>BERINERT, CINRYZE, HAEGARDA</td>
<td>18568</td>
<td></td>
<td></td>
</tr>
<tr>
<td>C1 ESTERASE INHIBITOR</td>
<td>RUCONEST</td>
<td>37766</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ICATIBANT</td>
<td>FIRAZYR</td>
<td>35962</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ECALLANTIDE</td>
<td>KALBITOR</td>
<td>36797</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LANADELUMAB-FLYO</td>
<td>TAKHZYRO</td>
<td>45177</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Hereditary Angioedema Medications

Prior Authorization Criteria

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Drug Status</th>
<th>Quantity Limits/Month</th>
<th>Approval Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>C1 esterase inhibitor (Berinert, Cinryze, Haegarda, Ruconest)</td>
<td>Medical benefit-Restricted</td>
<td>Weight-based number of vials (Haegarda)</td>
<td>6 months (Haegarda)</td>
</tr>
<tr>
<td></td>
<td>Nonpreferred-Restricted</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ecallantide (Kalbitor)</td>
<td>Medical benefit-Restricted</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Icatibant (Firazyr)</td>
<td>Medical benefit-Restricted</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td></td>
<td>Nonpreferred-Restricted</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lanadelumab (Takhzyro)</td>
<td>Medical benefit-Restricted</td>
<td>2</td>
<td>6 months</td>
</tr>
<tr>
<td></td>
<td>Nonpreferred-Restricted</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### CRITERIA FOR COVERAGE:
- Diagnosis of Hereditary Angioedema (HAE)
  - Low C4 AND low C1 inhibitor level or function OR
  - Normal C1 inhibitor level AND family history of HAE AND high dose antihistamines did not work
- Prescribed by an Allergist or other provider with experience in the treatment of HAE
- Confirm person is not taking medications that may cause angioedema (e.g. ACE inhibitors, estrogens, ARBS)
- For long term prophylaxis:
  - Haegarda and lanadelumab:
    - History of ≥ 2 attacks per month or person’s symptoms are moderate to severe
  - Cinryze:
    - History of ≥ 2 attacks per month or person’s symptoms are moderate to severe AND failure (no reduction in frequency of attacks or severity of attacks) or intolerable side effects with both Haegarda and lanadelumab OR
    - Age 6-12 years

### CRITERIA FOR QUANTITY EXCEPTIONS:
- Prescriber provides an evidence-based clinical rationale for using a dose outside of the quantity limit
CRITERIA FOR CONTINUATION (new to plan):
• Documentation from the previous 12 months of a clinical response with current therapy

CRITERIA FOR CONTINUATION (6-month renewal):
• Lanadelumab: Clinical documentation supporting no attacks through the preceding 6 months
• Haegarda: Confirmation there are no weight changes warranting different quantity limits.

FOR BADGERCARE COVERAGE (Takhzyro):
Medication must be billed to ForwardHealth under the pharmacy benefit. Refer to the ForwardHealth policy "Select High Cost, Orphan, and Accelerated Approval Drugs" for additional information.
Homozygous Familial Hypercholesterolemia Medication Prior Authorization Criteria

FORMULARY STATUS:
mipomersen sodium (Kynamro): Nonpreferred-Restricted
lomitapide (Juxtapid) Nonpreferred-Restricted

APPROVAL LIMITS: None

QUANTITY LIMITS: None

CRITERIA FOR COVERAGE:
• Diagnosis of homozygous familial hypercholesterolemia (HoFH) AND
• Medication prescribed/initiated by Cardiology or other lipid specialist AND
1. LDL-C ≥ 100 mg/dL (no previous event) despite lifestyle modification and 3 months of adherent treatment with a high-potency statin + ezetimibe + PCSK-9 inhibitor*
   OR
   LDL-C ≥ 70 mg/dL (hx of previous event) despite lifestyle modification and 3 months of adherent treatment with a high potency statin + ezetimibe + PCSK-9 inhibitor *
   OR
2. The person is considered “statin intolerant”** or has a contraindication to statin use such as active liver disease or persistently elevated serum transaminases AND
   LDL-C ≥ 100 mg/dL (no previous event) despite lifestyle modification and 3 months of adherent treatment with ezetimibe + PCSK-9 inhibitor
   OR
   LDL-C ≥ 70 mg/dL (hx of previous event) despite lifestyle modification and 3 months of adherent treatment with ezetimibe + PCSK-9 inhibitor

AND (for mipomersen only)
• Person or family member to self-administer the injectable medication.

Important information:
Lomitapide is only available through the Juxtapid REMS Program. Please call 1-855-898-2743 for more information.
Mipomersen sodium is only available through the Kynamro REMS Program. Please visit www.kynamrorems.com/ for more information.

*High potency statins are defined as atorvastatin ≥ 40 mg/day or rosuvastatin ≥ 20 mg/day. Adherent treatment is defined as a medication possession ratio ≥ 70% based on the previous 90 days of claims prior to the latest LDL-C check (prescription claims records will be required for approval). Persons intolerant to either atorvastatin or rosuvastatin will be required to trial the alternate high-potency statin before consideration of a PCSK-9 inhibitor.
Statin intolerance is defined as the inability to tolerate at least 2 statins, with:

- one started at the lowest starting dose AND
- statin dose reduction was attempted to resolve symptoms or lab abnormalities (not discontinuation) AND
- symptoms or lab abnormalities reversed with statin discontinuation but returned with re-challenge of statins AND
- symptoms or lab abnormalities are not due to established predispositions such as drug interactions, significant changes in physical activity, or underlying muscle disease

A retrial of a statin may be requested prior to consideration of approval of a PSCK-9 inhibitor based on the information provided.
Human Chorionic Gonadotropin (HCG) / Clomiphene
Prior Authorization Criteria

FORMULARY STATUS:
Clomiphene- Nonpreferred-Restricted
HCG- Nonpreferred-Restricted, Medical Benefit-Restricted

PRODUCTS INCLUDED:
Novarel, Pregnyl, Ovidrel
Generic clomiphene

APPROVAL LIMITS:
None

QUANTITY LIMITS:
None

1. CRITERIA FOR COVERAGE for Clomiphene:*
   • Men with hypogonadism and low testosterone level who are not seeking fertility treatment and are using the clomiphene to increase testosterone levels.
   AND
   • Clinically appropriate laboratory data demonstrating androgen deficiency (Levels should be drawn in the morning (or within 3 hours of waking for shift workers); 1st level should be total testosterone, 2nd set of labs could be: total testosterone with sex hormone binding globulin (SHBG) or free/bioavailable testosterone, luteinizing hormone (LH) and follicle stimulating hormone (FSH). Results and the normal ranges for the laboratory need to be provided.)
   AND
   • Are symptomatic with symptoms other than sexual dysfunction
   OR
   • Women who are undergoing surgical procedures unrelated to infertility where the goal is to reduce the lining/fibroid prior to the procedure (i.e. endometriosis, fibroids, etc)

*Coverage of clomiphene for use in infertility is limited to members who have the artificial insemination rider attached to their medical benefit and to the duration and amounts as defined in the rider.

2. CRITERIA FOR COVERAGE for HCG:
   Prescription Drug Benefit:
   • Men with hypogonadotrophic hypogonadism (hypogonadism due to pituitary deficiency) and low testosterone level who are not seeking fertility treatments and are not able to respond to clomiphene to increase testosterone levels
   Medical Benefit:
   • Covered for indications that are not excluded from coverage based by the person’s plan benefits (e.g infertility). Use for hypogonadism is limited to coverage on the prescription drug benefit.

3. (Illinois plans only) For clomiphene or HCG to treat infertility
   • Resident of the state of Illinois
• Documentation of inability to conceive after 12 months of unprotected intercourse or inability to sustain a successful pregnancy OR
• Documentation of a medical condition that renders conception impossible through unprotected intercourse (e.g. congenital absence of the uterus or ovaries) OR
• Documentation that 12 months of medically supervised methods of conception (e.g. artificial insemination) have failed and will not likely lead to a successful pregnancy
### Hydrocodone ER (Zohydro ER)

#### Prior Authorization Criteria

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Drug Status</th>
<th>Quantity Limits/Day</th>
<th>Approval Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrocodone ER</td>
<td>Nonpreferred-Restricted</td>
<td>2</td>
<td>None</td>
</tr>
</tbody>
</table>

#### CRITERIA FOR COVERAGE:
- Inadequate pain control after an adequate trial (both in dose and duration with appropriate breakthrough therapy available) from ≥ 2 preferred long-acting opioids or intolerable side effects from ≥ 2 preferred long-acting opioids.

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

#### CRITERIA FOR QUANTITY EXCEPTIONS:
- Therapeutic failure or intolerance to two dose units per day for the available strengths and the prescriber provides an evidence-based clinical rationale for use of a dose outside of the quantity limit
## Infertility Treatments (Illinois plans only)

**Prior Authorization Criteria**

### FORMULARY STATUS:

<table>
<thead>
<tr>
<th>Generic Name</th>
<th>Brand Name</th>
<th>HICL</th>
<th>GCN</th>
<th>Exception/Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>FOLLITROPIN ALFA, RECOMB</td>
<td>GONAL-F, GONAL-F RFF</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FOLLITROPIN BETA, RECOMB</td>
<td>FOLLISTIM AQ</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MENOTROPINS</td>
<td>MENOPUR</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>UROFOLLITROPIN</td>
<td>BRAVELLE</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### APPROVAL LIMITS:

12 months

### QUANTITY LIMITS:

None

### CRITERIA FOR INITIAL COVERAGE:

- Resident of the state of Illinois
- Documentation of inability to conceive after 12 months of unprotected intercourse or inability to sustain a successful pregnancy OR
- Documentation of a medical condition that renders conception impossible through unprotected intercourse (e.g. congenital absence of the uterus or ovaries) OR
- Documentation that 12 months of medically supervised methods of conception (e.g. artificial insemination) have failed and will not likely lead to a successful pregnancy

### IMPORTANT INFORMATION:

Coverage is excluded by certificate for some benefits.
Imiquimod (Zyclara equivalent)
Prior Authorization Criteria

FORMULARY STATUS: Nonpreferred-Restricted

APPROVAL LIMITS: None

QUANTITY LIMITS: None

CRITERIA FOR COVERAGE:
• Treatment-limiting local side effects with use of imiquimod 5% cream
## Infused Oncology Agents
### Prior Authorization Criteria

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Drug Status</th>
<th>Quantity Limits</th>
<th>Approval Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>ATEZOLIZUMAB (TECENTRIQ)</td>
<td>Medical Benefit-Restricted</td>
<td>None</td>
<td>Up to 12 months</td>
</tr>
<tr>
<td>AVELUMAB (BAVENCIO)</td>
<td>Medical Benefit-Restricted</td>
<td>None</td>
<td>Up to 12 months</td>
</tr>
<tr>
<td>CARFILZOMIB (KYPROLIS)</td>
<td>Medical Benefit-Restricted</td>
<td>None</td>
<td>Up to 12 months</td>
</tr>
<tr>
<td>CEMIPLIMAB (LIBTAYO)</td>
<td>Medical Benefit-Restricted</td>
<td>None</td>
<td>Up to 12 months</td>
</tr>
<tr>
<td>DARATUMUMAB (DARZELEX)</td>
<td>Medical Benefit-Restricted</td>
<td>None</td>
<td>Up to 12 months</td>
</tr>
<tr>
<td>DURVALUMAB (IMFINZI)</td>
<td>Medical Benefit-Restricted</td>
<td>None</td>
<td>Up to 12 months</td>
</tr>
<tr>
<td>ELOTUZUMAB (EMPLICITI)</td>
<td>Medical Benefit-Restricted</td>
<td>None</td>
<td>Up to 12 months</td>
</tr>
<tr>
<td>IOBENGUANE IODINE (AZEDRA)</td>
<td>Medical Benefit-Restricted</td>
<td>3 doses</td>
<td>Up to 12 months</td>
</tr>
<tr>
<td>IPILIMUMAB (YERVOY)</td>
<td>Medical Benefit-Restricted</td>
<td></td>
<td>Up to 12 months</td>
</tr>
<tr>
<td>LUTETIUM (Lu) 177 (LUTATHERA)</td>
<td>Medical Benefit-Restricted</td>
<td>4 doses</td>
<td>6 months</td>
</tr>
<tr>
<td>MOGAMULIZUMAB (POTELIGEO)</td>
<td>Medical Benefit-Restricted</td>
<td></td>
<td>Up to 12 months</td>
</tr>
<tr>
<td>MOXETUMOMAB (LUMOXITI)</td>
<td>Medical Benefit-Restricted</td>
<td></td>
<td>6 months</td>
</tr>
<tr>
<td>NECITUMUMAB (PORTRAZZA)</td>
<td>Medical Benefit-Restricted</td>
<td></td>
<td>Up to 12 months</td>
</tr>
<tr>
<td>NIVOLUMAB (OPDIVO)</td>
<td>Medical Benefit-Restricted</td>
<td></td>
<td>Up to 12 months</td>
</tr>
<tr>
<td>PEMBROLIZUMAB (KEYTRUDA)</td>
<td>Medical Benefit-Restricted</td>
<td></td>
<td>Up to 12 months</td>
</tr>
<tr>
<td>POLATUZUMAB VEDOTIN (POLIVY)</td>
<td>Medical Benefit-Restricted</td>
<td></td>
<td>Up to 12 months</td>
</tr>
<tr>
<td>RADIUM (Ra) 223 (XOFIGO)</td>
<td>Medical Benefit-Restricted</td>
<td></td>
<td>6 months</td>
</tr>
<tr>
<td>RAMUCIRUMAB (CYRAMZA)</td>
<td>Medical Benefit-Restricted</td>
<td></td>
<td>Up to 12 months</td>
</tr>
<tr>
<td>SILTUXIMAB (SYLVANT)</td>
<td>Medical Benefit-Restricted</td>
<td></td>
<td>Up to 12 months</td>
</tr>
<tr>
<td>TRABECTEDIN (YONDELIS)</td>
<td>Medical Benefit-Restricted</td>
<td></td>
<td>Up to 12 months</td>
</tr>
<tr>
<td>TAGRAXOFUSP-ERZS (ELZONRIS)</td>
<td>Medical Benefit-Restricted</td>
<td></td>
<td>Up to 12 months</td>
</tr>
</tbody>
</table>

### CRITERIA FOR COVERAGE:

Revised: 02/12/2020
Page 127
• Drug must be prescribed and monitored by an Oncologist, Hematologist, or other specialist in the treatment of malignancy

AND

• 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
• 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*
OR
• (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* in either the United States Pharmacopeia Drug Information or the American Hospital Formulary Service Drug Information or one article in a major peer-reviewed medical journal recognizes the safety and efficacy of the requested drug in the person’s specific condition
OR
• (Illinois 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* in the American Hospital Formulary Service Drug Information, Thompson Micromedex’s Drug Dex, Elsevier Gold Standard’s Clinical Pharmacology, or two articles in peer-reviewed professional medical journals from the United States or Great Britain recognize the safety and efficacy of the requested drug in the person’s specific condition.

*includes any relevant genetic testing, mutations, etc.

CONTINUATION/RENEWAL OF COVERAGE CRITERIA:

• Initial criteria for coverage met
<table>
<thead>
<tr>
<th>Generic</th>
<th>Brand</th>
<th>HICL</th>
<th>GCN</th>
<th>Exception/Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>INSULIN REGULAR, HUMAN</td>
<td>AFREZZA</td>
<td></td>
<td>37619, 37622, 37621, 37624, 38918, 42833, 45955, 38923</td>
<td></td>
</tr>
</tbody>
</table>

Inhaled Regular Insulin (Afrezza)
Prior Authorization Criteria

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Drug Status</th>
<th>Quantity Limit</th>
<th>Approval Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inhaled regular insulin (Afrezza)</td>
<td>Nonpreferred-Restricted</td>
<td>None</td>
<td>None</td>
</tr>
</tbody>
</table>

**CRITERIA FOR COVERAGE:**
- Diagnosis of diabetes mellitus
- Prescription is initiated by, or in consultation with, an Endocrinologist
- Documented disability that does not physically allow the administration of insulin from conventional vials or pens
- Does not have a documented chronic lung disease (asthma, COPD, etc.)
- Is a nonsmoker
**Inotersen (Tegsedi)**
**Prior Authorization Criteria**

**FORMULARY STATUS:** Nonpreferred-Restricted

**APPROVAL LIMITS:**
- Initial approval: 12 months
- Continuation approval: indefinite

**QUANTITY LIMITS:**
Four injections per month (#4)

**CRITERIA FOR COVERAGE:**
- Prescribed by a Neurologist, Cardiologist, or other expert in hereditary transthyretin-mediated amyloidosis (hATTR)
- Age 18 years or older
- Diagnosis of neuropathy due to hereditary transthyretin (hATTR) amyloidosis with documentation of TTR gene mutation and biopsy proven amyloid deposits

**CRITERIA FOR CONTINUATION OF COVERAGE:**
- Initiation criteria met AND clinical documentation from the previous 12 months of response to therapy or documentation of clinical stability (e.g. Karnofsky status or other functional measure)
- For members new to the plan, the prescriber must provide clinical documentation of the person’s initial response to therapy (e.g. clinical manifestation stability/improvement based upon the continuation criteria above).
- Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.

**CRITERIA FOR A QUANTITY EXCEPTION:**
- Clinical failure of one injection per week dosing and the prescriber provides an evidence-based clinical rationale for use of a dose outside of the quantity limit

**FOR BADGERCARE COVERAGE:**
Medication must be billed to ForwardHealth under the pharmacy benefit. Refer to the ForwardHealth policy **“Select High Cost, Orphan, and Accelerated Approval Drugs”** for additional information.
Generic | Brand | HICL | GCN | Exception/Other
---|---|---|---|---
INSULIN DEGLUDEC | TRESIBA, TRESIBA FLEXTOUCH | 40844 | | 

**Insulin Degludec (Tresiba)**
Prior Authorization Criteria

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Drug Status</th>
<th>Quantity Limit/30 Days</th>
<th>Approval Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insulin degludec (Tresiba, Tresiba FlexTouch)</td>
<td>Preferred-Restricted</td>
<td>U100: 30 mL U200: 18 mL</td>
<td>None</td>
</tr>
</tbody>
</table>

**CRITERIA FOR COVERAGE (for degludec U100):**
- Diagnosis of diabetes mellitus
  AND
- Prescription is initiated by, or in consultation with, an Endocrinologist
  AND
- The person 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
  - Documentation of use of a specific adherence intervention deployed by a health care provider
  OR
- The person is intolerant to insulin glargine

**CRITERIA FOR COVERAGE (for degludec U200):**
- All above criteria for coverage for U100 are met
  AND
- The person's daily basal insulin dose is greater than 100 units

**CRITERIA FOR QUANTITY EXCEPTIONS (for U200):**
- Person is using the U200 formulation (i.e. has a dose > 100 units/day)
- Clinical rationale for the prescribed dosing regimen is provided and the regimen is not possible within the quantity limits
Nonpreferred Insulin
Prior Authorization Criteria

FORMULARY STATUS:
Humalog Mix 50/50 Nonpreferred Restricted
Apidra Nonpreferred Restricted

APPROVAL LIMITS:
None

QUANTITY LIMITS:
30 mL per 30 days

CRITERIA FOR COVERAGE:
• Diagnosis of diabetes mellitus
AND
• Preferred Novolin/Novolog insulin failed after an adequate trial (including dose adjustments) or was not tolerated

CRITERIA FOR COVERAGE OF QUANTITY EXCEPTIONS:
• Clinical rationale for prescribed dosing regimen provided & regimen not possible within the quantity limits
<table>
<thead>
<tr>
<th>Generic</th>
<th>Brand</th>
<th>HICL</th>
<th>GCN</th>
<th>Exception/Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>HUMAN INSULIN ISOPHANE</td>
<td>NOVOLIN N, HUMULIN N VIAL</td>
<td></td>
<td>11660</td>
<td></td>
</tr>
<tr>
<td>HUMAN INSULIN NPH/REGULAR</td>
<td>NOVOLIN 70/30</td>
<td>06215</td>
<td></td>
<td>≠ HUMULIN 70/30 PEN</td>
</tr>
<tr>
<td>HUMAN INSULIN REGULAR</td>
<td>NOVOLIN R, HUMULIN R VIAL, HUMULIN R U500</td>
<td>11642, 9633, 40542</td>
<td></td>
<td></td>
</tr>
<tr>
<td>INSULIN ASPART</td>
<td>NOVOLOG</td>
<td>20769</td>
<td></td>
<td></td>
</tr>
<tr>
<td>INSULIN NPH/ASPART</td>
<td>NOVOLOG 70/30</td>
<td>23400</td>
<td></td>
<td></td>
</tr>
<tr>
<td>INSULIN GLARGINE</td>
<td>BASAGLAR</td>
<td>98637</td>
<td></td>
<td>≠ LANTUS</td>
</tr>
</tbody>
</table>

**Preferred and Unrestricted Insulin Quantity Limit Exception**

**Prior Authorization Criteria**

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Drug Status</th>
<th>Quantity Limit/30 Days</th>
<th>Approval Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insulin isophane (Novolin N), Insulin regular (Novolin R), Insulin isophane/regular mix (Novolin 70/30)</td>
<td>Preferred</td>
<td>30 mL</td>
<td>None</td>
</tr>
<tr>
<td>Insulin aspart and mix (Novolog, Novolog 70/30)</td>
<td>Preferred</td>
<td>30 mL</td>
<td>None</td>
</tr>
<tr>
<td>Insulin regular (Humulin R U500)</td>
<td>Preferred</td>
<td>Vials: 20 mL Pens: 6 mL</td>
<td>None</td>
</tr>
<tr>
<td>Insulin glargine (Basaglar)</td>
<td>Preferred</td>
<td>30 mL</td>
<td>None</td>
</tr>
</tbody>
</table>

**CRITERIA FOR COVERAGE OF QUANTITY EXCEPTIONS:**

- Person requires more than 100 units per 30 days or, for U500 vial, more than 333 units per 30 days based on daily prescribed dosing (documentation of insulin dosing and directions is required).
### Interferons

**Prior Authorization Criteria**

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Drug Status</th>
<th>Quantity Limit</th>
<th>Approval Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interferon alfa-2b (Intron A)</td>
<td>Preferred-Restricted</td>
<td>None</td>
<td>12 months</td>
</tr>
<tr>
<td>Interferon alfa-n3 (Alferon N)</td>
<td>Preferred-Restricted</td>
<td>None</td>
<td>12 months</td>
</tr>
<tr>
<td>Interferon gamma 1b (Actimmune)</td>
<td>Preferred-Restricted</td>
<td>None</td>
<td>12 months</td>
</tr>
<tr>
<td>Peginterferon alfa-2b (Sylatron)</td>
<td>Nonpreferred-Restricted</td>
<td>None</td>
<td>12 months</td>
</tr>
</tbody>
</table>

**CRITERIA FOR COVERAGE (general):**

- Medications are included in the Specialty Pharmaceutical Program. Medications must be received from one of the Specialty Pharmacies. Please refer to the Specialty Pharmaceuticals Program link in the Pharmacy Information section of the website (exception: Sylatron).
- Must be self-administered or administered by family member or caretaker

**AND**

A. **Intron A**

- Palliative treatment of AIDS related Kaposi's sarcoma OR
- Chronic Hepatitis C OR
- External genital or perianal warts OR
- Hepatitis B OR
- 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
- 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 person* OR

(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* in either the United States Pharmacopeia Drug Information or the American Hospital Formulary Service Drug Information or one article in a major peer-reviewed medical journal recognizes the safety and efficacy of the requested drug in the person’s specific condition OR

(Illinois 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* in the American Hospital Formulary Service Drug Information, Thompson Micromedex’s Drug Dex, Elsevier Gold Standard’s Clinical Pharmacology, or two articles in peer-reviewed professional medical journals from the United States or Great Britain recognize the safety and efficacy of the requested drug in the person’s specific condition.
*includes any relevant genetic testing, mutations, etc.

B. Sylatron
- 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
- 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 person* OR
- (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* in either the United States Pharmacopeia Drug Information or the American Hospital Formulary Service Drug Information or one article in a major peer-reviewed medical journal recognizes the safety and efficacy of the requested drug in the person’s specific condition OR
- (Illinois 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* in the American Hospital Formulary Service Drug Information, Thompson Micromedex’s Drug Dex, Elsevier Gold Standard’s Clinical Pharmacology, or two articles in peer-reviewed professional medical journals from the United States or Great Britain recognize the safety and efficacy of the requested drug in the person's specific condition.

C. Alfernon N
- External genital or perianal warts

D. Actimmune
- Chronic granulomatous disease OR
- Congenital malignant osteopetrosis

OR
- Other FDA-labeled indications not listed

IMPORTANT INFORMATION:
For PA criteria for Pegasys or Peg-Intron, refer to the Pegylated Interferon PA criteria.
For criteria for interferon beta (1-a and 1-b) please refer to the multiple sclerosis disease modifying therapy PA criteria.
Ivabradine (Corlanor)
Prior Authorization Criteria

**FORMULARY STATUS:**  Nonpreferred-Restricted

**APPROVAL LIMITS:**  None

**QUANTITY LIMITS:**  Tablets - 2 per day (#60)
                      Solution - None

**CRITERIA FOR COVERAGE:**
- Prescription originally initiated by a Cardiologist or in consultation with a Cardiologist
  AND
- Diagnosis of stable, symptomatic heart failure in sinus rhythm with a left ventricular ejection fraction ≤ 35% and a resting heart rate ≥ 70 beats per minute
  OR
- Diagnosis of Inappropriate Sinus Tachycardia
  AND
- Have symptoms despite use of maximally tolerated beta blocker therapy or have a contraindication to beta-blocker use

**CRITERIA FOR QUANTITY EXCEPTIONS:**
- Therapeutic failure or intolerance of two tablets per day dosing or prescriber presents rationale, clinical reason for utilizing a dosing regimen that is not possible within the quantity limits.
Ketorolac Injection
Quantity Exception Criteria

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Drug Status</th>
<th>Quantity Limits/Fill*</th>
<th>Approval Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ketorolac injection</td>
<td>Nonpreferred-Restricted</td>
<td>20 doses</td>
<td>None</td>
</tr>
</tbody>
</table>

*quantity limit before exception

CRITERIA FOR COVERAGE OF QUANTITY EXCEPTIONS:

- Documentation that the person does not have reduced kidney function or a history of gastrointestinal ulcers/bleeds.
Lefamulin (Xenleta)
Prior Authorization Criteria

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Formulary Status</th>
<th>Quantity Limits/Day</th>
<th>Approval Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lefamulin (Xenleta)</td>
<td>Nonpreferred-Restricted</td>
<td>2</td>
<td>One fill</td>
</tr>
</tbody>
</table>

**CRITERIA FOR COVERAGE:**
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

**AND**
- Report of susceptibilities documenting resistance to preferred alternatives

**CRITERIA FOR COVERAGE OF DURATION EXCEPTIONS:**
- The prescriber provides an evidence-based clinical reason for utilizing an extended duration

**CRITERIA FOR QUANTITY EXCEPTIONS:**
- The prescriber provides an evidence-based clinical reason for using a dose outside of the quantity limits

**CONTINUATION OF COVERAGE CRITERIA:**
- Persons new to the plan 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.
- Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.
Lesinurad (Zurampic, Duzallo)
Prior Authorization Criteria

FORMULARY STATUS: Nonpreferred-Restricted

APPROVAL LIMITS: None

QUANTITY LIMITS: One tablet per day (#30)

CRITERIA FOR COVERAGE:
- Persons with uric acid levels ≥ 6 mg/dL despite an adequate, dose-maximized, adherent trial of allopurinol or febuxostat
  AND
- Documented gout flare in the past 12 months
  AND
- Used in combination with allopurinol or febuxostat (for ZURAMPIC)

CRITERIA FOR QUANTITY EXCEPTIONS:
- Therapeutic failure or intolerance of one tablet per day dosing and the prescriber presents an evidence-based clinical rationale for utilizing a dosing regimen that is not possible within the quantity limits.

IMPORTANT INFORMATION:
It is not recommended to use lesinurad without a xanthine oxidase inhibitor.
LETERMOVIR (Prevymis)
Prior Authorization Criteria

FORMULARY STATUS: Preferred-Restricted
Medical Benefit Restricted (IV formulation)

APPROVAL LIMITS: To Day # 100 post-transplant

QUANTITY LIMITS: One tablet per day dosing (#30)

CRITERIA FOR COVERAGE:
• The drug is prescribed by a Hematologist
AND
• Covered for CMV prophylaxis in adults post allogeneic hematopoietic stem cell transplant
AND
• Are cytomegalovirus (CMV)-seropositive recipients (R+) or have CMV positive donor (D+)
AND
• Drug is initiated within the first 28 days post-transplant
AND
• The person does not have active CMV infection (CMV PCR level over 250 IU/mL) and not receiving preemptive treatment (ex. foscarnet)
AND
• For IV ONLY: Person is unable to tolerate/swallow an oral tablet

CONTINUATION OF COVERAGE CRITERIA:
• Persons new to coverage who are established on therapy will have coverage under their drug benefit for the remainder of the current treatment course (to a maximum of Day 100 post-transplant).
• Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.

IMPORTANT INFORMATION:
• Letermovir should not be given in autologous stem cell transplants.
• Use in solid organ transplants is considered experimental at this time.
Levodopa inhalation powder (Inbrija capsules)  
Prior Authorization Criteria

<table>
<thead>
<tr>
<th>Generic Name</th>
<th>Brand Name</th>
<th>GCN</th>
<th>HICL</th>
<th>Exception/Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>LEVODOPA INHALATION POWDER</td>
<td>INBRIJA</td>
<td>45975, 45867</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Levodopa inhalation powder (Inbrija capsules)**

**FORMULARY STATUS:** Nonpreferred-Restricted

**APPROVAL LIMITS:** None

**QUANTITY LIMITS:** 10 per day

**CRITERIA FOR COVERAGE:**
- Prescribed by a Neurologist
- Diagnosis of Parkinson's disease
- Current treatment with combination of long-acting and short-acting carbidopa/levodopa
- Person experiencing intermittent "off" episodes despite adequate trial with appropriate dosage adjustment with carbidopa/levodopa

**CRITERIA FOR A QUANTITY EXCEPTION:**
- Prescriber provides evidence-based clinical rationale for using a dose outside of the quantity limit.

**CONTINUATION OF COVERAGE CRITERIA:**
- Persons new to the plan 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.
- Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.
Levomilnacipran (Fetzima)  
Prior Authorization Criteria

<table>
<thead>
<tr>
<th>Drug</th>
<th>Drug Status</th>
<th>Quantity Limits/Day</th>
<th>Approval Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Levomilnacipran</td>
<td>Nonpreferred-</td>
<td>1</td>
<td>None</td>
</tr>
<tr>
<td>(Fetzima)</td>
<td>Restricted</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**CRITERIA FOR COVERAGE:**
- Lack of efficacy after an adequate trial of, or intolerance to, at least one preferred Selective Serotonin Reuptake Inhibitor (SSRI) antidepressant (e.g. citalopram, escitalopram, sertraline, paroxetine, fluoxetine)
- Lack of efficacy after an adequate trial of, or intolerance to, at least one preferred Serotonin Norepinephrine Reuptake Inhibitor (SNRI) antidepressant (e.g. venlafaxine, duloxetine)

**CRITERIA FOR COVERAGE OF QUANTITY EXCEPTIONS:**
- Failure or intolerance to once daily dosing of the commercially available dosage forms and the prescriber provides an evidence-based clinical rationale for using a dose outside of the quantity limits

**CONTINUATION OF COVERAGE CRITERIA:**
- Persons new to the plan who are being treated for depression or other mood disorders and are established on therapy will have coverage under their drug benefit with documentation of symptom improvement or disease stability.
- Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.
Lidocaine Patch (Ztildo)
Prior Authorization Criteria

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Drug Status</th>
<th>Quantity Limits/Day</th>
<th>Approval Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lidocaine patch (Ztildo)</td>
<td>Nonpreferred-Restricted</td>
<td>3</td>
<td>None</td>
</tr>
</tbody>
</table>

CRITERIA FOR COVERAGE:
- Person with a diagnosis of post-herpetic neuralgia
- Failure of an equivalent dose of generic lidocaine 5% transdermal patches
- Failure or intolerance to at least one other preferred drug with evidence for reducing symptoms of post-herpetic neuralgia symptoms
- The prescriber provides an evidence-based clinical rationale for why different results from those seen with generic 5% lidocaine patches would be expected

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

CRITERIA FOR COVERAGE OF QUANTITY EXCEPTIONS:
- Prescriber provides an evidence-based clinical rationale for using a dose outside of the quantity limits
Lisdexamfetamine (Vyvanse)
Prior Authorization Criteria

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Drug Status</th>
<th>Quantity Limits/Day</th>
<th>Approval Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lisdexamfetamine (Vyvanse)</td>
<td>Preferred-Restricted</td>
<td>1</td>
<td>None</td>
</tr>
</tbody>
</table>

CRITERIA FOR COVERAGE for binge eating disorder:
- Failure after an adequate trial of, or intolerance to, preferred selective serotonin reuptake inhibitor (e.g. citalopram, fluoxetine, escitalopram)

CRITERIA FOR COVERAGE for attention-deficit/hyperactivity disorder:
- Failure after an adequate trial of, or intolerance to, two preferred long-acting alternatives (e.g. generics of Adderall XR, Metadate CD, Ritalin LA, Focalin XR, Strattera, etc.)

CRITERIA FOR QUANTITY EXCEPTIONS:
Therapeutic failure or intolerance to an adequate trial of one tablet per day dosing and the prescriber presents an evidence-based clinical reason for utilizing a dosing regimen that is not possible within the quantity limits.

CONTINUATION OF COVERAGE CRITERIA:
- Persons new to the plan 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.
- Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.
Lofexidine (Lucemyra)
Prior Authorization Criteria

FORMULARY STATUS: Nonpreferred-Restricted

APPROVAL LIMITS: 14 days (1 fill)

QUANTITY LIMITS: 12 tablets per day (#168)

CRITERIA FOR COVERAGE:
• Use in abrupt opioid discontinuation
• Diagnosis of acute opioid withdrawal symptoms
• Documentation of an adequate clonidine trial with evidence of intolerance due to severe hypotension

CRITERIA FOR COVERAGE OF QUANTITY EXCEPTIONS:
• The prescriber provides an evidence-based rationale for using a dose outside of the quantity limit.

CRITERIA FOR DURATION EXCEPTIONS:
• The prescriber provides an evidence-based rationale for a duration of treatment greater than 14 days.

CRITERIA FOR COVERAGE FROM IN-PATIENT:
• Documentation of an adequate clonidine trial (4 days) with evidence of intolerance due to severe hypotension.
## Restricted Long-acting Morphine Sulfate

Prior Authorization Criteria

<table>
<thead>
<tr>
<th>Generic</th>
<th>Brand</th>
<th>HICL</th>
<th>GCN</th>
<th>Exception/Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>MORPHINE SULFATE</td>
<td>KADIAN</td>
<td></td>
<td>26490, 98135, 33158, 15868, 97508, 97534, 26494, 97535, 26492</td>
<td></td>
</tr>
<tr>
<td>MORPHINE SULFATE</td>
<td>AVINZA</td>
<td></td>
<td>17189, 17193, 16212, 17192, 16213, 17191</td>
<td></td>
</tr>
<tr>
<td>MORPHINE SULFATE</td>
<td>MORPHABOND ER</td>
<td></td>
<td>39854, 39856, 39853, 39855</td>
<td></td>
</tr>
</tbody>
</table>

### CRITERIA FOR COVERAGE (morphine ER capsules (Kadian and Avinza equiv.)):
- Inadequate pain control with an equivalent dose of generic extended release morphine tablets (MS Contin equivalent)
- OR
- Adverse effects with generic extended release morphine tablets related to pharmacokinetics (e.g., oversedation early in dosing interval)
- OR
- **(Minnesota plans only)** – the person has stage four metastatic cancer and the requested drug is being used to treat cancer-related pain

### CRITERIA FOR COVERAGE (Morphabond):
- Inadequate pain control with an equivalent dose of all other formulary morphine extended-release dose forms
- OR
- **(Minnesota plans only)** – the person has stage four metastatic cancer and the requested drug is being used to treat cancer-related pain

### CRITERIA FOR COVERAGE OF QUANTITY EXCEPTIONS
Therapeutic failure or intolerance to the commercially available dose forms within the quantity limits and the prescriber provides an evidence-based clinical rationale for using a dose outside of the quantity limit
Mecasermin (Increlex)  
Prior Authorization Criteria

FORMULARY STATUS: Nonpreferred-Restricted

APPROVAL LIMITS: To member age 18

QUANTITY LIMITS: None

CRITERIA FOR COVERAGE:
• Medications are included in the Specialty Pharmaceuticals Program. Medications must be obtained from one of the Specialty Pharmacies. Please refer to the Specialty Pharmaceuticals Program link in the Pharmacy Information section of the website for more information.

AND
• Diagnosis by Pediatric Endocrinologist
  a. Documented primary insulin-like growth factor deficiency (IGFD)
  OR
  b. Growth hormone deletion with neutralizing antibodies to growth hormone
  OR
  c. Lack of response to growth hormone following therapeutic trial of somatropin (in persons with growth hormone deficiency)
  OR
  d. Low IGF-1 level

AND
• Patient has confirmed open epiphyses

Non FDA labeled indications will be reviewed on a case-by-case basis

CRITERIA FOR COVERAGE OF DURATION EXCEPTIONS:
• Prescriber provides published clinical evidence to support a significant clinical benefit beyond age 18

IMPORTANT INFORMATION:
• Mecasermin is not indicated to treat secondary IGFD due to GH deficiency, malnutrition, hypothyroidism or other causes.
• Mecasermin is not covered for treatment of idiopathic short stature.
• Mecasermin is not a substitute for growth hormone (somatropin).
• Mecasermin contains recombinant DNA human insulin-like growth factor-1 (IGF-1) and is designed to replace IGF-1 in pediatric patients who are deficient.
• Somatropin (growth hormone) requires prior authorization.
Memantine ER (Namenda XR)
Prior Authorization Criteria

**FORMULARY STATUS:** Nonpreferred-Restricted

**APPROVAL LIMITS:** None

**QUANTITY LIMITS:**
Memantine ER- One capsule per day (#30)

**CRITERIA FOR COVERAGE:**
- An established diagnosis of moderate to severe Alzheimer's Disease
  - Mini Mental State Examination (MMSE) score <14
  - Reisberg Functional Assessment Staging Scale (FAST) ≥ 5
  - Montreal Cognitive Assessment (MoCA) ≤ 17
  - Clinical Dementia Rating Scale (CDR) ≥ 2
  - St Louis University Mental Status Examination (SLUMS) ≤ 17
AND
Therapeutic failure or intolerance of memantine IR

**CRITERIA FOR CONTINUED COVERAGE (for new members)**
- Therapeutic failure or intolerance of memantine IR AND clinical documentation supporting a response to therapy on memantine XR
- Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.

**IMPORTANT INFORMATION:**
Other dementia indications will be considered on a case-by-case basis
Restricted Methotrexate Injection
Prior Authorization Criteria

Formulary Status
Methotrexate (Otrexup): Nonpreferred-Restricted
Methotrexate (Rasuvo): Nonpreferred-Restricted

APPROVAL LIMITS: None
QUANTITY LIMITS: None

CRITERIA FOR COVERAGE:
• Documented disability that does not allow administration of methotrexate from conventional vials utilizing conventional syringes
AND
• The person or a family member/caregiver are self-administering the medication
Metreleptin (Myalept)
Prior Authorization Criteria

FORMULARY STATUS: Nonpreferred-Restricted

APPROVAL LIMITS: None

QUANTITY LIMITS: None

CRITERIA FOR COVERAGE:
• Diagnosed with congenital or acquired generalized lipodystrophy
AND
• Have experienced metabolic changes (e.g. increased triglycerides or fasting blood gluoses) despite an adequate trial of dietary modification
AND
• Do not have clinically adequate responses to standard therapies for elevated blood sugars and elevated lipids such as metformin and statin medications

Important Information:
The safety and effectiveness of metreleptin in the treatment of partial lipodystrophy, HIV-related lipodystrophy, liver disease (including NASH), and metabolic disease alone (such as diabetes mellitus or hypertriglyceridemia) has not been established.

Metreleptin is available under a limited distribution network. Please see the manufacturer website for the most up to date information regarding distribution and Risk Evaluation and Mitigation Strategy (REMS) requirements.
Nayzilam (midazolam) Nasal Spray
Prior Authorization Criteria

FORMULARY STATUS: Preferred-Restricted

APPROVAL LIMITS: None

QUANTITY LIMITS: 5 vials / 30 days

CRITERIA FOR COVERAGE (preferred agents)
• Person is at least 12 years old with a diagnosis of a seizure disorder (epilepsy)
  AND
• Medication was prescribed by a neurologist with experience in the management of epilepsy
  AND
• Medical notes are provided to support history of frequent episodes of acute seizure activity
  AND
• Acute seizure episodes are distinct from the person's usual seizure pattern

CRITERIA FOR COVERAGE OF QUANTITY EXCEPTIONS:
• Provider must provide a clinical reason and evidence-based clinical rationale for use of a dose outside of the quantity limit.
Generic Name | Brand Name | GCN | HICL | Exception/Other
--- | --- | --- | --- | ---
MIGALASTAT | GALAFOLD | | 44433 | |

**Migalastat (Galafold)**  
Prior Authorization Criteria

**FORMULARY STATUS:** Nonpreferred-Restricted

**APPROVAL LIMITS:** None

**QUANTITY LIMITS:** Fourteen capsules per 28 days (#14)

**CRITERIA FOR COVERAGE:**
- The person is age 16 or older
- The person has a confirmed diagnosis of Fabry disease with documentation of an amenable galactosidase alpha gene (GLA) variant as noted in the product labeling.
- The person does not have severe renal impairment (eGFR <30mL/min/1.73m2) or end-stage renal disease requiring dialysis.
- The person will not be using migalastat in combination with enzyme replacement therapy.

**CRITERIA FOR COVERAGE OF QUANTITY EXCEPTIONS:**
- Prescriber presents a published, evidence-based clinical rationale for utilizing a dosing regimen that is outside of the quantity limits
- Documentation submitted regarding individual adherence to every other day dosing and fasting for a minimum of four hours (2 hours before the dose and 2 hours after the dose) as recommended by the product label.
<table>
<thead>
<tr>
<th>Generic Name</th>
<th>Brand Name</th>
<th>HICL</th>
<th>GCN</th>
<th>Exception/Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>MINOCYCLINE</td>
<td>SOLODYN, COREMINO, generics</td>
<td></td>
<td>26957, 26958, 26960, 27396, 27397, 29040, 29044, 29045</td>
<td></td>
</tr>
</tbody>
</table>

**Restricted Minocycline ER**  
**Prior Authorization Criteria**

**FORMULARY STATUS:**  
Minocycline ER (Solodyn, Coremino, generics) - Nonpreferred-Restricted

**APPROVAL LIMITS:**  
None

**QUANTITY LIMITS:**  
None

**CRITERIA FOR COVERAGE:**
- Covered for persons with clinically significant side effects that limit use from a preferred minocycline product at equivalent doses  
  **AND**  
- The prescriber provides an evidence-based clinical rationale why a different result would be expected with use of minocycline ER
Milnacipran (Savella®)
Prior Authorization Criteria

FORMULARY STATUS: Preferred-Restricted

APPROVAL LIMITS: None

QUANTITY LIMITS: Two tablets per day (#60)

CRITERIA FOR COVERAGE:
• Diagnosis of fibromyalgia
AND
• Inadequate clinical response to at least 2 preferred alternatives with published evidence to support their use to treat fibromyalgia or intolerable side effects occur with 2 preferred alternatives used to treat fibromyalgia

CRITERIA FOR COVERAGE OF QUANTITY EXCEPTIONS:
• Therapeutic failure or intolerance of 2 tablets per day dosing and the prescriber provides an evidence-based clinical rationale for using a dose outside of the quantity limits

IMPORTANT INFORMATION:
Alternative drugs used for the treatment of fibromyalgia include tricyclic antidepressants (such as amitriptyline), cyclobenzaprine, venlafaxine, duloxetine, gabapentin, and pregabalin (Lyrica-prior authorization required).
Mirabegron (Myrbetriq)
Prior Authorization Criteria

FORMULARY STATUS: Preferred-Restricted

APPROVAL LIMITS: None

QUANTITY LIMITS: One tablet per day (#30)

CRITERIA FOR COVERAGE:
• Therapeutic failure or intolerance of at least one antimuscarinic medication (such as oxybutynin, tolterodine, solifenacin, etc.) used to treat overactive bladder

OR
• Person has a contraindication to antimuscarinic therapy

CRITERIA FOR COVERAGE OF QUANTITY EXCEPTIONS:
• Therapeutic failure or intolerance of 1 tablet per day dosing and the prescriber presents an evidence-based clinical reason for utilizing a dosing regimen that is not possible within the quantity limits.
## Mucosal Protectants

**Prior Authorization Criteria**

### Formulary Status:
- Bioadhesive Gel (Gelclair): Preferred Restricted
- Bioadhesive Mouthwash (Oramagic Rx): Preferred Restricted
- Bioadhesive Gel (Mugard): Nonpreferred Restricted
- Bioadhesive Oral Liquid (Episil): Nonpreferred Restricted
- Polymerized Sucralfate (Orafate, Prothelial): Nonpreferred Restricted

### Approval Limits:
- 12 months

### Quantity Limits:
- Gelclair #90 Packets per month
- Oramagic Rx (1800 mL) 5 bottles per month
- Mugard 600 mL (120 doses) 4 bottles per month
- Episil (10mL) 3 bottles per month
- Prothelial 250 mL 1 bottle per month
- Orafate (300 mL) 10 bottles per month

### Criteria for Coverage:
1. **Bioadhesive gels (i.e. Gelclair, Oramagic Rx, Mugard, Episil)**
   - 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
     - Failure or intolerance to a previous therapeutic trial of:
       - 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
     - ONE Muco-protectant with or without anesthetic agent [i.e, Mylanta, magic mouthwash (lidocaine/diphenhydramine/Mylanta)]

2. **Polymerized sucralfate products (i.e. Orafate, Prothelial)**
   - Above criteria are met AND failure/intolerance to ONE bioadhesive gel (i.e. Gelclair, Oramagic Rx, Mugard or Episil)

### Criteria for Quantity Exception:
Prescriber provides an evidence-based rationale for using a dose outside of the quantity limit.
CRITERIA FOR CONTINUATION OF COVERAGE:

- General criteria met
- Continuation of therapy coverage will not be applied to persons who were not previously approved for coverage, whose therapy was initiated using a manufacturer sponsored free drug program, provider samples and/or vouchers.
### Multiple Sclerosis Disease Modifying Therapies
#### Prior Authorization Criteria

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Drug Status</th>
<th>Quantity Limits/Day</th>
<th>Approval Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Quartz 1st line agents</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dimethyl fumarate (Tecfidera)</td>
<td>Preferred-Restricted</td>
<td>2</td>
<td>None</td>
</tr>
<tr>
<td>Fingolimod (Gilenya)</td>
<td>Preferred-Restricted</td>
<td>1</td>
<td>None</td>
</tr>
<tr>
<td>Glatiramer (generics, Glatopa)</td>
<td>Preferred-Restricted</td>
<td></td>
<td>None</td>
</tr>
<tr>
<td>Interferon beta-1a (Rebif)</td>
<td>Preferred-Restricted</td>
<td></td>
<td>None</td>
</tr>
<tr>
<td><strong>Quartz 2nd line agents</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cladribine (Mavenclad)</td>
<td>Nonpreferred-Restricted</td>
<td></td>
<td>None</td>
</tr>
<tr>
<td>Interferon beta-1a (Avonex)</td>
<td>Nonpreferred-Restricted</td>
<td></td>
<td>None</td>
</tr>
<tr>
<td>Interferon beta-1b (Extavia)</td>
<td>Nonpreferred-Restricted</td>
<td></td>
<td>None</td>
</tr>
<tr>
<td>Siponimod (Mayzent)</td>
<td>Nonpreferred-Restricted</td>
<td>1*</td>
<td>None</td>
</tr>
</tbody>
</table>

*after titration

**GENERAL CRITERIA FOR COVERAGE (all drugs):**
- Diagnosed and treated by a Neurologist
- Medications are included in the Specialty Medication Outcomes Management program. Medications must be obtained from one of the Specialty Pharmacies*. Please refer to the Pharmacy Benefits section of the website
- Drug to be self-administered at home
- Diagnosis of a relapsing form of multiple sclerosis (includes relapsing-remitting, active secondary progressive, or relapsing-progressive disease)
- OR
  - Diagnosis of Clinically Isolated Syndrome (CIS) with a high probability of developing Clinically Definite MS (CDMS) (i.e. ≥ 3 T2 white matter lesions or ≥ 2 GdE lesions on MRI)

  *Except siponimod (Mayzent)

**CRITERIA FOR COVERAGE (nonpreferred drugs):**
- General criteria met
• Failure (acute relapse or new lesion formation), intolerance, or labeled contraindication with BOTH dimethyl fumarate and fingolimod

CRITERIA FOR QUANTITY EXCEPTIONS:
• The prescriber provides an evidence-based clinical rationale for using a dose outside of the quantity limits

CRITERIA FOR CONTINUATION OF THERAPY (new to plan):
Clinical assessment by the treating Neurologist from the past 12 months documenting a relapsing form of multiple sclerosis and that the person is established on therapy

Note:
Continuation of therapy criteria will not be applied to persons who are not new to the plan who were not previously approved for coverage of their current therapy (such as those who initiate therapy through provider samples or manufacturer-sponsored free drug programs).
Infused Disease Modifying Therapies for Multiple Sclerosis
Prior Authorization Criteria

FORMULARY STATUS:
Natalizumab (Tysabri) Medical Benefit-Restricted
Alemtuzumab (Lemtrada) Medical Benefit-Restricted
Ocrelizumab (Ocrevus) Medical Benefit-Restricted

APPROVAL LIMITS:
None

QUANTITY LIMITS:
Natalizumab One infusion per month
Alemtuzumab First 12 months: 60mg (12mg x 5)
Thereafter: 36mg (12mg x 3)
Ocrelizumab 600 mg every six months

CRITERIA FOR COVERAGE (Ocrelizumab):
Drug must be prescribed and monitored by a Neurologist or other expert in the treatment of multiple sclerosis
AND
1. Relapsing forms of multiple sclerosis
   o Person with clinical documentation of a diagnosis of relapsing multiple sclerosis
   o Treatment failure, clinically significant side effect, or labeled contraindication to:*
     ▪ A preferred oral drug (Gilenya or Tecfidera)
OR
2. Progressive forms of multiple sclerosis
   o Person with clinical documentation of a diagnosis of a progressive form of multiple sclerosis
     (secondary progressive, primary progressive, or relapsing progressive)

CRITERIA FOR COVERAGE (Alemtuzumab or Natalizumab):
• Medication must be prescribed and monitored by a Neurologist or other expert in the treatment of multiple sclerosis
• Person with a diagnosis of a relapsing form of multiple sclerosis
• Person must have had a treatment failure, a clinically significant side effect, or a labeled contraindication to:*
  1. a preferred oral drug (Gilenya, Tecfidera)
*if side effect or contraindication the alternative oral therapy must be trialed

CRITERIA FOR CONTINUATION OF THERAPY:
• For people new to plan drug coverage: clinical assessment from the treating Neurologist from the previous 12 months documenting a relapsing form of multiple sclerosis (all therapies) or progressive form of multiple sclerosis (ocrelizumab only).

Note: Continuation of therapy criteria will not be applied to persons who are not new to the plan who were not previously approved for coverage of their current therapy (such as those who initiate therapy through provider samples or manufacturer-sponsored free drug programs). For criteria for coverage of natalizumab for patients with a diagnosis of inflammatory bowel disease please see the attached Biologic Therapies for Gastroenterology criteria.

IMPORTANT INFORMATION:

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Natalizumab can only be administered as monotherapy. Proper wash-out periods of prior therapy are required. Natalizumab, ocrelizumab and alemtuzumab are clinic administered medications, which are covered under the medical benefit.

**DEFINITIONS:**

*Treatment failure:* clinical documentation of an acute relapse (requiring treatment) or imaging demonstrating new or enlarged lesions despite adherent use of the prerequisite DMT (with claims data to support).

*Clinically significant side effect:* side effect that prevents adherent use of the prerequisite DMT despite interventions from the specialty pharmacist and other health care providers to minimize or mitigate the side effect.
Nabilone (Cesamet®)
Prior Authorization Criteria

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Drug Status</th>
<th>Quantity Limits/Cycle</th>
<th>Approval Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nabilone (Cesamet)</td>
<td>Nonpreferred-Restricted</td>
<td>14</td>
<td>12 months</td>
</tr>
</tbody>
</table>

CRITERIA FOR COVERAGE:

- For treatment of chemotherapy associated nausea and vomiting when other alternatives have failed. Person must have failed therapy with a 5HT3 antagonist (dolasetron, granisetron or ondansetron) plus corticosteroids plus one other agent (such as benzodiazepines, prochlorperazine, metoclopramide or aprepitant)

OR

- (Minnesota plans only): the person has stage four metastatic cancer and the requested drug is being used to treat chemotherapy-related nausea and vomiting

QUANTITY LIMIT EXCEPTION CRITERIA:

- Prescriber presents an evidence-based clinical rationale for utilizing a dosing regimen that is not possible within the quantity limits

CONTINUATION OF COVERAGE CRITERIA:

- Persons new to the plan 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.
- Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.
Naltrexone extended-release injectable suspension (Vivitrol)
Prior Authorization Criteria

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Drug Status</th>
<th>Quantity Limits/Month</th>
<th>Approval Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Naltrexone (Vivitrol)</td>
<td>Medical Benefit-Restricted</td>
<td>1</td>
<td>18 months</td>
</tr>
</tbody>
</table>

CRITERIA FOR COVERAGE:
- Diagnosis of alcohol use disorder or opioid use disorder AND
- The person is actively participating in recovery program (i.e. individual and/or group therapy, etc.) as documented in the medical records provided

CRITERIA FOR COVERAGE OF QUANTITY EXCEPTIONS:
- The prescriber presents an evidence-based rationale for using a dosing regimen outside of the quantity limit.

CONTINUATION OF COVERAGE CRITERIA:
- Persons new to the plan who are being treated with naltrexone ER injections and are stabilized (i.e. abstinent and adherent to therapy/counseling) on therapy will be approved for a total duration of 18 months therapy.
- Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.

CRITERIA FOR DURATION EXCEPTIONS:
- For use beyond 18 months, documentation of continued active participation in counseling/therapy sessions and clinical rationale provided for continued use beyond 18 months. Consideration may be made for time to transition to oral naltrexone therapy should continuation of medication be required.

FOR BADGERCARE COVERAGE:
- See the Forward Health Diagnosis Code-Restricted Physician-Administered Drug List (Table 1)

IMPORTANT INFORMATION:
Naltrexone ER injection is administered via intramuscular injection by a health care provider, typically at an outpatient office visit and is billed as part of the medical benefit.
When naltrexone ER injection is used, it should only be a component within a comprehensive management program that includes psychosocial support.
For details on how to locate and access a Behavioral Health or AODA provider, contact UW Behavioral Health Care Management at 800-683-2300 and ask for a consultation specialist.

TABLE 1
For BadgerCare+ members only-
Claims are covered for the following diagnosis codes:

<table>
<thead>
<tr>
<th>Diagnosis Code</th>
<th>Diagnosis Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>F1010</td>
<td>ALCOHOL ABUSE, UNCOMPLICATED</td>
</tr>
<tr>
<td>F1011</td>
<td>ALCOHOL ABUSE, IN REMISSION</td>
</tr>
<tr>
<td>F1014</td>
<td>ALCOHOL ABUSE WITH ALCOHOL-INDUCED MOOD DISORDER</td>
</tr>
<tr>
<td>F10150</td>
<td>ALCOHOL ABUSE WITH ALCOHOL-INDUCED PSYCHOTIC DISORDER WITH DELUSIONS</td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
</tr>
<tr>
<td>-------</td>
<td>-----------------------------------------------------------------------------</td>
</tr>
<tr>
<td>F10151</td>
<td>ALCOHOL ABUSE WITH ALCOHOL-INDUCED PSYCHOTIC DISORDER WITH HALLUCINATIONS</td>
</tr>
<tr>
<td>F10159</td>
<td>ALCOHOL ABUSE WITH ALCOHOL-INDUCED PSYCHOTIC DISORDER, UNSPECIFIED</td>
</tr>
<tr>
<td>F10180</td>
<td>ALCOHOL ABUSE WITH ALCOHOL-INDUCED ANXIETY DISORDER</td>
</tr>
<tr>
<td>F10181</td>
<td>ALCOHOL ABUSE WITH ALCOHOL-INDUCED SEXUAL DYSFUNCTION</td>
</tr>
<tr>
<td>F10182</td>
<td>ALCOHOL ABUSE WITH ALCOHOL-INDUCED SLEEP DISORDER</td>
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<tr>
<td>F10188</td>
<td>ALCOHOL ABUSE WITH OTHER ALCOHOL-INDUCED DISORDER</td>
</tr>
<tr>
<td>F1019</td>
<td>ALCOHOL ABUSE WITH UNSPECIFIED ALCOHOL-INDUCED DISORDER</td>
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<td>F1020</td>
<td>ALCOHOL DEPENDENCE, UNCOMPlicated</td>
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<tr>
<td>F1021</td>
<td>ALCOHOL DEPENDENCE, IN REMISSION</td>
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<td>ALCOHOL DEPENDENCE WITH ALCOHOL-INDUCED MOOD DISORDER</td>
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<td>F10250</td>
<td>ALCOHOL DEPENDENCE WITH ALCOHOL-INDUCED PSYCHOTIC DISORDER WITH DELUSIONS</td>
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<td>F10251</td>
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<td>F10259</td>
<td>ALCOHOL DEPENDENCE WITH ALCOHOL-INDUCED PSYCHOTIC DISORDER, UNSPECIFIED</td>
</tr>
<tr>
<td>F1026</td>
<td>ALCOHOL DEPENDENCE WITH ALCOHOL-INDUCED PERSISTING AMNESTIC DISORDER</td>
</tr>
<tr>
<td>F1027</td>
<td>ALCOHOL DEPENDENCE WITH ALCOHOL-INDUCED PERSISTING DEMENTIA</td>
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<td>ALCOHOL DEPENDENCE WITH ALCOHOL-INDUCED SLEEP DISORDER</td>
</tr>
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</tr>
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<td>F1029</td>
<td>ALCOHOL DEPENDENCE WITH UNSPECIFIED ALCOHOL-INDUCED DISORDER</td>
</tr>
<tr>
<td>F1094</td>
<td>ALCOHOL USE, UNSPECIFIED WITH ALCOHOL-INDUCED MOOD DISORDER</td>
</tr>
<tr>
<td>F10950</td>
<td>ALCOHOL USE, UNSPECIFIED WITH ALCOHOL-INDUCED PSYCHOTIC DISORDER WITH DELUSIONS</td>
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<td>F10951</td>
<td>ALCOHOL USE, UNSPECIFIED WITH ALCOHOL-INDUCED PSYCHOTIC DISORDER WITH HALLUCINATIO</td>
</tr>
<tr>
<td>F10959</td>
<td>ALCOHOL USE, UNSPECIFIED WITH ALCOHOL-INDUCED PSYCHOTIC DISORDER, UNSPECIFIED</td>
</tr>
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<td>F1096</td>
<td>ALCOHOL USE, UNSPECIFIED WITH ALCOHOL-INDUCED PERSISTING AMNESTIC DISORDER</td>
</tr>
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<td>F1097</td>
<td>ALCOHOL USE, UNSPECIFIED WITH ALCOHOL-INDUCED PERSISTING DEMENTIA</td>
</tr>
<tr>
<td>F10980</td>
<td>ALCOHOL USE, UNSPECIFIED WITH ALCOHOL-INDUCED ANXIETY DISORDER</td>
</tr>
<tr>
<td>F10981</td>
<td>ALCOHOL USE, UNSPECIFIED WITH ALCOHOL-INDUCED SEXUAL DYSFUNCTION</td>
</tr>
<tr>
<td>F10982</td>
<td>ALCOHOL USE, UNSPECIFIED WITH ALCOHOL-INDUCED SLEEP DISORDER</td>
</tr>
<tr>
<td>F10988</td>
<td>ALCOHOL USE, UNSPECIFIED WITH OTHER ALCOHOL-INDUCED DISORDER</td>
</tr>
<tr>
<td>F1099</td>
<td>ALCOHOL USE, UNSPECIFIED WITH UNSPECIFIED ALCOHOL-INDUCED DISORDER</td>
</tr>
<tr>
<td>F1120</td>
<td>OPIOID DEPENDENCE, UNCOMPlicated</td>
</tr>
<tr>
<td>F1121</td>
<td>OPIOID DEPENDENCE, IN REMISSION</td>
</tr>
<tr>
<td>F1124</td>
<td>OPIOID DEPENDENCE WITH OPIOID-INDUCED MOOD DISORDER</td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
</tr>
<tr>
<td>---------</td>
<td>-----------------------------------------------------------------------------</td>
</tr>
<tr>
<td>F11250</td>
<td>OPIOID DEPENDENCE WITH OPIOID-INDUCED PSYCHOTIC DISORDER WITH DELUSIONS</td>
</tr>
<tr>
<td>F11251</td>
<td>OPIOID DEPENDENCE WITH OPIOID-INDUCED PSYCHOTIC DISORDER WITH HALLUCINATIONS</td>
</tr>
<tr>
<td>F11259</td>
<td>OPIOID DEPENDENCE WITH OPIOID-INDUCED PSYCHOTIC DISORDER, UNSPECIFIED</td>
</tr>
<tr>
<td>F11281</td>
<td>OPIOID DEPENDENCE WITH OPIOID-INDUCED SEXUAL DYSFUNCTION</td>
</tr>
<tr>
<td>F11282</td>
<td>OPIOID DEPENDENCE WITH OPIOID-INDUCED SLEEP DISORDER</td>
</tr>
<tr>
<td>F11288</td>
<td>OPIOID DEPENDENCE WITH OTHER OPIOID-INDUCED DISORDER</td>
</tr>
<tr>
<td>F1129</td>
<td>OPIOID DEPENDENCE WITH UNSPECIFIED OPIOID-INDUCED DISORDER</td>
</tr>
</tbody>
</table>
### Restricted Nasal Steroids

#### Prior Authorization Criteria

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Sunshine Cluster</th>
<th>Medicare Drug Number</th>
<th>Generic Code</th>
<th>Drug Status</th>
<th>Quantity Limits/30 days</th>
<th>Approval Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluticasone furoate (RX only - Veramyst)</td>
<td></td>
<td></td>
<td></td>
<td>Non-Preferred Restricted</td>
<td>Two bottles (#2)</td>
<td>None</td>
</tr>
<tr>
<td>Triamcinolone (RX only – generics)</td>
<td></td>
<td></td>
<td></td>
<td>Non-Preferred Restricted</td>
<td>Two bottles (#2)</td>
<td>None</td>
</tr>
</tbody>
</table>

**CRITERIA FOR COVERAGE:**
- Person had therapeutic failure with, or could not tolerate, both fluticasone propionate (generics or Flonase OTC) and triamcinolone (Nasacort OTC) nasal.

**PREFERRED ALTERNATIVES:** Fluticasone propionate (Flonase equivalent), budesonide (RX only) -- prior authorization required.
Nitisinone- Orfadin®
Prior Authorization Criteria

FORMULARY STATUS:
Nitisinone (Orfadin, Nityr) - Nonpreferred-Restricted

APPROVAL LIMITS: None

QUANTITY LIMITS: None

CRITERIA FOR COVERAGE:
• Diagnosis of hereditary tyrosinemia type I.
  AND
• Detectable succinylacetone blood or urine levels.
Non-Sedating Antihistamine
Prior Authorization Criteria

FORMULARY STATUS:
Desloratadine: Nonpreferred-Restricted
Desloratadine/pseudoephedrine (Clarinex D): Nonpreferred-Restricted

APPROVAL LIMITS: Indefinite

QUANTITY LIMITS: None

CRITERIA FOR COVERAGE:
1. ALLERGIC RHINITIS
   • Failure of over the counter (OTC) loratadine AND cetirizine AND fexofenadine AND levocetirizine AND
   • Failure of, or contraindication to nasal steroids*

   *Note: The nasal steroid criterion does not apply in the case of predictable situational exposures where nasal steroids would not be the best clinical choice or for children ≤ age 12.

2. URTICARIAL DISEASE
   • Failure of OTC loratadine AND cetirizine AND fexofenadine AND levocetirizine

IMPORTANT INFORMATION: OTC products are not covered benefits
Norelgestromin/ethinyl estradiol (Xulane)
Quantity exception criteria

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Drug Status</th>
<th>Quantity Limit/28 Days*</th>
<th>Approval Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Norelgestromin/ethinyl estradiol (Xulane)</td>
<td>Preferred</td>
<td>3</td>
<td>None</td>
</tr>
</tbody>
</table>

*quantity limit before exception

CRITERIA FOR QUANTITY LIMIT EXCEPTION:
- History of endometriosis, menstrual migraines, premenstrual syndrome, menorrhagia, dysmenorrhea, amenorrhea
OR
- Hormonally induced seizure disorders or arthritis
OR
- Bleeding disorders: anemia, von Willebrand's disease, patients undergoing chemotherapy or BMT, etc.

AND
- An adequate trial of a preferred oral contraceptive was not tolerated
Nusinersen (Spinraza)
Prior Authorization Criteria

FORMULARY STATUS: Medical Benefit Restricted

APPROVAL LIMITS: 12 months

QUANTITY LIMITS: None

CRITERIA FOR COVERAGE:
- Diagnosis of Spinal muscle atrophy (SMA) based on genetic testing documenting 5q SMA (homozygous gene deletion or mutation) and having at least 2 copies of SMN2 gene.
  AND
- Ordered by Neurologist or other clinician with expertise in management and treatment of SMA
  AND
- Age < 18 years at initiation
  AND
- Medical records documentation provided to establish baseline level of function as appropriate for age and motor function (e.g. HINE, HFSME, ULM, or CHOP INTEND, based on age and motor ability). For patients diagnosed as a result of newborn screening or those that are pre-symptomatic, baseline assessment is still required.
  AND
- Not dependent upon invasive ventilation or tracheostomy or requires non-invasive ventilation for less than 16 hours per day (for naps and nighttime sleep)
  AND
- Has not received prior onasemnogene abeparvovec-xioi (Zolgensma) therapy

CONTINUATION OF COVERAGE CRITERIA:
Annual review (12 months):
- Patients that meet initial criteria above and are established on therapy
  AND
- Medical record documentation of clinically significant improvement in SMA-related symptoms (improvement, stabilization or decreased decline since previous approval). Documentation should include specific scale used based on age and motor function and comparison to baseline. Response is defined as improvement in more categories of motor milestones than worsening
  o For infants age <24 months, provision of CHOP-INTEND and HINE-2 evaluation to document motor status and efficacy of therapy
    ▪ Response to therapy based on at least 2-point increase overall or at least one point increase from baseline
  o For HFSME, a change of 3 or more points from baseline is considered clinically meaningful.
  OR
  o Patient achieved and then maintained any new motor milestones from pretreatment baseline when they would otherwise be unexpected to do so.

- Continuation of therapy/coverage criteria may not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.

FOR BADGERCARE COVERAGE:
Medication must be billed to ForwardHealth under the pharmacy benefit. Refer to the ForwardHealth policy “Select High Cost, Orphan, and Accelerated Approval Drugs” for additional information.

**IMPORTANT INFORMATION:**
Use of Nusinersen is considered experimental when used for other indications. Nusinersen has not been proven for use in SMA without chromosomal 5q mutations or deletions despite the FDA-label for adult patients, limited data are available to support use at this time. Use of onasemnogene-abeparvoc-xioi (Zolgensma) in combination with nusinersen has not been fully evaluated in clinical trials for efficacy and safety and combination therapy is not covered at this time.

HINE=Hammersmith Infant Neurologic Exam (used in infants to early childhood)
HFSME=Hammersmith Functional Motor Scale Expanded
ULM=Upper Limb Module test (used in non-ambulatory patients)
CHOP INTEND=Children’s hospital of Philadelphia Infant Test of Neuromuscular Disorders

**Types of SMA and characteristics**

<table>
<thead>
<tr>
<th>Type</th>
<th>Number of copies of SMN2</th>
<th>Onset</th>
<th>Incidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Two</td>
<td>Before 6 months</td>
<td>60%</td>
</tr>
<tr>
<td>2</td>
<td>Three or Four</td>
<td>6-18 months</td>
<td>27%</td>
</tr>
<tr>
<td>3</td>
<td>Three or Four</td>
<td>Early childhood</td>
<td>13%</td>
</tr>
</tbody>
</table>
Obeticholic acid (Ocaliva)
Prior Authorization Criteria

FORMULARY STATUS: Nonpreferred-Restricted
APPROVAL LIMITS: None
QUANTITY LIMITS: One tablet per day (#30)

CRITERIA FOR COVERAGE:
• Covered for persons with a diagnosis of primary biliary cholangitis
  AND
• Have an alkaline phosphatase level > 1.6 times the upper limit of normal (ULN) and/or a total bilirubin between 1-2 times the ULN without cirrhosis or other significant hepatic decompensation
  AND
• Is being used in combination with ursodeoxycholic acid (UDCA or ursodiol)
OR
• The person is intolerant to UDCA

CRITERIA FOR QUANTITY EXCEPTIONS:
• Prescriber provides an evidence-based clinical rationale for using a dosing regimen outside of the quantity limit.
<table>
<thead>
<tr>
<th>Generic</th>
<th>Brand</th>
<th>HICL</th>
<th>GCN</th>
<th>Exception/Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>OMADACYCLINE TOSYLATE</td>
<td>NUZYRA</td>
<td>45315</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Omadacycline (Nuzyra)**

**Prior Authorization Criteria**

**FORMULARY STATUS:** Nonpreferred-Restricted

**APPROVAL LIMITS:** One fill (usual course is 7-14 days)

**QUANTITY LIMITS:** Three tablets per day

**CRITERIA FOR COVERAGE:**
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

**AND**
- Report of susceptibilities documenting resistance to preferred alternatives

**CRITERIA FOR COVERAGE OF DURATION EXCEPTIONS:**
- The prescriber provides an evidence-based clinical reason for utilizing an extended duration

**CRITERIA FOR QUANTITY EXCEPTIONS:**
- The prescriber provides an evidence-based clinical reason for using a dose outside of the quantity limits

**CONTINUATION OF COVERAGE CRITERIA:**
- Persons new to the plan 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.
- Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.
Omalizumab (Xolair®)
Prior Authorization Criteria

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Drug Status</th>
<th>Quantity Limit</th>
<th>Approval Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Omalizumab (Xolair)</td>
<td>Medical Benefit-Restricted</td>
<td>None</td>
<td>Asthma – 12 months Urticaria: Initial – 6 months Subsequent – 12 months</td>
</tr>
</tbody>
</table>

CRITERIA FOR INITIAL COVERAGE:

1. ASTHMA
   - Age ≥6
   - Diagnosis of allergic asthma
   - Moderate-to-severe persistent asthma as defined by Global Initiative for Asthma (GINA) Global Strategy for Asthma Management and Prevention Guidelines (Step 5)
   - Serum IgE level ≥30 international units/mL
   - Positive skin tests or in vitro reactivity to common aeroallergens (e.g. dust mites, pet dander, cockroaches, etc.)
   - Person is a non-smoker or smoking cessation therapy has been recommended
   - Not well controlled or poorly controlled asthma despite episodic use of systemic corticosteroids or at least 3 months of high-dose inhaled corticosteroids (ICS) in combination with long acting beta₂ agonist (LABA) or leukotriene modifiers
   - Exceptions based on adverse effects from high dose ICS or 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
   - Omalizumab in combination with an IL-5 inhibitor will only be considered on a case by case basis if each individual agent with combination high dose ICS/LABA did not control symptoms.

2. URTICARIA
   - Person with chronic (at least 3 months), refractory urticaria despite use of ALL of the following:
     - scheduled, high dose non-sedating antihistamines
     - at least one short course of corticosteroids

3. For use in cluster or rush immunotherapy protocols before and during allergen-specific immunotherapy (short-term use only) under the supervision of an Allergist

CRITERIA FOR CONTINUATION:

1. ASTHMA
   - Documentation in an office visit in the preceding 12 months there was clinical improvement from prior to initiating omalizumab, including at least one of the following:
     - Decreased frequency of corticosteroid use to treat or prevent an exacerbation
     - Decreased frequency of unscheduled clinic, urgent care or emergency department visits due to asthma
     - Increase in percent predicted FEV₁ from pre-treatment baseline
Reduction in reported symptoms: chest tightness, coughing, shortness of breath, nocturnal waking wheezing, sustained improvement in ACT scores
Reduction use of ICS, leukotriene or beta agonist therapy

Continuation of case by case approved IgE inhibitor and IL-5 inhibitor combination therapy will only be considered if ICS/LABA therapy was also continued AND there was reduction in oral steroid dose, exacerbations or hospitalizations

2. URTICARIA
- Documentation in an office visit in the preceding 12 months there was clinical improvement from prior to initiating omalizumab, including at least one of the following
  - Decrease in oral corticosteroid use
  - Reduction in exacerbation frequency
  - Reduction in exacerbation intensity

Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.

IMPORTANT INFORMATION:
If the medication is going to be administered in the clinic, the medication is not covered under the pharmacy benefit, but may be covered under the medical benefit.
**Note:** Requests for omalizumab for indications other than asthma and chronic urticaria will be considered experimental as defined in the Certificate of Coverage and are not covered.

<table>
<thead>
<tr>
<th>Measure</th>
<th>Not Well Controlled</th>
<th>Very Poorly Controlled</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline symptoms (outside of exacerbation)</td>
<td>&gt; 2 days/week</td>
<td>Throughout the day</td>
</tr>
<tr>
<td>Nighttime awakening</td>
<td>1-3 times/week</td>
<td>≥ 4 times/week</td>
</tr>
<tr>
<td>Interference with normal activity</td>
<td>Some limitation</td>
<td>Extremely limited</td>
</tr>
<tr>
<td>Short acting beta agonist use for symptom control</td>
<td>&gt; 2 days/week</td>
<td>Several times per day</td>
</tr>
<tr>
<td>FEV1</td>
<td>60-80% predicted or personal best</td>
<td>&lt; 60% predicted or personal best</td>
</tr>
<tr>
<td>Asthma exacerbations requiring oral steroids ≥ 2 times in the past year</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Asthma Control Test (ACT)</td>
<td>16-19</td>
<td>≤ 15</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Drug</th>
<th>High Daily Dose</th>
<th>Child 5-11</th>
<th>Adult</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beclomethasone HFA</td>
<td>&gt;200 mcg</td>
<td>&gt;400 mcg</td>
<td></td>
</tr>
<tr>
<td>Budesonide DPI</td>
<td>&gt;400 mcg</td>
<td>&gt;800 mcg</td>
<td></td>
</tr>
<tr>
<td>Budesonide inhaled Inhalation for suspension</td>
<td>&gt;1000 mcg</td>
<td>NA</td>
<td></td>
</tr>
<tr>
<td>Ciclesonide HFA</td>
<td>&gt;160 mcg</td>
<td>&gt;320 mcg</td>
<td></td>
</tr>
<tr>
<td>80 or 160 mcg</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td>---</td>
<td></td>
</tr>
<tr>
<td><strong>Flunisolide</strong> HFA 80 mcg/puff</td>
<td>≥640 mcg</td>
<td>&gt;640 mcg</td>
<td></td>
</tr>
<tr>
<td><strong>Fluticasone</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HFA/MDI: 44, 110 mcg/puff</td>
<td>&gt;500 mcg</td>
<td>&gt;500 mcg</td>
<td></td>
</tr>
<tr>
<td>DPI: 50, 100, 250 mcg/inhalation</td>
<td>&gt;400 mcg</td>
<td>&gt;500 mcg</td>
<td></td>
</tr>
<tr>
<td><strong>Mometasone</strong> DPI</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>200 mcg/inhalation</td>
<td>≥440 mcg</td>
<td>&gt;440 mcg</td>
<td></td>
</tr>
</tbody>
</table>
Onasemnogene abeparvovec (Zolgensma)  
Prior Authorization Criteria

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Drug Status</th>
<th>Quantity Limit/Lifetime</th>
<th>Approval Limits/Lifetime</th>
</tr>
</thead>
<tbody>
<tr>
<td>Onasemnogene abeparvovec (Zolgensma)</td>
<td>Medical benefit- Restricted</td>
<td>1 kit (weight-based)</td>
<td>1 treatment</td>
</tr>
</tbody>
</table>

**CRITERIA FOR COVERAGE:**
- Diagnosis of spinal muscle atrophy (SMA) based on documentation of gene mutation analysis with bi-allelic SMN1 mutations (point mutation/deletion) and has at least 2 copies of SMN2 gene.
- Baseline antibody titers of anti AAV9 antibodies are ≤1:50 (based on ELISA), documented within one month prior to administration
- Ordered by Neurologist or other clinician with expertise in management and treatment of SMA
- Age < 2 years at administration
- Does not have advanced SMA (e.g. permanent ventilatory dependence, complete limb paralysis, etc.)
- For infants established on nusinersen, will not continue nusinersen (Spinraza) post onasemnogene infusion (not studied)

**FOR BADGERCARE COVERAGE:**
Medication must be billed to ForwardHealth under the pharmacy benefit. Refer to the ForwardHealth policy "Select High Cost, Orphan, and Accelerated Approval Drugs" for additional information.

**IMPORTANT INFORMATION:**
Use of onasemnogene abeparvovec in combination with nusinersen would be considered experimental at this time as it has not been fully evaluated. Despite the broad FDA-label for all SMA types, published data do not yet support broad use of therapy in all SMA types and ages.
### Itraconazole/Onychomycosis

#### Prior Authorization Criteria

**FORMULARY STATUS:**
- Itraconazole (generic of Sporanox) Preferred-Restricted
- Itraconazole (Onmel) Nonpreferred-Restricted
- Itraconazole (Tolsura) Nonpreferred-Restricted
- Ciclopirox 8% nail lacquer Nonpreferred-Restricted
- Efinaconazole (Jublia) topical Nonpreferred-Restricted
- Tavaborole (Kerydin) topical Nonpreferred-Restricted

**APPROVAL LIMITS:**
- Onychomycosis: ≤ 4 months for itraconazole; ≤ 48 weeks for all topical therapies
- Other indications: For duration of prescription

**QUANTITY LIMITS:**
- None

**CRITERIA FOR COVERAGE:**

#### 1. Onychomycosis:
- **Infection caused by fungus or mold confirmed by culture** OR **positive KOH test.**

**AND**

- Person has peripheral vascular disease, diabetes, is immunosuppressed, immunocompromised, or has recurrent cellulitis.
- OR
  - Person with documented functional disability due to onychomycosis

**AND**
- Person has contraindications to both oral terbinafine and oral itraconazole (for topical therapies)
- OR
  - Person has failed terbinafine therapy (for itraconazole)

#### 2. Systemic Infections: (Itraconazole only)
- Diagnosis of Blastomycosis or Histoplasmosis or Aspergillosis or other verified systemic fungal infection susceptible to itraconazole

**CRITERIA FOR COVERAGE OF NONPREFERRED ITRACONAZOLE (ONMEL, TOLSURA):**
• Meets criteria for 1 or 2 above
AND
• Contraindication to use of generic itraconazole (Sporanox equivalent)

CRITERIA FOR COVERAGE OF DURATION EXCEPTIONS:
• Adequate time has elapsed after 4 months of treatment for nail to grow out (6 months)

CONTINUATION OF COVERAGE CRITERIA (for systemic fungal infections only):
• Persons new to the plan 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.
• Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.

IMPORTANT INFORMATION:
CNL-8 is a 6 month supply, so 6 copays will be charged
Opioid Risk Management Program
7 Day Opioid First Fill Exception
Prior Authorization Criteria

FORMULARY STATUS: Drug Specific

APPROVAL LIMITS: Once

QUANTITY LIMITS: None (unless noted in drug-specific criteria)

CRITERIA FOR COVERAGE (for an initial fill > 7 days):
- Person meets one of the following:
  - Long-term care resident
  - Receiving hospice, palliative, or other end-of-life care
  - Treatment of cancer-related pain
  - The prescriber documents that the current prescription is a continuation of a stable, on-going opioid treatment regimen
Opioid Risk Management Program
Opioid Concurrent Use Edit
Prior Authorization Criteria

FORMULARY STATUS: Drug Specific

APPROVAL LIMITS: See criteria for coverage

QUANTITY LIMITS: None (unless noted in drug-specific criteria)

CRITERIA FOR COVERAGE:
1. Prescriber documents that the person has stopped opioid dependency treatment with a buprenorphine-containing drug and is resuming other opioid treatment (12 month authorization)
OR
2. Prescriber documents that the person is continuing opioid dependency treatment with a buprenorphine-containing drug but requires acute opioid treatment (1 fill authorization)
Opioid Risk Management Program
Dose > 120 Morphine Milligram Equivalents (MME)
Prior Authorization Criteria

FORMULARY STATUS: Drug Specific

APPROVAL LIMITS: See criteria for coverage

QUANTITY LIMITS: None (unless noted in drug-specific criteria)

CRITERIA FOR COVERAGE:
1. Person meets one of the following (indefinite approval):
   a. Long-term care resident
   b. Receiving hospice, palliative, or other end-of-life care
   c. Treatment of cancer-related pain

2. Person meets ALL of the following (12 month approval):
   a. Prescriber states the opioid dose requested is medically necessary
   b. Documentation that the state prescription drug monitoring program (PDMP) site has been checked in the past month
   c. Documentation of a current pain contract
   d. Documentation that use of naloxone has been discussed
   e. Documentation of urine compliance screen in the previous 12 months

3. Person is changing medications and the new medication regimen does not exceed 120 MME (1 time approval)

4. Person discharged from an inpatient stay after a severe, acute trauma (3 month approval):
   a. Prescriber states the opioid dose requested is medically necessary
   b. Documentation that the state PDMP site has been checked prior to discharge
   c. Documentation that use of naloxone has been discussed

IMPORTANT INFORMATION:

<table>
<thead>
<tr>
<th>Drug Name (strength units)</th>
<th>MME Conversion Factor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Butorphanol (mg)</td>
<td>7</td>
</tr>
<tr>
<td>Codeine (mg)</td>
<td>0.15</td>
</tr>
<tr>
<td>Dihydrocodeine (mg)</td>
<td>0.25</td>
</tr>
<tr>
<td>Fentanyl buccal/SL tabs, lozenge, troche (mcg)</td>
<td>0.13</td>
</tr>
<tr>
<td>Fentanyl film, oral spray (mcg)</td>
<td>0.18</td>
</tr>
<tr>
<td>Fentanyl nasal spray (mcg)</td>
<td>0.16</td>
</tr>
<tr>
<td>Fentanyl patch (mcg)</td>
<td>7.2</td>
</tr>
<tr>
<td>Hydrocodone (mg)</td>
<td>1</td>
</tr>
<tr>
<td>Hydromorphone (mg)</td>
<td>4</td>
</tr>
<tr>
<td>Levorphanol (mg)</td>
<td>11</td>
</tr>
<tr>
<td>Meperidine (mg)</td>
<td>0.1</td>
</tr>
<tr>
<td>Methadone 1 mg to 20 mg</td>
<td>4</td>
</tr>
<tr>
<td>Drug</td>
<td>Maximum Dose</td>
</tr>
<tr>
<td>----------------------</td>
<td>--------------</td>
</tr>
<tr>
<td>Methadone 21 mg – 40 mg</td>
<td>8</td>
</tr>
<tr>
<td>Methadone 41 mg – 60 mg</td>
<td>10</td>
</tr>
<tr>
<td>Methadone &gt; 60 mg</td>
<td>12</td>
</tr>
<tr>
<td>Opium (mg)</td>
<td>1</td>
</tr>
<tr>
<td>Oxycodone (mg)</td>
<td>1.5</td>
</tr>
<tr>
<td>Oxymorphone (mg)</td>
<td>3</td>
</tr>
<tr>
<td>Pentazocine (mg)</td>
<td>0.37</td>
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<td>Abemaciclib</td>
<td>VERZENIO</td>
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<tr>
<td>Abiraterone submicronized</td>
<td>YONSA</td>
</tr>
<tr>
<td>Acalabrutinib</td>
<td>CALQUENCE</td>
</tr>
<tr>
<td>Apalutamide</td>
<td>ERLEADA</td>
</tr>
<tr>
<td>Binimetinide</td>
<td>MEKTOVI</td>
</tr>
<tr>
<td>Brigatinib</td>
<td>ALUNBRIG</td>
</tr>
<tr>
<td>Cabozantinib S-Malate</td>
<td>COMETRIQ</td>
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<tr>
<td>Dacomitinib</td>
<td>VIZIMPRO</td>
</tr>
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<td>Duvelisib</td>
<td>COPIKTRA</td>
</tr>
<tr>
<td>Enasidenib</td>
<td>IDHIFA</td>
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<tr>
<td>Encorafenib</td>
<td>BRAFTOVI</td>
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<tr>
<td>Erdafitinib</td>
<td>BALVERSA</td>
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<tr>
<td>Gilteritinib</td>
<td>XOSPATA</td>
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<td>Glasdegib</td>
<td>DAURISMO</td>
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<td>Ivosidenib</td>
<td>TIBSOVO</td>
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<td>Laronotrectinib</td>
<td>VITRAKVI</td>
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<tr>
<td>Lenvatinib Mesylate</td>
<td>LENVIMA</td>
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<tr>
<td>Lorlatinib</td>
<td>LORBRENA</td>
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<tr>
<td>Midostaurin</td>
<td>RYDAPT</td>
</tr>
<tr>
<td>Neratinib Maleate</td>
<td>NERLYNX</td>
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<tr>
<td>Niraparib Tosylate</td>
<td>ZEJULA</td>
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<tr>
<td>Pexidartinib Hydrochloride</td>
<td>TURALIO</td>
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<tr>
<td>Ponatinib</td>
<td>ICLUSIG</td>
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<tr>
<td>Selinexor</td>
<td>XPOVIO</td>
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<tr>
<td>Talazoparib</td>
<td>TALZENNA</td>
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<tr>
<td>Vandetanib</td>
<td>CAPRELSA</td>
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</table>

**Restricted Oral Oncology Drug Prior Authorization Criteria**

<table>
<thead>
<tr>
<th>DRUG NAME</th>
<th>DRUG STATUS</th>
<th>DAILY QUANTITY LIMITS</th>
<th>APPROVAL LIMITS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abemaciclib (Verzenio)</td>
<td>Nonpreferred-Restricted</td>
<td>2</td>
<td>12 months</td>
</tr>
<tr>
<td>Abiraterone submicronized (Yonsa)</td>
<td>Nonpreferred-Restricted</td>
<td></td>
<td>12 months</td>
</tr>
<tr>
<td>Acalabrutinib (Calquence)</td>
<td>Nonpreferred-Restricted</td>
<td>2</td>
<td>12 months</td>
</tr>
<tr>
<td>Apalutamide (Erleada)</td>
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<td>4</td>
<td>12 months</td>
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<tr>
<td>Binimetinib (Mektovi)</td>
<td>Nonpreferred-Restricted</td>
<td>6</td>
<td>12 months</td>
</tr>
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<td>Drug Name</td>
<td>Formulation</td>
<td>Criteria</td>
<td>Duration</td>
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<td>---------------------------------</td>
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<tr>
<td>Brigatinib (Alunbrig)</td>
<td>Nonpreferred-Restricted</td>
<td>30 mg tablet: 4 90 mg tablet: 1 180 mg tablet: 1 90 mg/180 mg pack: 1</td>
<td>12 months</td>
</tr>
<tr>
<td>Cabozantinib s-malate (Cometriq)</td>
<td>Nonpreferred-Restricted</td>
<td></td>
<td>12 months</td>
</tr>
<tr>
<td>Dacomitinib (Vizimpro)</td>
<td>Nonpreferred-Restricted</td>
<td>1</td>
<td>12 months</td>
</tr>
<tr>
<td>Duvelisib (Copiktra)</td>
<td>Nonpreferred-Restricted</td>
<td>2</td>
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<tr>
<td>Enasidenib (Idhifa)</td>
<td>Nonpreferred-Restricted</td>
<td>1</td>
<td>12 months</td>
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<tr>
<td>Encorafenib (Braftovi)</td>
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<td>Erdafitinib (Balversa)</td>
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<tr>
<td>Gilteritinib (Xospata)</td>
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<td>12 months</td>
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<td>Glasdegib (Daurismo)</td>
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<td>25 mg tablet: 2 100 mg tablet: 1</td>
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<td>Ivosidenib (Tibsovo)</td>
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<tr>
<td>Larotrectinib (Vitrakvi)</td>
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<td>Lorlatinib (Lorbrena)</td>
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<td>25 mg tablet: 3 100 mg tablet: 1</td>
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<td>Midostaurin (Rydapt)</td>
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<td>Neratinib Maleate (Nerlynx)</td>
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<td>Niraparib tosylate (Zejula)</td>
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<td>Pexidartinib (Turalio)</td>
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<td>4</td>
<td>12 months</td>
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<td>Ponatinib (Iclusig)</td>
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<td>Selinexor (Xpovi)</td>
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<td>12 months</td>
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<tr>
<td>Talazoparib (Talzenna)</td>
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<td>0.25 mg capsule: 3 1 mg capsule: 1</td>
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<tr>
<td>Vandetanib (Caprelsa)</td>
<td>Nonpreferred-Restricted</td>
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<td>12 months</td>
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</table>

**CRITERIA FOR COVERAGE:**
- Drug must be prescribed and monitored by an Oncologist, Hematologist, or other specialist in the treatment of malignancy
AND

- 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

- 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 person*

  OR

- (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* in either the United States Pharmacopeia Drug Information or the American Hospital Formulary Service Drug Information or one article in a major peer-reviewed medical journal recognizes the safety and efficacy of the requested drug in the person’s specific condition

  OR

- (Illinois 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* in the American Hospital Formulary Service Drug Information, Thompson Micromedex’s Drug Dex, Elsevier Gold Standard’s Clinical Pharmacology, or two articles in peer-reviewed professional medical journals from the United States or Great Britain recognize the safety and efficacy of the requested drug in the person’s specific condition.

*includes any relevant genetic testing, mutations, etc.

CONTINUATION/RENEWAL OF COVERAGE CRITERIA:

- Initial criteria for coverage met

CRITERIA FOR QUANTITY EXCEPTION:

- Requested dosing schedule cannot be met within the drug’s quantity limit(s) and the prescriber provides an evidence-based rationale for using a dose outside of the quantity limit.

IMPORTANT INFORMATION:

Many of these drugs are not available at all pharmacies as the manufacturer has limited the drug’s distribution. Please see the specific drug’s website for details on where the drug can be dispensed from.
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<thead>
<tr>
<th>Generic</th>
<th>Brand</th>
<th>HICL</th>
<th>GCN</th>
<th>Exception/Other</th>
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<td>ZYTIGA</td>
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<td>ALPELISIB</td>
<td>PIQRAY</td>
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<td>CABOZANTINIB S-MALATE</td>
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<td>DAROLUTAMIDE</td>
<td>NUBEQA</td>
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<td>ENTRECTINIB</td>
<td>ROZLYTREK</td>
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<td>FEDRATINIB DIHYDROCHLORIDE</td>
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<td>IBRUTINIB</td>
<td>IMBRUVICA</td>
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<td>ZYDELIG</td>
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<td>NINLARO</td>
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<td>FARYDAK</td>
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<td>POMALIDOMIDE</td>
<td>POMALYST</td>
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<td>REGORAFENIB</td>
<td>STIVARGA</td>
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<td>RIBOCICLIB SUCCINATE</td>
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<td>RIBOCICLIB SUCCINATE/LETRIOZOLE</td>
<td>KISQALI FEMARA COPACK</td>
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<td>RUCAPARIB CAMSYLATE</td>
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<td>SONIDEGIB PHOSPHATE</td>
<td>ODOMZO</td>
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<td>TOPOTECAN HCL</td>
<td>HYCAMTIN</td>
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<td>TRAMETINIB DIMETHYL SULFOXIDE</td>
<td>MEKINIST</td>
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<td>TRIFLURIDINE/LIPIRACIL HCL</td>
<td>LONSURF</td>
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<td>VENETOCLAX</td>
<td>VENCLEXTA</td>
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<td>VISMODEGIB</td>
<td>ERIVEDGE</td>
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<td>VORINOSTAT</td>
<td>ZOLINZA</td>
<td>34070</td>
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Restricted Oral Oncology Medications
Quartz Specialty Pharmacy Network
Prior Authorization Criteria

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<tr>
<th>DRUG NAME</th>
<th>DRUG STATUS</th>
<th>DAILY QUANTITY LIMITS*</th>
<th>APPROVAL LIMITS</th>
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<tbody>
<tr>
<td>Abiraterone (Zytiga)</td>
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<td>Alpelisib (Piqray)</td>
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<td>Drug Name</td>
<td>Status</td>
<td>Days Taken</td>
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<tr>
<td>Cabozantinib s-malate (Cabometyx)</td>
<td>Nonpreferred-Restricted</td>
<td>1</td>
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<tr>
<td>Cobimetinib fumarate (Cotellic)</td>
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<td>Three tablets per day for a 21 day cycle (#63)</td>
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<td>Dabrafenib mesylate (Tafinlar)</td>
<td>Nonpreferred-Restricted</td>
<td>4</td>
<td>12 months</td>
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<tr>
<td>Darolutamide (Nubeqa)</td>
<td>Nonpreferred-Restricted</td>
<td>3 for 200mg 5 for 100mg</td>
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<tr>
<td>Entrectinib (Rozlytrek)</td>
<td>Nonpreferred-Restricted</td>
<td>12 months</td>
<td></td>
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<tr>
<td>Ibrutinib (Imbruvica)</td>
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<td>12 months</td>
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<td>Idelalisib (Zydelig)</td>
<td>Nonpreferred-Restricted</td>
<td>2</td>
<td>12 months</td>
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<td>Inrelic (Fedratinib Dihydrochloride)</td>
<td>Nonpreferred-Restricted</td>
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<td>Ixazomib citrate (Ninlaro)</td>
<td>Nonpreferred-Restricted</td>
<td>Three capsules per 28 days (#3)</td>
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<td>Lapatinib ditosylate (Tykerb)</td>
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<td>Lenalidomide (Revlimid)</td>
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<td>12 months</td>
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<td>Palbociclib (Ibrance)</td>
<td>Nonpreferred-Restricted</td>
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<td>12 months</td>
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<tr>
<td>Panobinostat (Farydak)</td>
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<td>Six capsules per 21 day cycle (#6)</td>
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<td>Pomalidomide (Pomalyst)</td>
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<td>Regorafenib (Stivarga)</td>
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<td>Ribociclib succinate (Kisqali)</td>
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<td>Ribociclib succinate/letrozole (Kisqali Femara Copack)</td>
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<td>Rucaparib camsylate (Rubraca)</td>
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<td>Sonidegib phosphate (Odomzo)</td>
<td>Nonpreferred-Restricted</td>
<td>1</td>
<td>12 months</td>
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<tr>
<td>Topotecan (Hycamtin)</td>
<td>Nonpreferred-Restricted</td>
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<tr>
<td>Trametinib dimethyl sulfoxide (Mekinist)</td>
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<td>12 months</td>
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<td>Trifluridine/tipiracil (Lonsurf)</td>
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<td>Venetoclax (Venclexta)</td>
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</tr>
<tr>
<td>Vismodegib (Erivedge)</td>
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</table>
CRITERIA FOR COVERAGE:

- Medication is included in the Specialty Medication Outcomes Management program. Drug must be obtained from one of the Quartz Specialty Pharmacies. Please refer to the Pharmacy Benefits section of the website.
- Drug must be prescribed and monitored by an Oncologist, Hematologist, or other specialist in the treatment of malignancy.

AND

- 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
- 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.*
- OR
- (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* in either the United States Pharmacopeia Drug Information or the American Hospital Formulary Service Drug Information or one article in a major peer-reviewed medical journal recognizes the safety and efficacy of the requested drug in the person’s specific condition.
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*includes any relevant genetic testing, mutations, etc.

CONTINUATION/RENEWAL OF COVERAGE CRITERIA:

- Initial criteria for coverage met

CRITERIA FOR QUANTITY EXCEPTION:

- Requested dosing schedule cannot be met within the drug’s quantity limit(s) and the prescriber provides an evidence-based rationale for using a dose outside of the quantity limit.
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<thead>
<tr>
<th>Generic</th>
<th>Brand</th>
<th>HICL</th>
<th>GCN</th>
<th>Exception/Other</th>
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<tr>
<td>AFATINIB DIMALEATE</td>
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<tr>
<td>NILOTINIB</td>
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<tr>
<td>OLAPARIB</td>
<td>LYNPARZA</td>
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<tr>
<td>OSIMERTINIB</td>
<td>TAGRISIO</td>
<td>42803</td>
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<tr>
<td>PAZOPANIB HYDROCHLORIDE</td>
<td>VOTRIENT</td>
<td>36709</td>
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<tr>
<td>RUXOLITINIB</td>
<td>JAKAFI</td>
<td>38202</td>
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<tr>
<td>SORAFENIB</td>
<td>NEXAVAR</td>
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<tr>
<td>SUNITINIB</td>
<td>SUTENT</td>
<td>33445</td>
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<tr>
<td>VEMURAFENIB</td>
<td>ZELBORAF</td>
<td>37837</td>
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</tr>
</tbody>
</table>

**Restricted Oral Oncology Medications**

**Split Fill Program**

**Prior Authorization Criteria**

<table>
<thead>
<tr>
<th>DRUG NAME</th>
<th>DRUG STATUS</th>
<th>DAILY QUANTITY LIMITS</th>
<th>APPROVAL LIMITS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Afatinib dimaleate (Gilotrif)</td>
<td>Nonpreferred-Restricted</td>
<td>1</td>
<td>12 months</td>
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<tr>
<td>Alectinib hydrochloride (Alecensa)</td>
<td>Nonpreferred-Restricted</td>
<td>8</td>
<td>12 months</td>
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<tr>
<td>Axitinib (Inlyta)</td>
<td>Nonpreferred-Restricted</td>
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<td>12 months</td>
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<tr>
<td>Bosutinib (Bosulif)</td>
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</tr>
<tr>
<td>Drug Name</td>
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<td>Duration</td>
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<td>---------------------------</td>
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<tr>
<td>Ceritinib (Zykadia)</td>
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<tr>
<td>Crizotinib (Xalkori)</td>
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<tr>
<td>Dasatinib (Sprycel)</td>
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<tr>
<td>Enzalutamide (Xtandi)</td>
<td>Nonpreferred-Restricted</td>
<td>12 months</td>
<td></td>
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<tr>
<td>Erlotinib hydrochloride (Tarceva equivalent)</td>
<td>Preferred-Restricted</td>
<td>1</td>
<td>12 months</td>
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<tr>
<td>Everolimus (Afinitor, Afinitor Disperz)</td>
<td>Nonpreferred-Restricted</td>
<td>12 months</td>
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<tr>
<td>Gefitinib (Iressa)</td>
<td>Nonpreferred-Restricted</td>
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<tr>
<td>Imatinib mesylate (Gleevec)</td>
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<td>100 mg tablet- 7 400 mg tablet- 2</td>
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<tr>
<td>Nilotinib (Tasigna)</td>
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<tr>
<td>Olaparib (Lynparza)</td>
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<tr>
<td>Osimertinib mesylate (Tagrisso)</td>
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<td>1</td>
<td>12 months</td>
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<tr>
<td>Pazopanib hydrochloride (Votrient)</td>
<td>Nonpreferred-Restricted</td>
<td>12 months</td>
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<tr>
<td>Ruxolitinib phosphate (Jakafi)</td>
<td>Nonpreferred-Restricted</td>
<td>12 months</td>
<td></td>
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<tr>
<td>Sorafenib (Nexavar)</td>
<td>Preferred-Restricted</td>
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<td></td>
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<tr>
<td>Sunitinib (Sutent)</td>
<td>Preferred-Restricted</td>
<td>12 months</td>
<td></td>
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<tr>
<td>Vemurafenib (Zelboraf)</td>
<td>Nonpreferred-Restricted</td>
<td>12 months</td>
<td></td>
</tr>
</tbody>
</table>

**CRITERIA FOR COVERAGE:**

- Medication is included in the Specialty Medication Outcomes Management program. Drug must be obtained from one of the Quartz Specialty Pharmacies. Please refer to the Pharmacy Benefits section of the website.
- Drug must be prescribed and monitored by an Oncologist, Hematologist, or other specialist in the treatment of malignancy.

AND

- 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

- 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.

OR

- (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 in either the United States Pharmacopeia Drug Information or the American Hospital Formulary Service Drug Information or one article in a major peer-reviewed medical journal recognizes the safety and efficacy of the requested drug in the person’s specific condition.

OR
• (Illinois 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* in the American Hospital Formulary Service Drug Information, Thompson Micromedex’s Drug Dex, Elsevier Gold Standard’s Clinical Pharmacology, or two articles in peer-reviewed professional medical journals from the United States or Great Britain recognize the safety and efficacy of the requested drug in the person’s specific condition.

*includes any relevant genetic testing, mutations, etc.

Oral Oncology Program requirements:
• Initial therapy- partial dispensing of 15 days supply for initial 3 three months of this therapy
• Maintenance therapy- dispensing of 1 month supply after first 3 months
• Participation in medication therapy program coordinated by oncology pharmacist from the specialty pharmacy

CONTINUATION/RENEWAL OF COVERAGE CRITERIA:
• Initial criteria for coverage met

CRITERIA FOR QUANTITY EXCEPTION:
• Requested dosing schedule cannot be met within the drug’s quantity limit(s) and the prescriber provides an evidence-based rationale for using a dose outside of the quantity limit.
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Romosozumab-aqqg (Evenity)
Prior Authorization Criteria

FORMULARY STATUS: Medical benefit – Restricted
APPROVAL LIMITS: 12 months
QUANTITY LIMITS: None

CRITERIA FOR COVERAGE:
1. Medication must be administered by a health care provider
AND
2. Total duration of treatment will not exceed 12 months over a person's lifetime
AND
3. Person has not had a myocardial infarction or stroke within the preceding year and consider the benefits versus the risks in people with other cardiovascular risk factors
AND
4. For the treatment of postmenopausal women who have one of the following diagnosis and the associated criteria:
   A. 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 AT LEAST ONE of the following:
      i. Has had a low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm
      ii. Is at high risk for fracture (advanced age, frailty, glucocorticoids, very low T scores (less than or equal to -3.5), or increased fall risk)
      iii. Has failed therapy with at least one bisphosphonate (e.g. low-trauma fractures or decrease in BMD while on alendronate 70 mg per week)
   OR
   B. 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 10 year probability of a hip fracture of at least 3% or major osteoporosis-related fracture of at least 20% AND AT LEAST ONE of the following:
      i. Has had a low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm
      ii. Is at high risk for fracture (advanced age, frailty, glucocorticoids, very low T scores (less than or equal to -3.5), or increased fall risk)
      iii. Has failed therapy with at least one bisphosphonate (e.g. low-trauma fractures or decrease in BMD while on alendronate 70 mg per week)

*fracture risk to be assessed with FRAX score, number of osteoporosis related fractures, increased fall risk; indicators of higher fracture risk include: advanced age, glucocorticosteroids, very low T score, increased fall risk (many of these factors will reflect in the FRAX score; however, some risk factors are not incorporated, like number of fractures, time of fracture (recent), increased fall risk.

CONTINUATION OF CARE CRITERIA:
- Persons new to the plan 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 pharmacies and participation in medication management programs may apply.
- Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.
- Persons new to the plan 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.
Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.

Important information:
- Medications administered in the clinic are not included in the pharmacy benefit. They are covered by the medical benefit and must be procured by the clinic that is administering the medication.
### Tedizolid (Sivextro)

**Oxazolidinone Antibiotic**

**Prior Authorization Criteria**

**FORMULARY STATUS:**
Tedizolid (Sivextro)  Preferred-Restricted

**APPROVAL LIMITS:**
Approve for the duration of treatment-usually 6-14 days, or 14 to 28 days for Vancomycin-resistant enterococcus

**QUANTITY LIMITS:**
None

**CRITERIA FOR COVERAGE:**
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
   AND
   • Report of susceptibilities documenting resistance to alternatives including linezolid
   OR
   • (If linezolid is the only viable alternative due to resistance) Person is taking serotonergic agents (e.g. SSRI, tricyclic antidepressants, triptans, etc.)

**CRITERIA FOR COVERAGE OF DURATION EXCEPTIONS:**
• Prescriber presents an evidence-based clinical reason for utilizing an extended duration

**CONTINUATION OF COVERAGE CRITERIA:**
• Persons new to the plan 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.
• Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.

**IMPORTANT INFORMATION:**
These drugs are indicated for infections caused by aerobic gram-positive bacteria. The primary use of these drugs should be restricted to resistant bacterial strains including Vancomycin-resistant Enterococcus faecium and Methicillin-resistant Staphylococcal aureus. This does not include penicillin-resistant strains of Streptococcal pneumoniae.
<table>
<thead>
<tr>
<th>Generic Name</th>
<th>Brand Name</th>
<th>HICL</th>
<th>GCN</th>
<th>Exception/Other</th>
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<tbody>
<tr>
<td>OXANDROLONE</td>
<td>OXANDRIN</td>
<td>01412</td>
<td></td>
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</tr>
</tbody>
</table>

**Oxandroline**  
Prior Authorization Criteria

**FORMULARY STATUS:** Preferred-Restricted

**APPROVAL LIMITS:** None

**QUANTITY LIMITS:** None

**CRITERIA FOR COVERAGE:**
- Persons unable to gain or maintain normal weight following extensive surgery, chronic infections or severe trauma **OR**
- To offset protein catabolism due to chronic corticosteroids **OR**
- HIV wasting syndrome & HIV associated muscle weakness **OR**
- Constitutional delay of growth and puberty
<table>
<thead>
<tr>
<th>Generic</th>
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<th>HICL</th>
<th>GCN</th>
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<td>OXYMORPHONE HCL</td>
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<td>OXYMORPHONE HCL</td>
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### Oxymorphone Hydrochloride
#### Prior Authorization Criteria

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<th>Drug Status</th>
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<th>Approval Limits</th>
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</thead>
<tbody>
<tr>
<td>Oxymorphone immediate-release</td>
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<td>None</td>
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<tr>
<td>Oxymorphone extended-release</td>
<td>Nonpreferred-Restricted</td>
<td>2</td>
<td>None</td>
</tr>
</tbody>
</table>

#### CRITERIA FOR COVERAGE:

1. **Oxymorphone Extended Release:**
   - Inadequate pain control after an adequate trial with generic extended release morphine AND extended release oxycodone
   - OR
   - Intolerance to generic extended release morphine AND extended release oxycodone
   - OR
   - *(Minnesota plans only)* – the person has stage four metastatic cancer and the requested drug is being used to treat cancer-related pain

2. **Oxymorphone Immediate Release:**
   - Inadequate pain control after an adequate trial with two generic immediate-release narcotics
   - OR
   - Intolerance to two generic immediate-release narcotics
   - OR
   - *(Minnesota plans only)* – the person has stage four metastatic cancer and the requested drug is being used to treat cancer-related pain

#### CRITERIA FOR COVERAGE OF QUANTITY EXCEPTIONS:
Therapeutic failure or intolerance to two dose units per day for available strengths and the prescriber provides an evidence-based clinical rationale for using a dosing regimen outside of the quantity limit
Palifermin (Kepivance)  
Prior Authorization PA Criteria

FORMULARY STATUS:  
Palifermin (Kepivance)  Medical Benefit-Restricted

APPROVAL LIMITS:  
12 months

QUANTITY LIMITS:  
6 doses per cycle

CRITERIA FOR COVERAGE:

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

AND  

• Persons at high risk for grade 3 or 4 mucositis associated with high dose chemotherapy and/or radiotherapy with hematologic malignancies requiring a hematopoietic stem cell transplant (HSCT).

CRITERIA FOR COVERAGE:

• Initial criteria met  
• Continuation of therapy coverage will not be applied to persons who were not previously approved for coverage, whose therapy was initiated using a manufacturer sponsored free drug program, provider samples and/or vouchers.
Palivizumab (Synagis®)
Prior Authorization Criteria

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Drug Status</th>
<th>Quantity Limits/Season</th>
<th>Approval Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Palivizumab (Synagis)</td>
<td>Medical Benefit-Restricted</td>
<td>5 doses</td>
<td>One season (November/April)</td>
</tr>
</tbody>
</table>

CRITERIA FOR COVERAGE:
- Infants born at ≤ 29 weeks, 0 days gestation and less than 1 year old on start of RSV season (November)
  OR
- Chronic lung disease of prematurity (defined as gestational age <32 weeks, 0 days at birth and required >21% oxygen for at least the first 28 days after birth)
  - In the first year of life for preterm infants as defined above
  - In the second year of life for infants who continue to require medical support (corticosteroids, diuretics, or oxygen) during the 6 months prior to season (since May of current year)
  OR
- In the first year of life for infants with congenital heart disease with at least ONE of the following:
  - Congestive heart failure requiring medications
  - Moderate to severe pulmonary hypertension
  - Acyanotic heart disease requiring medications
  OR
- For infants in the first year of life who have congenital airway abnormalities or severe neuromuscular disease that impairs the ability to clear secretions from the upper airway because of ineffective cough.
  OR
- Infant less than 2 years of age and immunocompromised (i.e. SCID, HIV infection, solid organ or hematopoietic transplant or on chemotherapy) during RSV season.
  OR
- Infant less than 2 years of age and will undergo cardiac transplantation during RSV season

For infants receiving palivizumab and have been hospitalized with RSV infection, palivizumab will no longer be covered.

CRITERIA FOR A DURATION EXCEPTIONS:
The prescriber provides an evidence-based clinical rationale for requesting a treatment duration outside of the traditional RSV season based on the current year’s prevalence data

IMPORTANT INFORMATION:
- The RSV season in Wisconsin is typically from November to April but has extended into May and started earlier in October.
- Treatment for a second RSV season will be evaluated on a case-by-case basis in situations not described above.
- The diagnosis of cystic fibrosis on newborn screening without other indications as noted above will not be covered.
Parathyroid Hormone (Natpara)
Prior Authorization Criteria

FORMULARY STATUS: Nonpreferred-Restricted

APPROVAL LIMITS: None

QUANTITY LIMITS: Two cartridges per 30 days

CRITERIA FOR COVERAGE:
• Prescribed by an Endocrinologist AND
• Diagnosis of hypoparathyroidism AND
• Have symptomatic hypocalcemia or a corrected serum calcium < 8.0 mg/dL despite at least six months of consistent treatment with;
  o 1500-2000 mg elemental calcium/day
  o 0.25-2 mcg calcitriol/day (or equivalent)
OR
• Have symptomatic hypocalcemia or a corrected serum calcium < 8.0 mg/dL and experience significant/life threatening intolerances preventing the use of oral calcium supplementation

CRITERIA FOR QUANTITY EXCEPTIONS:
• Prescriber presents an evidence-based clinical rationale for utilizing a dosing regimen that is not possible within the quantity limits.

IMPORTANT INFORMATION:
Corrected serum calcium is recommended to be > 7.5 mg/dL before initiating parathyroid hormone. Parathyroid hormone is restricted to prescribing by certified providers and dispensing from certified pharmacies. Please see www.NATPARAREMS.com for details.
Patisiran (Onpattro)
Prior Authorization Criteria

FORMULARY STATUS: Medical Benefit-Restricted

APPROVAL LIMITS: Initial approval: 12 months
Continuation approval: indefinite

QUANTITY LIMITS: None

CRITERIA FOR COVERAGE:
• Prescribed by a Neurologist, Cardiologist, or other expert in hereditary transthyretin-mediated amyloidosis (hATTR)
• Age 18 years or older
• Diagnosis of neuropathy due to hereditary transthyretin (hATTR) amyloidosis with documentation of TTR gene mutation and biopsy proven amyloid deposits
• Prior use with treatment failure or intolerance to inotersen (Tegsedi) or clinical rationale why inotersen (Tegsedi) cannot be used

CRITERIA FOR CONTINUATION OF COVERAGE:
• Initiation criteria met AND clinical documentation from the previous 12 months of response to therapy or documentation of clinical stability (e.g. Karnofsky status, or other functional measure)
• For members new to the plan, the prescriber must provide clinical documentation of the person's initial response to therapy (e.g. clinical manifestation stability/improvement based upon the continuation criteria above)
• Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.

FOR BADGERCARE COVERAGE:
Medication must be billed to ForwardHealth under the pharmacy benefit. Refer to the ForwardHealth policy “Select High Cost, Orphan, and Accelerated Approval Drugs” for additional information.
# Restricted Paroxetine

**Prior Authorization Criteria**

<table>
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<tr>
<th>Drug</th>
<th>Formulary Status</th>
<th>Quantity Limits</th>
<th>Approval Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paroxetine mesylate (Brisdelle equiv.)</td>
<td>Nonpreferred-Restricted</td>
<td>None</td>
<td>None</td>
</tr>
</tbody>
</table>

**CRITERIA FOR COVERAGE (Brisdelle generic equivalent):**
- Diagnosis of vasomotor symptoms due to menopause
- Failure of a trial of generic paroxetine (Paxil generic) at an equivalent dose
- The prescriber provides an evidence-based clinical rationale for why the requested formulation would provide different results.
<table>
<thead>
<tr>
<th>Generic Name</th>
<th>Brand Name</th>
<th>HICL</th>
<th>GCN</th>
<th>Exception/Other</th>
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<tbody>
<tr>
<td>PASIREOTIDE DIASPARTATE</td>
<td>SIGNIFOR</td>
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</tr>
</tbody>
</table>

Pasireotide (Signifor)
Prior Authorization Criteria

**FORMULARY STATUS:** Nonpreferred-Restricted

**APPROVAL LIMITS:** None

**QUANTITY LIMITS:** None

**CRITERIA FOR COVERAGE:**
- Covered for adults with Cushing disease for whom pituitary surgery is not an option, or is not curative.
  
  **AND**
  - Inadequate clinical response to octreotide
  
  **OR**
  - Other FDA labeled indications

**Important information:**
Signifor is only available through a limited specialty pharmacy distribution network. Please see their website at [www.signifor.us/](http://www.signifor.us/) for more information.

Pasireotide long-acting (Signifor LAR) is a clinic administered drug and is not covered on the prescription benefit.
**CRITERIA FOR COVERAGE (evolocumab 140 mg, 420 mg):**

- **For evolocumab 140 mg, 420 mg:** Diagnosis of Heterozygous Familial Hypercholesteremia or diagnosis of established arteriosclerotic cardiovascular disease (ASCVD)*; **OR for evolocumab 420 mg only:** diagnosis of Homozygous Familial Hypercholesterolemia

AND

- Prescribed by, or in consultation with, a specialist (e.g. Cardiologist, Endocrinologist, or Lipidologist-documentation required)

AND

- Person has LDL-C ≥ 70 mg/dL while on maximally tolerated statin doses

AND

- For statin TOLERANT persons
  - Adherent treatment with a high potency statin (e.g. atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily) for a minimum of 8 weeks duration
  - OR
  - Adherent treatment with a maximally tolerated dose of any statin for a minimum of 8 weeks duration if the patient cannot tolerate a high potency statin
  - AND
  - Person will continue statin treatment in combination with PCSK9

- For statin INTOLERANT persons
  - The person is considered "statin intolerant"** or has a contraindication to statin use such as active liver disease or persistently elevated serum transaminases

AND

- Prescription benefit medications must be self-administered and are included in the Specialty Pharmaceuticals Program. Medications must be obtained from one of the Specialty Pharmacies. Contact 1-866-894-3784 or 877-208-1096 for more details.

**CRITERIA FOR CONTINUATION OF COVERAGE:**

- Clinical documentation from the previous 12 months demonstrating a reduction in LDL-C from baseline

- Continued adherent treatment to baseline lipid-lowering therapies

- Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiates using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.

**CRITERIA FOR COVERAGE OF QUANTITY EXCEPTIONS:**

- **For evolocumab 140 mg (3 x 140 mg = 420 mg/month)**
  - Person not controlled on the 420 mg Pushtrone product and rationale provided why use of the 140 mg syringe/sureclick would be expected to be effective (e.g. published literature, administration issues)
For all other products and dosing:
• Symptoms not controlled on at least 12 weeks of a "standard regimen" and rationale provided with published literature supporting why an alternative dosing regimen would be expected to be effective

DEFINITIONS:
*ASCVD refers to the following conditions: coronary heart disease such as myocardial infarction, angina, coronary artery stenosis >50%; cerebrovascular disease such as transient ischemic attack, ischemic stroke, or carotid artery stenosis > 50%; peripheral artery disease such as claudication; and aortic atherosclerotic disease such as abdominal aortic aneurysm and descending thoracic aneurysm.

***Statin intolerance is defined as the inability to tolerate at least 2 statins, with:
• One started at the lowest starting dose
AND
• Statin dose reduction was attempted to resolve symptoms or lab abnormalities (not discontinuation)
AND
• Symptoms or lab abnormalities reversed with statin discontinuation but returned with re-challenge of statins
AND
• Symptoms or lab abnormalities are not due to established predispositions such as drug interactions, significant changes in physical activity, or underlying muscle disease

A retrial of a statin may be requested prior to consideration of approval of a PSCK-9 inhibitor based on the information provided.
**Generic**

<table>
<thead>
<tr>
<th>Brand</th>
<th>HICL</th>
<th>GCN</th>
<th>Exception/Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>PEGFILGRASTIM-JMDB</td>
<td>FULPHILA</td>
<td>45010</td>
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<tr>
<td>PEGFILGRASTIM-CBQV</td>
<td>UDENYCA</td>
<td>45445</td>
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<tr>
<td>PEGFILGRASTIM-BMEZ</td>
<td>ZIEXTENZO</td>
<td>46183</td>
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</table>

### Pegfilgrastim

**Prior Authorization Criteria**

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Drug Status</th>
<th>Quantity Limits/Fill</th>
<th>Approval Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pegfilgrastim-jmdb (Fulphila)</td>
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<td>12 months</td>
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<tr>
<td>Pegfilgrastim-cbqv (Udenyca)</td>
<td>Preferred-Restricted Medical Benefit-Restricted</td>
<td>1</td>
<td>12 months</td>
</tr>
<tr>
<td>Pegfilgrastim-bmez (Ziextenzo)</td>
<td>Preferred-Restricted Medical Benefit-Restricted</td>
<td>1</td>
<td>12 months</td>
</tr>
</tbody>
</table>

**Nonformulary/Not Covered**

| Pegfilgrastim (Neulasta, Neulasta OnPro) | Nonformulary – Not Covered (Pharmacy Benefit) Not Covered (Medical Benefit) |

### CRITERIA FOR COVERAGE of biosimilar pegfilgrastim products (e.g. Fulphila, Udenyca, Ziextenzo):

A. Filgrastim-product was not tolerated or there was a therapeutic failure (e.g. febrile neutropenia or chemotherapy delayed despite maximized filgrastim use)

AND

B. Indication/Reason for use of a filgrastim product was any one of the following:

1. Nonmyeloid malignancies receiving myelosuppressive chemotherapy with a febrile neutropenia rate of 20% or greater
2. Nonmyeloid malignancies receiving myelosuppressive chemotherapy who are at high risk for developing febrile neutropenia regardless of the expected rate of febrile neutropenia due to ANY of the following:
   a. Prior radiotherapy or chemotherapy
   b. Extraordinary high doses of myelosuppressive chemotherapy agents
   c. Persistent neutropenia
   d. History of recurring FN receiving chemotherapy of similar or less intensity
   e. Poor performance status
   f. Advanced cancer
   g. Bone marrow involvement
   h. Decreased immune function
   i. Current infection
   j. Age > 65 years
   k. Liver dysfunction (bilirubin >2.0), Renal dysfunction (Creatinine clearance <50)
3. Receiving dose dense chemotherapy regimen
4. Person had febrile neutropenia during prior chemotherapy cycle, when no GCSF therapy was used
5. Chemotherapy dose reduction was not a viable option for preventing febrile neutropenia
6. Prolonged neutropenia caused a delay in chemotherapy treatment

OR

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A. (Minnesota plans only) – the person has stage four metastatic cancer and the requested drug is being used as supportive care for their cancer treatment

QUANTITY LIMIT EXCEPTION CRITERIA:
For self-administration/prescription drug benefit: One additional dose (total of two doses/copay) will be considered for coverage for persons on a chemotherapy regimen that would require more than one dose of pegfilgrastim per 30 days (ex. dose dense regimens).
Pegloticase (Krystexxa)
Prior Authorization Criteria

FORMULARY STATUS: Medical Benefit - restricted

APPROVAL LIMITS:
- Initial – 6 months
- Renewal – 12 months

QUANTITY LIMITS: None

CRITERIA FOR COVERAGE:
- Drug must be prescribed and monitored by a Rheumatologist
  AND
- The person has a serum uric acid level > 6.0 mg/dL despite an adequate trial of maximized therapeutic doses of both allopurinol and febuxostat in combination with lesinurad OR allopurinol, febuxostat, and lesinurad are not tolerated
  AND
- The person has severe symptomatic tophaceous gout (chronic tophaceous gouty arthropathy in ≥ 4 joints or ≥ 1 unstable, complicated, or severe articular tophi) despite appropriate urate lowering therapy (as above) and appropriate NSAID, colchicine, and glucocorticoid use for acute attacks.
  AND
- Documentation that the person does not have glucose-6-phosphate dehydrogenase (G6PD) deficiency

CRITERIA FOR CONTINUATION OF THERAPY:
- Clinical documentation demonstrating the person has achieved and maintained (most recent value must be within the previous 2 months) a serum uric acid level < 6.0 mg/DL
  AND
- Clinical documentation from the previous 12 months demonstrating an objective reduction in gout symptoms such as reduction in tophi or number of acute attacks

Note: Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage by the plan whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.
Pegvaliase (Palynziq)
Prior Authorization Criteria

FORMULARY STATUS: Nonpreferred-Restricted

QUANTITY LIMITS:
- 10 mg dose: 1-10 mg syringe per day dosing (15 mL)
- 20 mg dose: 1-20 mg syringe per day dosing (30 mL)
- 40 mg dose: 2-20 mg syringes per day dosing (60 mL)

DURATION LIMITS:
- 40 mg daily trial: 4 months
- Reauthorization: Every 12 months

CRITERIA FOR COVERAGE:
1. Initial coverage
   • Age ≥ 18 years
   • Clinically diagnosed with PKU
   • Blood phenylalanine (Phe) concentration > 600 micromol/L (10 mg/dL) despite at least six months of adherent use of a Phe restricted diet and at least two months of sapropterin (Kuvan)
   • Sapropterin must be discontinued prior to start of pegvaliase

2. Coverage of 40 mg daily dosing:
   • Initial criteria for coverage met
   • Failure to achieve a 20% reduction from baseline Phe levels or levels remain greater than 600 micromol/L (10 mg/dL) despite 24 weeks of 20 mg/day dosing

3. Continuation of coverage:
   • Used in conjunction with a Phe restricted diet
   • Person achieved a 20% reduction in Phe levels from baseline or Phe levels less than 600 micromol/L (10 mg/dL)
   • Not on concurrent sapropterin

IMPORTANT INFORMATION:
Nutritional supplements are considered medical foods and are not covered under the prescription drug benefit.

FOR BADGERCARE COVERAGE:
Medication must be billed to ForwardHealth under the pharmacy benefit. Refer to the ForwardHealth policy “Select High Cost, Orphan, and Accelerated Approval Drugs” for additional information.
### Pegvisomant (Somavert®)
#### Prior Authorization Criteria

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Drug Status</th>
<th>Quantity Limits/Day</th>
<th>Approval Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pegvisomant (Somavert)</td>
<td>Nonpreferred-Restricted</td>
<td>1 vial</td>
<td>None</td>
</tr>
</tbody>
</table>

**CRITERIA FOR COVERAGE:**
- Prescribed by, or in consultation with, an Endocrinologist
- Diagnosis of acromegaly with inadequate response to surgery and failure, intolerance, or contraindication to an adequate trial of somatostatin therapy
- Person or family member self-administering medication

**CONTINUATION OF COVERAGE CRITERIA:**
- Persons new to the plan 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.
- Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.
### Pegylated Interferons

**Prior Authorization Criteria**

<table>
<thead>
<tr>
<th>Generic</th>
<th>Brand</th>
<th>HICL</th>
<th>GCN</th>
<th>Exception/Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>PEGINTERFERON ALFA-2A</td>
<td>PEGASYS</td>
<td>24035</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PEGINTERFERON ALFA-2B</td>
<td>PEGINTRON</td>
<td></td>
<td>12671</td>
<td>12672 12673 89387</td>
</tr>
</tbody>
</table>

#### FORMULARY STATUS:
- Peg-Intron: Preferred-Restricted
- Pegasys: Preferred-Restricted

#### APPROVAL LIMITS:
- For hepatitis C: as indicated in package labeling or hcvguidelines.org
- For hepatitis B: 48 weeks

#### QUANTITY LIMITS:
- One month supply: Peg-Intron 4 kits or 4 vials
- Pegasys 4 vials (#4), 4 syringes/pen injectors (#2mL) or 1 kit

#### CRITERIA FOR COVERAGE:
- Must be self-administered or administered by a family member
- Medications are included in the Hepatitis C Medication Adherence program. Medications must be obtained from one of the Specialty Pharmacies. See Specialty Pharmaceuticals Program in the Pharmacy Information section of the website for more information.

AND

#### HEPATITIS C (HCV)
- Used for the treatment of persons with HCV as part of a multidrug regimen
- Dosing and duration of therapy will be determined by genotype being treated and concurrent direct acting antiviral being used and will be based on package labeling or hcvguidelines.org accepted regimens

OR

#### HEPATITIS B
- Used for treatment of adults with HBeAg positive or HBeAg negative chronic hepatitis B who have compensated liver disease and evidence of viral replication and liver inflammation

OR

#### OTHER USES
- Other uses such as treatment for longer durations than recommended in labeling or guidelines, or retreatment of a patient previously treated will be evaluated on a case-by-case basis

#### CRITERIA FOR COVERAGE OF QUANTITY EXCEPTIONS:
- Therapeutic failure or intolerance to one dose unit per week for available strengths and the prescriber provides an evidence-based clinical rationale for using a dose outside of the quantity limit

#### CRITERIA FOR COVERAGE OF DURATION EXCEPTIONS:
- Prescriber presents rational clinical reason and data to support utilization for an extended duration

#### CONTINUATION OF COVERAGE CRITERIA:

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• Persons new to the plan 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.
• Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.
Pimavanserin (Nuplazid)
Prior Authorization Criteria

<table>
<thead>
<tr>
<th>Drug</th>
<th>Drug Status</th>
<th>Quantity Limits/Day</th>
<th>Approval Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pimavanserin (Nuplazid)</td>
<td>Nonpreferred-Restricted</td>
<td>1</td>
<td>None</td>
</tr>
</tbody>
</table>

CRITERIA FOR COVERAGE:
- Drug is prescribed by, or in consultation with, a Neurologist
- Covered for persons with a diagnosis of Parkinson’s disease psychosis with documented hallucinations or delusions
- Dose reductions and alterations in scheduling of dopaminergic agents led to increased Parkinson’s symptoms

CRITERIA FOR QUANTITY EXCEPTIONS:
- Failure or intolerance to once daily dosing of the commercially available dosage forms and the prescriber provides an evidence-based clinical rationale for using a dose outside of the quantity limits

CONTINUATION OF COVERAGE CRITERIA:
- Persons 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.
- Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.
Prednisone DR (Rayos)
Prior Authorization Criteria

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Drug Status</th>
<th>Quantity Limits</th>
<th>Approval Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prednisone DR (Rayos)</td>
<td>Nonpreferred-Restricted</td>
<td>None</td>
<td>None</td>
</tr>
</tbody>
</table>

CRITERIA FOR COVERAGE:
- Person with a failure of immediate-release prednisone (unable to achieve symptom control due to therapy-limiting side effects) despite dose adjustment and/or timing modification
- The prescriber provides an evidence-based clinical rationale for why the side effects are not likely to occur with the extended-release formulation
OR
- (Minnesota plans only): person 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


Propranolol Solution 4.28 mg/ml (Hemangeol)
Prior Authorization Criteria

FORMULARY STATUS: Nonpreferred-Restricted

APPROVAL LIMITS: 12 months

QUANTITY LIMITS: None

CRITERIA FOR COVERAGE:
- Person with a diagnosis of proliferating infantile hemangioma requiring systemic therapy.
  AND
- Therapeutic failure or intolerance to the preferred propranolol solution options at an equivalent dose.
  AND
- The prescriber provides an evidence-based clinical rationale as to why the Hemangeol product would be expected to produce superior therapeutic results

CRITERIA FOR DURATION EXCEPTIONS:
- General criteria for coverage met (preferred propranolol solution must be retried)

IMPORTANT INFORMATION:
Propranolol 4 mg/ml and 8 mg/ml are available as generics without restriction
Lansoprazole Solutab
Prior Authorization Criteria

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Drug Status</th>
<th>Quantity Limits/Day</th>
<th>Approval Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lansoprazole rapid tabs (Prevacid Solutab equivalent)</td>
<td>Preferred-Restricted</td>
<td>1</td>
<td>12 months</td>
</tr>
</tbody>
</table>

CRITERIA FOR COVERAGE
• Unable to tolerate solid dose form
• Age < 18 years of age
OR
• (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

CRITERIA FOR COVERAGE OF QUANTITY EXCEPTION:
• Extraesophageal symptoms
OR
• Failed once daily dosing of highest strength of medication
OR
• Prescriber provides an evidence-based clinical rationale for a dosing regimen that will not fit within the quantity limits using commercially available dose forms

CRITERIA FOR RE-APPROVAL/CONTINUATION OF THERAPY:
• Criteria for coverage met
### Restricted Nonpreferred Proton Pump Inhibitor

**Prior Authorization Criteria**

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Drug Status</th>
<th>Quantity Limits/Day</th>
<th>Approval Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Esomeprazole (Nexium packs)</td>
<td>Nonpreferred-Restricted</td>
<td>1</td>
<td>None</td>
</tr>
<tr>
<td>Esomeprazole strontium</td>
<td>Nonpreferred-Restricted</td>
<td>1</td>
<td>None</td>
</tr>
<tr>
<td>Dextansoprazole (Dexilant)</td>
<td>Nonpreferred-Restricted</td>
<td>1</td>
<td>None</td>
</tr>
</tbody>
</table>

**CRITERIA FOR COVERAGE OF NONPREFERRED PPI:**
- Therapeutic failure or intolerant to at least three preferred PPI options (omeprazole, pantoprazole, lansoprazole, rabeprazole tablets, or esomeprazole capsules)

**OR**
- *(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

**CRITERIA FOR COVERAGE OF QUANTITY EXCEPTION:**
- Extraesophageal symptoms or failed once daily dosing of highest strength of medication **OR**
- Compounded prescriptions where the quantity would interfere with processing (12 month duration)
Restricted Medications with Miscellaneous Codes
Prior Authorization Criteria

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Drug Status</th>
<th>Quantity Limits</th>
<th>Approval Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Varies</td>
<td>Medical Benefit-Restricted</td>
<td>Varies</td>
<td>Up to 12 months</td>
</tr>
</tbody>
</table>

CRITERIA FOR COVERAGE OF RESTRICTED NON-ONCOLOGY MEDICATIONS WITH MISCELLANEOUS CODES:
- FDA approved indications unless there are drug product specific prior authorization criteria (e.g. mepolizumab (Nucala®), daratumumab (Darzalex®), etc.); if there are drug product specific criteria those criteria apply and must be met for coverage.

CRITERIA FOR COVERAGE OF RESTRICTED ONCOLOGY MEDICATIONS WITH MISCELLANEOUS CODES:
- The requested drug is being used alone or in a combination regimen that is FDA-labeled for the treatment of the specific condition of the person.
  OR
- 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.
  OR
- (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 in either the United States Pharmacopeia Drug Information or the American Hospital Formulary Service Drug Information or one article in a major peer-reviewed medical journal recognizes the safety and efficacy of the requested drug in the person’s specific condition.
  OR
- (Illinois plans only) - the requested drug is being used alone or in a combination that is recommended for use in the specific condition of the person in the American Hospital Formulary Service Drug Information, Thompson Micromedex’s Drug Dex, Elsevier Gold Standard’s Clinical Pharmacology, or two articles in peer-reviewed professional medical journals from the United States or Great Britain recognize the safety and efficacy of the requested drug in the person’s specific condition.

CONTINUITY OF COVERAGE CRITERIA:
- Person new to the plan who are being treated for a diagnosis that is not excluded by certificate of coverage and is established on therapy will have coverage under their medical benefit if drug product specific continuation of therapy criteria met; if no product specific criteria, with documentation of symptom improvement or disease stability.
- Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.
Speak of the document: This document contains information about the formulary status and prior authorization criteria for progesterone medications. The medications listed include Crinone, Progesterone injection, Endometrin insert, Makena (hydroxyprogesterone), and Hydroxyprogesterone compounded. The formulary status for these medications is Nonpreferred-Restricted or Medical Benefit Restricted, depending on the specific medication.

The prior authorization criteria are detailed for each pregnancy trimester and for treatment of infertility. For the first trimester, women must be currently pregnant and need progesterone to maintain pregnancy. For the second trimester, women must have a singleton pregnancy, a history of preterm birth, and be using Prochieve, Crinone, or Endometrin insert. For the treatment of infertility, women must be residents of Illinois and have documented inability to conceive or sustain a successful pregnancy.

The document also notes that Hydroxyprogesterone is covered under the Medical Benefit and must be administered in the clinic, which requires the clinic to purchase the medication for administration.

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• Documentation that 12 months of medically supervised methods of conception (e.g. artificial insemination) have failed and will not likely lead to a successful pregnancy

CONTINUATION OF COVERAGE CRITERIA:
• Persons new to the plan 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.
• Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.

IMPORTANT INFORMATION:
Medications will not be covered to improve libido or for sexual dysfunction.
Risedronate Prior Authorization Criteria

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Drug Status</th>
<th>Quantity Limits/Fill</th>
<th>Approval Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risedronate 5 mg</td>
<td>Nonpreferred-Restricted</td>
<td>None</td>
<td>None</td>
</tr>
</tbody>
</table>

CRITERIA FOR COVERAGE:

- For treatment or prevention of osteoporosis due to corticosteroid: failure or intolerance of alendronate

OR

- All other indications: failure or intolerance of alendronate, ibandronate, and other strengths of risedronate (35 mg, 150 mg)
Generic  | Brand       | HICL       | GCN          | Exception/Other
--- | --- | --- | --- | ---
SILDENAFIL CITRATE | REVATIO | 24758, 33186 |  |  |
TADALAFIL | ADCIRCA | 26587 |  |  |
BOSENTAN | TRACLEER | 22990 |  |  |
AMBRISSENTAN | LETAIRIS | 34849 |  |  |
MACITENTAN | OPSUMIT | 40677 |  |  |
ILOPROST | VENTAVIS | 26287 |  |  |
TREPROSTINIL DIOLAMINE | ORENITRAM ER | 40827 |  |  |
SELEXIPAG | UPTRAVI | 42922 |  |  |
RIOCIGUAT | ADEMPAS | 40644 |  |  |

**Pulmonary Hypertension Medication**  
**Prior Authorization Criteria**

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Drug Status</th>
<th>Quantity Limits/Day</th>
<th>Approval Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ambrisentan (Letairis equiv.)</td>
<td>Preferred-Restricted</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Bosentan (Tracleer equiv.)</td>
<td>Preferred-Restricted</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Macitentan (Opsumit)</td>
<td>Preferred-Restricted</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Selexipag (Uptravi)</td>
<td>Preferred-Restricted</td>
<td>2*</td>
<td>None</td>
</tr>
<tr>
<td>Sildenafil (Revatio equiv.)</td>
<td>Preferred-Restricted</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Iloprost (Ventavis)</td>
<td>Nonpreferred-Restricted</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Riociguat (Adempas)</td>
<td>Nonpreferred-Restricted</td>
<td>3*</td>
<td>None</td>
</tr>
<tr>
<td>Tadalafil (Adcirca equiv., Alyq)</td>
<td>Nonpreferred-Restricted</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Treprostinil ER (Orenitram ER)</td>
<td>Nonpreferred-Restricted</td>
<td>None</td>
<td>None</td>
</tr>
</tbody>
</table>

*after titration

**CRITERIA FOR COVERAGE (all agents):**
- Diagnosis of pulmonary arterial hypertension
- Prescriber is a Cardiologist or Pulmonologist

AND
1. **For tadalafil:**
   - Therapeutic failure or intolerance to sildenafil

2. **For inhaled iloprost:**
   - Therapeutic failure or intolerance to inhaled treprostinil

3. **For oral treprostinil (Orenitram ER):**
   - Therapeutic failure or intolerance to inhaled treprostinil

4. **For riociguat (Adempas)**

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• General criteria met
  OR
• Has diagnosis of persistent/recurrent chronic thromboembolic pulmonary hypertension (WHO group 4) after surgical treatment or for persons deemed inoperable and prescriber is a cardiologist or pulmonologist

IMPORTANT INFORMATION:
Sildenafil and tadalafil are not covered as part of the pharmacy benefit for use in erectile dysfunction or for status post prostatectomy.
Quantity Exception
Prior Authorization Criteria

FORMULARY STATUS: Drug specific

APPROVAL LIMITS: Request specific

QUANTITY LIMITS: Drug specific

CRITERIA FOR COVERAGE OF QUANTITY EXCEPTIONS:
1. For medications with a one unit per day quantity limit:
   • Therapeutic failure of, or intolerance to, one unit per day for commercially available strengths and
     the prescriber provides an evidence-based clinical rationale for use of a dose outside of the quantity
     limit

2. For medications with a quantity limit of more than one unit per day:
   • Person's total daily dose cannot be met within the quantity limit using commercially available
     strengths and the prescriber provides an evidence-based clinical rationale for use of a dose outside
     of the quantity limit

3. For multidose packaged medications that have a quantity limit of two package per fill:
   • Prescriber provides an evidence-based clinical rationale for prescribed quantity & regimen is not
     possible within the listed quantity limits

IMPORTANT INFORMATION:
Medications that have quantity limits are indicated with a “QL” on the formulary document. Specific
limits for individual drugs are available in Appendix A of the formulary PDF. Please see the website for
more information.
Restricted Nonpreferred Medication
Prior Authorization Criteria

FORMULARY STATUS: Nonpreferred-Restricted for some benefits
APPROVAL LIMITS: Drug specific
QUANTITY LIMITS: Drug specific

CRITERIA FOR COVERAGE OF RESTRICTED NONPREFERRED DRUGS:
• Therapeutic failure after an adequate trial, intolerance, or contraindication to clinically appropriate preferred alternatives.
  o For drug classes with ≥ 5 alternatives, 2 preferred alternatives must be tried.
  o For drug classes with < 5 alternatives, 1 preferred alternative must be tried.
OR
• Drug product specific prior authorization criteria are met (e.g. non-sedating antihistamines)
OR
• (Minnesota plans only): person has stage four metastatic cancer and the requested drug is being used as supportive care to treat symptoms directly related to their cancer diagnosis

CONTINUITY OF COVERAGE CRITERIA:
• Persons new to the plan who are being treated for depression or other mood disorders and are established on a nonpreferred therapy will have coverage under their drug benefit with documentation of symptom improvement or disease stability.
• Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.

IMPORTANT INFORMATION:
These criteria are general prior authorization criteria for persons with closed drug benefits designs (e.g. HSA plans). Drug-specific criteria will still apply.
### Retinoid Products

#### Prior Authorization Criteria

<table>
<thead>
<tr>
<th>Generic</th>
<th>Brand</th>
<th>HICL</th>
<th>GCN</th>
<th>Exception/Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADAPALENE</td>
<td>DIFFERIN, PLIXDA</td>
<td>11233</td>
<td>GCN 48590</td>
<td>NOT OTC</td>
</tr>
<tr>
<td>CLINDAMYCIN/TRETINOIN</td>
<td>VELTIN, ZIANA</td>
<td>34216</td>
<td>GCN 18782</td>
<td>NOT GCN 18782</td>
</tr>
<tr>
<td>TAZAROTENE</td>
<td>FABIOR, TAZORAC</td>
<td>13315</td>
<td>GCN 48590</td>
<td>NOT GCN 48590</td>
</tr>
<tr>
<td>HALOBETASOL/TAZAROTENE</td>
<td>DUOBRII</td>
<td>45706</td>
<td></td>
<td></td>
</tr>
<tr>
<td>TRETINOIN</td>
<td>ATRALIN, AVITA, RETIN-A, ALTRENO</td>
<td>02468</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**FORMULARY STATUS:**
- adapalene 0.1% gel OTC: Preferred
- adapalene 0.1% gel (federal legend), cream; 0.3% gel: Preferred-Restricted
- adapalene lotion, solution (generics, Plixda): Nonpreferred-Restricted
- clindamycin/tretinoin (generic Ziana, Veltin): Nonpreferred-Restricted
- tazarotene (Tazorac, Fabior): Preferred-Restricted
- halobetasol/tazarotene (Duobrii): Preferred-Restricted
- tretinoin (generic, Altreno): Preferred-Restricted

**APPROVAL LIMITS:** None

**QUANTITY LIMITS:**
- Halobetasol/tazarotene (Duobrii): 200 grams per month

**CRITERIA FOR COVERAGE:**

**For preferred tretinoin:**
- Diagnosis of acne or rosacea

**For nonpreferred tretinoin:**
- Diagnosis of acne or rosacea
- Failure or intolerance to BOTH a preferred tretinoin and adapalene

**For adapalene products:**
- Diagnosis of acne or rosacea AND
- Failure or intolerance of adapalene 0.1% gel
- For adapalene 0.1% federal legend gel: Prescriber provides clinical rationale why adapalene 0.1% federal legend gel will produce different results from adapalene 0.1% OTC gel

**For tazarotene products:**
- Diagnosis of psoriasis OR
- Diagnosis of acne or rosacea AND failure/intolerance of tretinoin AND failure/intolerance of adapalene
For combination halobetasol/tazarotene
- Diagnosis of psoriasis AND
- Failure or intolerance to one preferred high or super-high potency topical corticosteroids

For combination products (generics of Ziana, Veltin):
- Diagnosis of acne or rosacea AND
- Failure of concurrent use of the individual products.
Rilonacept (Arcalyst™)
Prior Authorization Criteria

FORMULARY STATUS:  Medical Benefit-Restricted

APPROVAL LIMITS:  None

QUANTITY LIMITS:  None

CRITERIA FOR COVERAGE:
• Diagnosis of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS) in adults and children ≥ age 12
• Prescribed by a Rheumatologist or Immunologist
• Failure or intolerance to an adequate trial of Kineret (Anakinra)
Riluzole (Tiglutik)
Prior Authorization Criteria

FORMULARY STATUS: Nonpreferred-Restricted

APPROVAL LIMITS: None

QUANTITY LIMITS: None

CRITERIA FOR COVERAGE:
• Person with a diagnosis of amyotrophic lateral sclerosis (ALS)
AND
• A trial of generic riluzole tablets was not tolerated due to an inability to swallow solid dosage forms
Sacubitril/valsartan (Entresto)
Prior Authorization Criteria

FORMULARY STATUS: Preferred-Restricted

APPROVAL LIMITS: None

QUANTITY LIMITS: Two tablets per day (#60)

CRITERIA FOR COVERAGE:
- Diagnosis of heart failure (NYHA Class II-IV) with an ejection fraction ≤ 40%.
  AND
- Individual is on ACCF/AHA guideline directed therapy, unless not tolerated or contraindicated.

CRITERIA FOR COVERAGE OF QUANTITY EXCEPTIONS:
- Prescriber provides an evidence-based clinical rationale for using a dose outside of the quantity limits

IMPORTANT INFORMATION:
Sacubitril/valsartan is contraindicated with concomitant use of ACEI.
Sapropterin-Kuvan®
Prior Authorization Criteria

FORMULARY STATUS: Nonpreferred-Restricted

QUANTITY LIMITS: None

DURATION LIMITS: Initial 2 months
Reauthorization-every 12 months

CRITERIA FOR COVERAGE:

1. Initial coverage (2 months):
   • Clinically diagnosed with PKU
   • Used in conjunction with a phenylalanine (Phe) restricted diet
   • Person is not on concurrent pegvaliase therapy

2. Continuation of coverage (after initial 2 months):
   • Person has demonstrated at least a 30% reduction in Phe levels from baseline on saproterin treatment
   • Used in conjunction with a Phe restricted diet
   • Person will continue to have blood Phe levels measure periodically during treatment
   • Person is not on concurrent pegvaliase therapy
   • Continuation of therapy/coverage criteria may not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.

3. Continuation of coverage (annual renewal)
   • Used in conjunction with a Phe restricted diet
   • Person will continue to have blood Phe levels measured periodically during treatment
   • Person is not on concurrent pegvaliase therapy
   • Continuation of therapy/coverage criteria may not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.

CRITERIA FOR COVERAGE OF DURATION EXCEPTIONS:
• Prescriber presents rationale, clinical reason for utilizing an extended duration

IMPORTANT INFORMATION:
Nutritional supplements are considered medical foods and are not covered under the prescription drug benefit.
<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Drug Status</th>
<th>Quantity Limits</th>
<th>Approval Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sargramostim (Leukine)</td>
<td>Nonpreferred-Restricted</td>
<td>None</td>
<td>12 months</td>
</tr>
</tbody>
</table>

**CRITERIA FOR PHARMACY BENEFIT COVERAGE (of Sargramostim):**

- Therapeutic failure or intolerance to tbo-filgrastim (i.e. Granix)
  
- (Minnesota plans only) – the person has stage four metastatic cancer and the requested drug is being used as supportive care for their cancer treatment
## Medical Benefit Coverage of Drugs That Are Typically Self-Administered

### Prior Authorization Criteria

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Drug Status</th>
<th>Quantity Limit</th>
<th>Approval Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abatacept (Orencia) syringe</td>
<td>Medical Benefit-Restricted</td>
<td>4/28 Days</td>
<td>Up to 12 months</td>
</tr>
<tr>
<td>Adalimumab (Humira)</td>
<td>Medical Benefit-Restricted</td>
<td>2/28 Days</td>
<td>Up to 12 months</td>
</tr>
<tr>
<td>Anakinra (Kineret)</td>
<td>Medical Benefit-Restricted</td>
<td>1/Day</td>
<td>Up to 12 months</td>
</tr>
<tr>
<td>Asfotase alfa (Stremsiq)</td>
<td>Medical Benefit-Restricted</td>
<td>None</td>
<td>Up to 12 months</td>
</tr>
<tr>
<td>Benralizumab (Fasenra)</td>
<td>Medical Benefit-Restricted</td>
<td>1mL/56 Days</td>
<td>Up to 12 months</td>
</tr>
<tr>
<td>Brodalumab (Siliq)</td>
<td>Medical Benefit-Restricted</td>
<td>2/28 Days</td>
<td>Up to 12 months</td>
</tr>
<tr>
<td>Certolizumab (Cimzia)</td>
<td>Medical Benefit-Restricted</td>
<td>2/28 days</td>
<td>Up to 12 months</td>
</tr>
<tr>
<td>Dupilumab (Dupixent)</td>
<td>Medical Benefit-Restricted</td>
<td>4mL/28 Days</td>
<td>Up to 12 months</td>
</tr>
<tr>
<td>Elicizumab (Remlibra)</td>
<td>Medical Benefit-Restricted</td>
<td>None</td>
<td>Up to 12 months</td>
</tr>
<tr>
<td>Etanercept (Enbrel)</td>
<td>Medical Benefit-Restricted</td>
<td>Varies</td>
<td>Up to 12 months</td>
</tr>
<tr>
<td>Golimumab injection (Simponi)</td>
<td>Medical Benefit-Restricted</td>
<td>1/28 Days</td>
<td>Up to 12 months</td>
</tr>
<tr>
<td>Guselklumab (Tremfya)</td>
<td>Medical Benefit-Restricted</td>
<td>1/56 Days</td>
<td>Up to 12 months</td>
</tr>
<tr>
<td>Inoterens (Tegsedi)</td>
<td>Medical Benefit-Restricted</td>
<td>None</td>
<td>Up to 12 months</td>
</tr>
<tr>
<td>Interferon alfa-2b (Intron A)</td>
<td>Medical Benefit-Restricted</td>
<td>None</td>
<td>Up to 12 months</td>
</tr>
<tr>
<td>Interferon alfa-n3 (Alferon N)</td>
<td>Medical Benefit-Restricted</td>
<td>None</td>
<td>Up to 12 months</td>
</tr>
<tr>
<td>Interferon beta-1a (Rebif, Avonex)</td>
<td>Medical Benefit-Restricted</td>
<td>None</td>
<td>Up to 12 months</td>
</tr>
<tr>
<td>Interferon gamma 1b (Actimmune)</td>
<td>Medical Benefit-Restricted</td>
<td>None</td>
<td>Up to 12 months</td>
</tr>
<tr>
<td>Ixekizumab (Taltz)</td>
<td>Medical Benefit-Restricted</td>
<td>1/28 Days</td>
<td>Up to 12 months</td>
</tr>
<tr>
<td>Mepolizumab (Nucala)</td>
<td>Medical Benefit-Restricted</td>
<td>1 mL/month or 3mL/month</td>
<td>Up to 12 months</td>
</tr>
<tr>
<td>Mipomersen (Kynamro)</td>
<td>Medical Benefit-Restricted</td>
<td>None</td>
<td>Up to 12 months</td>
</tr>
<tr>
<td>Parathyroid Hormone (Natpara)</td>
<td>Medical Benefit-Restricted</td>
<td>None</td>
<td>Up to 12 months</td>
</tr>
<tr>
<td>Peginterferon alfa-2a</td>
<td>Medical Benefit-Restricted</td>
<td>None</td>
<td>Up to 12 months</td>
</tr>
<tr>
<td>Drug Name</td>
<td>Medical Benefit</td>
<td>Quantity Exception</td>
<td>Duration</td>
</tr>
<tr>
<td>------------------------------------------</td>
<td>-------------------</td>
<td>--------------------</td>
<td>--------------</td>
</tr>
<tr>
<td>Peginterferon alfa-2b (PegIntron, Sylatron)</td>
<td>Restricted</td>
<td>None</td>
<td>Up to 12 months</td>
</tr>
<tr>
<td>Peginterferon beta-1a (Plegridy)</td>
<td>Restricted</td>
<td>None</td>
<td>Up to 12 months</td>
</tr>
<tr>
<td>Sarilumab (Kevzara)</td>
<td>Restricted</td>
<td>2/28 Days</td>
<td>Up to 12 months</td>
</tr>
<tr>
<td>Secukinumab (Cosentyx)</td>
<td>Restricted</td>
<td>Varies</td>
<td>Up to 12 months</td>
</tr>
<tr>
<td>Somatropin (Genotropin, Humatrope, Norditropin, Nutropin AQ Omnитrove, Saizen, Serostim, Zomacton, Zorbtive)</td>
<td>Restricted</td>
<td>None</td>
<td>Up to 12 months</td>
</tr>
<tr>
<td>Tocilizumab (Actemra) injection</td>
<td>Restricted</td>
<td>2/28 Days</td>
<td>Up to 12 months</td>
</tr>
<tr>
<td>Ustekinumab (Stelara)</td>
<td>Restricted</td>
<td>Varies</td>
<td>Up to 12 months</td>
</tr>
</tbody>
</table>

**CRITERIA FOR COVERAGE:**
- Requests for coverage on the medical benefit will be assessed for Medical Necessity

**CRITERIA FOR QUANTITY EXCEPTIONS:**
- Requests for quantity exceptions will be reviewed for medical necessity based on the diagnosis, relevant drug and antibody levels, concurrent medications, and published clinical evidence to support the requested regimen
Sildenafil (Viagra Equivalent)
Quantity Limit Exception Criteria

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Drug Status</th>
<th>Quantity Limit/30 Days*</th>
<th>Approval Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sildenafil (Viagra equiv.)</td>
<td>Nonpreferred-Restricted</td>
<td>5</td>
<td>None</td>
</tr>
</tbody>
</table>

*prior to quantity exception

QUANTITY LIMIT EXCEPTION CRITERIA:
- Comorbid conditions which may contribute to erectile dysfunction are medically managed to the maximally tolerated level.
- Prescriber provides objective documentation of the actual number of intercourse events within a 30-day period and dose required to achieve erection and this quantity cannot be met with the commercially available dose forms within the quantity limit. Maximum: 15 doses per 30 days.

*Excluded on some benefits. Please see your plan Prescription Drug Rider or Summary Plan Document for details.
Sebelipase Alfa (Kanuma)
Prior Authorization Criteria

FORMULARY STATUS: Medical Benefit-Restricted

APPROVAL LIMITS: 12 months

QUANTITY LIMITS: None

CRITERIA FOR COVERAGE:
• Covered for persons with Lysosomal Acid Lipase (LAL) deficiency (Wolman disease or Cholesterol ester storage disease (CEST)) confirmed by dried blood spot testing
AND
• Two separate elevated alanine aminotransferase levels ≥ 1.5 times the ULN
AND
• Prescribed by a specialist in Genetics and Metabolism

CONTINUATION OF THERAPY:
Clinical documentation from the previous 12 months demonstrating response to therapy such as improvements from baseline in liver function tests, cholesterol levels, or reductions in hepatic fat.

IMPORTANT INFORMATION:
Sebelipase alfa is a clinic administered medication and is not covered under the prescription drug benefit.
Secnidazole (Solosec)
Prior Authorization Criteria

FORMULARY STATUS: Non-preferred Restricted

APPROVAL LIMITS: One fill

QUANTITY LIMITS: One packet (#1)

CRITERIA FOR COVERAGE:
- Person has diagnosis of bacterial vaginosis AND there was therapeutic failure/intolerance/contraindication to metronidazole (oral or vaginal gel) and clindamycin

CRITERIA FOR DURATION AND QUANTITY EXCEPTIONS:
- Prescriber presents an evidence-based clinical rationale for utilizing a dosing regimen that is not possible within the quantity and duration limits.
**Serotonin Modulating Antidepressants**

**Prior Authorization Criteria**

<table>
<thead>
<tr>
<th>Drug</th>
<th>Formulary Status</th>
<th>Quantity Limits/Day</th>
<th>Approval Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vilazodone (Viibryd)</td>
<td>Nonpreferred-Restricted</td>
<td>1</td>
<td>None</td>
</tr>
<tr>
<td>Vortioxetine (Trintellix)</td>
<td>Nonpreferred-Restricted</td>
<td>1</td>
<td>None</td>
</tr>
</tbody>
</table>

**CRITERIA FOR COVERAGE:**
- Intolerance or failure of an adequate trial of two preferred antidepressants within the Selective Serotonin Reuptake Inhibitor (SSRI) or Serotonin Norepinephrine Reuptake Inhibitor (SNRI) categories

**CRITERIA FOR COVERAGE OF QUANTITY EXCEPTIONS:**
- Failure or intolerance to one dose unit per day for commercially available dosage forms and the prescriber provides an evidence-based clinical rationale for using a dose outside of the quantity limit

**CONTINUATION OF COVERAGE CRITERIA:**
- Persons new to the plan who are being treated for depression or other mood disorders and are established on therapy will have coverage under their drug benefit with documentation of symptom improvement or disease stability.
- Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.

**IMPORTANT INFORMATION:**
Preferred SSRI and SNRIs include citalopram, escitalopram, fluoxetine, paroxetine, sertraline, duloxetine, and venlafaxine
<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Formulary Status</th>
<th>Quantity Limit/day</th>
<th>Approval Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dapagliflozin (Farxiga)</td>
<td>Preferred-Restricted</td>
<td>#1</td>
<td>None</td>
</tr>
<tr>
<td>Dapagliflozin/metformin ER (Xigduo XR)</td>
<td>Preferred-Restricted</td>
<td>#1</td>
<td>None</td>
</tr>
<tr>
<td>Ertugliflozin (Steglatro)</td>
<td>Preferred-Restricted</td>
<td>#1</td>
<td>None</td>
</tr>
<tr>
<td>Ertugliflozin/sitagliptin (Steglujan)</td>
<td>Preferred-Restricted</td>
<td>#1</td>
<td>None</td>
</tr>
<tr>
<td>Ertugliflozin/metformin (Segluromet)</td>
<td>Preferred-Restricted</td>
<td>#2</td>
<td>None</td>
</tr>
</tbody>
</table>

**CRITERIA FOR COVERAGE:**
- Inadequate glucose control (e.g. A1C, fasting plasma glucose, postprandial glucose)
  AND
- An adequate trial (defined as maximum tolerated doses) of metformin for 3 months or until intolerable side effects occur OR metformin is contraindicated
  OR
- Hemoglobin A1C ≥ 9.0 and being started/used in combination with metformin or another treatment for diabetes mellitus if metformin is contraindicated/not tolerated

**CRITERIA FOR COVERAGE OF QUANTITY EXCEPTIONS:**
- Therapeutic failure or intolerance to one dose unit per day for available strengths and the prescriber provides an evidence-based clinical rationale for using a dosing regimen outside of the quantity limits
## Smoking Cessation Therapy
### Prior Authorization Criteria

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Drug Status</th>
<th>Quantity Limits/30 Days</th>
<th>Approval Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nicotine inhaler (Nicotrol)</td>
<td>Nonpreferred-Restricted</td>
<td>None</td>
<td>Smoking cessation therapy is limited to 180 days per 365-day period*</td>
</tr>
<tr>
<td>Nicotine nasal spray (Nicotrol NS)</td>
<td>Nonpreferred-Restricted</td>
<td>40 mL</td>
<td>Smoking cessation therapy is limited to 180 days per 365-day period*</td>
</tr>
</tbody>
</table>

*Approval limits do not apply to the Federal Employee Health Benefit (FEHB)

### CRITERIA FOR COVERAGE:
- Requires a smoking cessation product that is designed to alleviate acute cravings and/or replace behavioral activities of smoking
- Has failed or could not tolerate nicotine gum or nicotine lozenges
- **(Minnesota plans only)** – person with stage four metastatic cancer and smoking cessation therapy is in supportive care related to their cancer diagnosis

### CRITERIA FOR QUANTITY EXCEPTIONS:
- Prescriber must provide an evidence-based clinical rationale for using a dose outside of the quantity limit
Sodium Oxybate (Xyrem®)
Prior Authorization Criteria

**FORMULARY STATUS:** Nonpreferred-Restricted

**APPROVAL LIMITS:** Initial 3 months; thereafter indefinite

**QUANTITY LIMITS:** None

**CRITERIA FOR COVERAGE:**
- For diagnosis of cataplexy in narcolepsy or excessive daytime sleepiness in narcolepsy
  - AND
- Person intolerant of preferred narcolepsy medications
  - OR
- Person with contraindications to preferred narcolepsy medications
  - OR
- Person with therapeutic failure of preferred narcolepsy medications

**CRITERIA FOR COVERAGE OF DURATION EXCEPTIONS:**
- Prescriber presents an evidence-based rationale or clinical reason for an initial duration that exceeds 3 months

**CRITERIA FOR CONTINUATION OF COVERAGE:**
- Clinical documentation of objective symptom improvement after 3 months for consideration of continued coverage.
- Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.

**IMPORTANT INFORMATION:**
In the clinical trials with sodium oxybate, the majority of patients were on concomitant stimulant therapy. Preferred narcolepsy medications include stimulants such as methylphenidate (generics of Concerta, Ritalin LA, Metadate CD, etc.), amphetamines (generics of Adderall XR, Dexedrine, etc.), and modafinil. Please see the formulary on the plan's website for a complete listing of options.
Solifenacin (Vesicare)  
Prior Authorization Criteria

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Drug Status</th>
<th>Quantity Limits/Day</th>
<th>Approval Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Solifenacin (Vesicare equiv.)</td>
<td>Nonpreferred-Restricted</td>
<td>1</td>
<td>None</td>
</tr>
</tbody>
</table>

CRITERIA FOR COVERAGE:
1. Persons < age 65
   • Therapeutic failure with an adequate trial of, or intolerance to, oxybutynin ER, tolterodine ER, and trospium ER
OR
2. Persons ≥ age 65
   • Therapeutic failure with an adequate trial of, or intolerance to, tolterodine ER and trospium ER

CRITERIA FOR QUANTITY EXCEPTIONS:
• Therapeutic failure or intolerance of one tablet per day dosing of the commercially available dose forms and the prescriber provides an evidence-based clinical rationale for using a dose outside of the quantity limits.
Solriamfetol (Sunosi™)
Prior Authorization Criteria

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Formulary Status</th>
<th>Quantity Limits/Day</th>
<th>Approval Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Solriamfetol (Sunosi)</td>
<td>Nonpreferred-Restricted</td>
<td>1</td>
<td>None</td>
</tr>
</tbody>
</table>

CRITERIA FOR COVERAGE:
- Person is aged 18 years of age or older
- Prescribed by a Sleep Specialist, Neurologist or Psychiatrist
AND
1. Diagnosis of narcolepsy or excessive daytime sleepiness in narcolepsy
OR
2. 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
   • Inadequate clinical response after a 3-month trial, intolerable side effects, or contraindication to at least two other therapeutic alternatives (e.g. modafinil, armodafinil, stimulants)

CRITERIA FOR QUANTITY EXCEPTIONS:
- Failure or intolerance to daily dosing of the commercially available dose forms and the prescriber provides an evidence-based clinical rational for using a dose outside of the quantity limits

CONTINUATION OF COVERAGE CRITERIA:
- Persons new to plan who are on established on therapy coverage will have coverage under the drug benefit for the remainder of the treatment course.
- Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated through manufacturer-sponsored free drug program, provider samples, and/or vouchers.
<table>
<thead>
<tr>
<th>Generic</th>
<th>Brand</th>
<th>HICL</th>
<th>GCN</th>
<th>Exception/Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>SOMATROPIN</td>
<td>ZORBIVIE, SEROSTIM, NORDITROPIN</td>
<td>12767, 63405, 25955, 25960, 24145, 24146, 24147, 25816</td>
<td>≠ SAIZEN, ZOMACTON</td>
<td></td>
</tr>
</tbody>
</table>

Somatropin (Growth Hormone)
Prior Authorization Criteria

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Drug Status</th>
<th>Quantity Limits</th>
<th>Approval Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Somatropin (Norditropin)</td>
<td>Preferred-Restricted</td>
<td>None</td>
<td>Pediatric indication: to age 18 Adult indication: 12 months</td>
</tr>
<tr>
<td>Somatropin (Serostim)*</td>
<td>Preferred-Restricted</td>
<td>None</td>
<td>Initial: 1 month Continuation: 12 months</td>
</tr>
<tr>
<td>Somatropin (Zorbivie)*</td>
<td>Nonpreferred-Restricted</td>
<td>None</td>
<td>12 months</td>
</tr>
</tbody>
</table>

*Serostim and Zorbivie are not indicated in the treatment of GH deficiency; see separate criteria below for these products

Criteria for Coverage (Norditropin):
- Included in the Specialty Pharmaceuticals Program. Medications must be obtained from a participating pharmacy. Contact 1-866-894-3784 or 1-877-208-1096 for more details.
  AND
  - Diagnosis by Endocrinologist
  AND
  - For pediatric patients (< 18 years old)
    o ALL of the following must be met:
      ▪ Radiological evidence of open epiphyses with date completed AND
      ▪ Child’s growth velocity is subnormal (age specific growth rate < 25th percentile). Provide growth velocity value AND
      ▪ Child has delayed bone age. Provide date completed and value of bone age AND
      ▪ Child has subnormal GH response to at least one provocative stimulation test (< 10 ng/mL). Provide date and value of test.
      OR
      o Diagnosis of Turner syndrome
  - For adult patients (≥ 18 years old)
    o GH deficiency as a child AND continue to have low IGF-1 or evidence of GH deficiency as noted by stimulation testing
    o Adults with abnormal structure of the hypothalamus or pituitary gland on MRI as a result of injury, tumor, infection or inflammation and evidence of GH deficiency as noted by stimulation testing or when the diagnosis is panhypopituitarism.
Criteria for Coverage (Serostim):
- Diagnosis of AIDS wasting or cachexia and patient continues on antiviral therapy
- Included in the Specialty Pharmaceuticals Program. Medications must be obtained from a participating pharmacy. Contact 1-866-894-3784 or 1-877-208-1096 for more details

Criteria for Coverage (Zorbitive):
- Diagnosis of Short Bowel Syndrome and on specialized diet
- Included in the Specialty Pharmaceuticals Program. Medications must be obtained from a participating pharmacy. Contact 1-866-894-3784 or 1-877-208-1096 for more details.

Criteria for Re-approval/continuation of therapy:
- For pediatric patients
  - New to the plan, established on GH therapy
    - Above pediatric criteria must be met for consideration of continued coverage
  - At 18 years of age
    - Refer to criteria for coverage for treatment of adult patients at the beginning of the document (would be an initial PA for consideration of coverage of an adult patient)
- For adult patients (18 years or older)
  - Prescriber documents treatment benefit (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.
  - Preferred product must be used unless meets criteria for coverage of nonpreferred products
- For adult patients on Serostim
  - Prescriber documents benefit if therapy (i.e. weight gain, increased muscle mass) including dates/values.
- For adult patients on Zorbitive
  - Prescriber documents benefit of therapy (i.e. improvements in necessary intravenous feeding requirements such as calories required or volumes infused) including dates/values
- Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.

Important Information:
Specific Benefit language limits the coverage of somatropin to the following language: Treatment of growth retardation is covered only when: (a) a Prescription Drug Benefit Rider is part of the benefit plan; and (b) production of the growth hormone is inadequate. Coverage is not extended for short stature syndrome or other related growth abnormalities.
### HMG CoA Reductase Inhibitors (Statins)
#### Prior Authorization Criteria

<table>
<thead>
<tr>
<th>Product</th>
<th>Formulary Status</th>
<th>Quantity Limit/Day</th>
<th>Approval Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluvastatin</td>
<td>Nonpreferred-Restricted</td>
<td>#1</td>
<td>None</td>
</tr>
<tr>
<td>Fluvastatin XR</td>
<td>Nonpreferred-Restricted</td>
<td>#1</td>
<td>None</td>
</tr>
<tr>
<td>Simvastatin suspension</td>
<td>Nonpreferred-Restricted</td>
<td>NA</td>
<td>None</td>
</tr>
</tbody>
</table>

**CRITERIA FOR COVERAGE of nonpreferred-restricted statins (not including simvastatin suspension):**
- Intolerance to all generic preferred statins (atorvastatin, lovastatin, pravastatin, rosuvastatin and simvastatin)

**CRITERIA FOR COVERAGE of simvastatin suspension:**
- Intolerance to all preferred statins (atorvastatin, lovastatin, pravastatin, rosuvastatin and simvastatin,) AND compounded simvastatin

**CRITERIA FOR COVERAGE OF QUANTITY EXCEPTIONS:**
- Therapeutic failure or intolerance to one dose unit per day for available strengths and the prescriber provides an evidence-based clinical rationale for use of a dose outside of the quantity limit
Stiripentol (Diacomit)
Prior Authorization Criteria

FORMULARY STATUS:
Stiripentol - Nonpreferred – Restricted

APPROVAL LIMITS:
None

QUANTITY LIMITS:
Stiripentol - 500mg - Six capsules or powder packets/day
250mg - Twelve capsules or powder packets/day

CRITERIA FOR COVERAGE:
• Prescribed by or in consultation with Neurology
• Individual ≥ 2 years old with diagnosis of Dravet Syndrome
• Used in combination with clobazam and valproate

CRITERIA FOR COVERAGE OF QUANTITY EXCEPTIONS:
• The prescriber provides an evidence-based rationale for using a dose outside of the quantity limit.

IMPORTANT INFORMATION
Stiripentol has not been studied as monotherapy and supporting literature should be submitted if requested as monotherapy request.
Restricted Phosphate Binders
Prior Authorization Criteria

FORMULARY STATUS:
Sucroferric Oxyhydroxide (Velphoro) - Nonpreferred-Restricted

APPROVAL LIMITS:
None

QUANTITY LIMITS:
None

CRITERIA FOR COVERAGE:
• Diagnosis of chronic kidney disease (CKD) requiring dialysis
AND
• Failure after an adequate trial of, or intolerable side effects from, BOTH a sevelamer product (Renagel, Renvela) and lanthanum (Fosrenol)
<table>
<thead>
<tr>
<th>Generic Name</th>
<th>Brand Name</th>
<th>HICL</th>
<th>GCN</th>
<th>Exception/Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>SUVOREXANT</td>
<td>BELSOMRA</td>
<td>41333</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Suvorexant (Belsomra)**  
**Prior Authorization Criteria**

**FORMULARY STATUS:**  
Nonpreferred-Restricted

**APPROVAL LIMITS:**  
Indefinite

**QUANTITY LIMITS:**  
One tablet per day dosing (#30)

**CRITERIA FOR COVERAGE:**  
- Person needs the medication for sleep  
**AND**  
- Two preferred alternatives have failed, were not tolerated or are contraindicated.

**CRITERIA FOR COVERAGE OF QUANTITY EXCEPTIONS:**  
- Therapeutic failure or intolerance to one dose unit per day for available strengths OR  
- Clinical rationale for prescribed dosing regimen provided & regimen not possible within the quantity limits

**IMPORTANT INFORMATION:**  
Preferred alternatives include drugs such as zolpidem IR, zaleplon, temazepam, eszopiclone, trazodone, and mirtazapine.
<table>
<thead>
<tr>
<th>Generic</th>
<th>Brand</th>
<th>HICL</th>
<th>GCN</th>
<th>Exception/Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>TACROLIMUS</td>
<td>ASTAGRAF XL</td>
<td></td>
<td>98662, 98663, 98664</td>
<td></td>
</tr>
<tr>
<td>TACROLIMUS</td>
<td>ENVARSUS XR</td>
<td></td>
<td>39120, 39123, 39124</td>
<td></td>
</tr>
<tr>
<td>TACROLIMUS GRANULES</td>
<td>PROGRAF</td>
<td></td>
<td>28251, 28249</td>
<td></td>
</tr>
</tbody>
</table>

### Restricted Tacrolimus Formulations

**Prior Authorization Criteria**

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Drug Status</th>
<th>Quantity Limits</th>
<th>Approval Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tacrolimus granule packets (Prograf)</td>
<td>Preferred-Restricted</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Tacrolimus ER (Astagraf XL, Envarsus XR)</td>
<td>Nonpreferred-Restricted</td>
<td>None</td>
<td>None</td>
</tr>
</tbody>
</table>

**CRITERIA FOR COVERAGE (granule packets):**
- Person with swallowing impairment or other medical condition that prevents use of solid dose forms
- An adequate trial of an alternative (e.g. sirolimus or cyclosporine) failed, was not tolerated, is contraindicated, or the provider supplies an evidence-based rationale for why the alternatives would not be medically appropriate for the person’s condition

**CRITERIA FOR COVERAGE (extended-release formulations):**
- Person with documented inability to achieve goal trough drug levels (documentation of levels and results required) with an adequate trial of immediate release tacrolimus despite appropriate dose adjustment AND teaching/adherence interventions from a pharmacist and other health care providers.
Tadalafil (Cialis equivalent)
Prior Authorization Criteria

**FORMULARY STATUS:** Nonpreferred-Restricted

**APPROVAL LIMITS:** None

**QUANTITY LIMITS:** One tablet per day (#30)

**CRITERIA FOR COVERAGE:**
- Diagnosis of benign prostatic hyperplasia (BPH)
  AND
- Person has had a therapeutic failure/intolerance to at least one agent in BOTH of the following drug classes:
  - Alpha blocker (ex. doxazosin, terazosin, tamsulosin, alfuzosin, silodosin)
  - 5 alpha-reductase inhibitor; if has enlarged prostate (ex. finasteride, dutasteride)

**CRITERIA FOR COVERAGE OF QUANTITY EXCEPTIONS:**
- Therapeutic failure or intolerance to one dose unit per day for available strengths and the prescriber provides an evidence-based clinical rationale for using a dose outside of the quantity limits

**IMPORTANT NOTE:** Medications used to treat erectile dysfunction are specifically excluded from coverage on the pharmacy benefit. Tadalafil is not covered as part of the pharmacy benefit for status post prostatectomy.
Tafamidis (Vyndaqel, Vyndamax) Prior Authorization Criteria

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Drug Status</th>
<th>Quantity Limit/Day</th>
<th>Approval Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tafamidis meglumine (Vyndaqel)</td>
<td>Nonpreferred-Restricted</td>
<td>4</td>
<td>12 months</td>
</tr>
<tr>
<td>Tafamidis (Vyndamax)</td>
<td>Nonpreferred-Restricted</td>
<td>1</td>
<td>12 months</td>
</tr>
</tbody>
</table>

CRITERIA FOR COVERAGE:
- Prescribed by or in consultation with cardiology, transthyretin amyloidosis (ATTR) specialist, or medical geneticist
- 18 years or older
- Diagnosis of cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis (ATTR-CM)
- New York Heart Association (NYHA) functional class I, II, or III heart failure
- No previous history of heart transplantation or estimated glomerular filtration rate less than 25mL per minute per 1.73m² of body-surface area

CRITERIA FOR COVERAGE OF QUANTITY EXCEPTIONS:
- The prescriber provides an evidence-based rationale for using a dose outside of the quantity limit.

CONTINUATION CRITERIA (renewal):
- Initial criteria met
- Clinical documentation from the previous 12 months indicating a response to therapy.
- Individual has not progressed to NYHA Class IV heart failure.

CONTINUATION CRITERIA (new to plan):
- For members new to the plan, the prescriber must provide clinical documentation from the previous 12 months of the person’s response to therapy and meets initial criteria.
- Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.
Tasimelteon (Hetlioz)
Prior Authorization Criteria

FORMULARY STATUS: Nonpreferred-Restricted

APPROVAL LIMITS: None

QUANTITY LIMITS: One tablet per day (#30)

CRITERIA FOR COVERAGE:
- Completely blind persons with non-24-hour sleep-wake disorder diagnosed by a Sleep Specialist AND
- Inadequate response, or intolerable side effects, after a 3-month trial of ramelteon (Rozerem)

CRITERIA FOR COVERAGE OF QUANTITY EXCEPTIONS:
- Therapeutic failure or intolerance to one dose unit per day for available strengths and prescriber provides an evidence based clinical rationale for use of a dose outside of the quantity limit.
### Teduglutide (Gattex)

**Prior Authorization Criteria**

**FORMULARY STATUS:**  Nonpreferred-Restricted

**APPROVAL LIMITS:**  6 months, indefinite thereafter

**QUANTITY LIMITS:**  None

**CRITERIA FOR COVERAGE:**
- Diagnosis of Short Bowel Syndrome (defined as less than 200 centimeters of small intestine)
  **AND**
- Person dependent on parenteral nutrition
  **AND**
- Prescribed by a Gastroenterologist

**CONTINUATION OF COVERAGE CRITERIA (6 months):**
- Prescriber provides clinical documentation from the previous six months demonstrating a $\geq 20\%$ reduction in parenteral support requirement
<table>
<thead>
<tr>
<th>Generic</th>
<th>Brand</th>
<th>HICL</th>
<th>GCN</th>
<th>Exception/Other</th>
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</thead>
<tbody>
<tr>
<td>TELOTRISTAT</td>
<td>XERMEO</td>
<td>44132</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Telotristat (Xermelo)**  
**Prior Authorization Criteria**

**FORMULARY STATUS:** Nonpreferred-Restricted  
**APPROVAL LIMITS:** Indefinite  
**QUANTITY LIMITS:** Three tablets per day (#90)

**CRITERIA FOR COVERAGE:**  
• Person has a diagnosis of diarrhea secondary to carcinoid syndrome  
  **AND**  
• Is age 18 years or older  
  **AND**  
• Symptomatic (≥4 bowel movements per day) despite 3 months of treatment with a somatostatin analog such as octreotide, lanreotide, or pasireotide.  
  **AND**  
• Used in combination with a somatostatin analog
Tenofovir alafenamide (Vemlidy)
Prior Authorization Criteria

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Drug Status</th>
<th>Quantity Limit/Day</th>
<th>Approval Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tenofovir alafenamide</td>
<td>Nonpreferred-Restricted</td>
<td>1</td>
<td>None</td>
</tr>
<tr>
<td>(Vemlidy)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

CRITERIA FOR COVERAGE:
• Covered for persons with chronic hepatitis B who have failed entecavir (exception: documented lamivudine resistance)
• Developed an intolerance to tenofovir disoproxil fumarate

OR
• (Minnesota plans only): person with stage four metastatic cancer and the requested drug is being used to treat cancer-related hepatitis B infection

CONTINUATION OF COVERAGE CRITERIA:
• Persons new to coverage 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.
• Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.
Generic | Brand | HICL | GCN | Exception/Other
---|---|---|---|---
TESTOSTERONE | ANDROGEL | | 23141, 47851, 47852, 33452, 33453, 29905 | ≠ TESTIM, VOGELXO
TESTOSTERONE | STRIANT | | 19948 |
TESTOSTERONE | ANDRODERM | | 30796, 29171 |
TESTOSTERONE | AXIRON | | 29647 |
CYPIONATE | DEPO-TESTOSTERONE | | 10191, 10194 | Not 38586, which is excluded

**Testosterone Prior Authorization Criteria**

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Drug Status</th>
<th>Quantity Limits/Day</th>
<th>Approval Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Testosterone 1% (generics)</td>
<td>Preferred-Restricted</td>
<td>25 mg packet: 1</td>
<td>None</td>
</tr>
<tr>
<td>Testosterone 1.6% (generics)</td>
<td>Preferred-Restricted</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Testosterone injection (generics)</td>
<td>RX: Preferred-Restricted Medical Benefit-Restricted</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Testosterone buccal (Striant)</td>
<td>Nonpreferred-Restricted</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Testosterone patches (Androderm)</td>
<td>Nonpreferred-Restricted</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Testosterone underarm solution (generics)</td>
<td>Nonpreferred-Restricted</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Testosterone extended-release injection (Aveed)</td>
<td>Medical Benefit-Restricted</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Testosterone implant (Testopel)</td>
<td>Medical Benefit-Restricted</td>
<td>None</td>
<td>None</td>
</tr>
</tbody>
</table>

**CRITERIA FOR COVERAGE (preferred testosterone products):**
- Diagnosis of gender dysphoria or transsexualism, unless excluded by certificate OR
- Diagnosis of primary or secondary hypogonadism or mixed hypogonadism with clinically appropriate laboratory data demonstrating androgen deficiency* AND are symptomatic with symptoms other than sexual dysfunction
- Not for decreased libido or other sexual dysfunction

**CRITERIA FOR COVERAGE (nonpreferred testosterone products):**
- Preferred product criteria met AND documented intolerance to at least one preferred testosterone option (with the same route of administration if available)

**CRITERIA FOR COVERAGE (extended release injections and implants):**

Revised: 02/12/2020
Page 258
• Preferred product criteria met AND documented intolerance to a preferred topical testosterone AND a preferred non-extended release injection.

CRITERIA FOR CONTINUATION OF THERAPY:
• Persons new to coverage who are established on therapy with a preferred testosterone product 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.
• For non-preferred formulations: above continuation of therapy criteria met AND documented intolerance to at least one preferred testosterone formulation.
• Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage but whose therapy was initiated using a manufacturer-sponsored 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 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.
Parathyroid Hormone Analogues for Osteoporosis
Prior Authorization Criteria

**FORMULARY STATUS:**
Abaloparatide (Tymlos) - Preferred-Restricted
Teriparatide (Forteo) - Nonpreferred-Restricted

**APPROVAL LIMITS:**
24 months

**QUANTITY LIMITS:**
None

**CRITERIA FOR COVERAGE:**
1. Medication must be self-administered or administered by family member/friend
AND
2. Total duration of treatment with parathyroid hormone analogs (both abaloparatide and teriparatide) will not exceed 24 months over a person's lifetime
AND
3. If for teriparatide, person did not tolerate therapy with abaloparatide
AND one of the following diagnosis and the associated criteria:

A. 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 AT LEAST ONE of the following:
   a. Has had a low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm
   b. Is at high risk for fracture (advanced age, frailty, glucocorticoids, very low T scores, (less than or equal to -3.5), or increased fall risk)
   c. Has failed therapy with at least one bisphosphonate (i.e. low-trauma fractures or decrease in BMD while on alendronate 70 mg per week)

OR

B. 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 10 year probability of a hip fracture of at least 3% or major osteoporosis-related fracture of at least 20% AND AT LEAST ONE of the following:
   d. Has had a low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm
   e. Is at high risk for fracture (advanced age, frailty, glucocorticoids, very low T scores, (less than or equal to -3.5) or increased fall risk)
   f. Has failed therapy with at least one bisphosphonate (i.e. low-trauma fractures or decrease in BMD while on alendronate 70 mg per week)

OR

C. Diagnosis of osteoporosis related to prolonged steroid use AND has failed therapy with at least one bisphosphonate (i.e. low-trauma fractures or decrease in BMD while on alendronate 70 mg per week)
CRITERIA FOR COVERAGE OF DURATION EXCEPTIONS:

- Prescriber provides an evidence-based clinical rationale for using an extended duration beyond 24 months

CONTINUATION OF COVERAGE CRITERIA:

- Persons new to the plan 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 pharmacies and participation in medication management programs may apply.
- Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.
- Persons new to the plan 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.
- Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.
FORMULARY STATUS:
Eltrombopag olamine (Promacta)  Nonpreferred-Restricted
Romiplostim (Nplate)    Medical Benefit Restricted

APPROVAL LIMITS: up to 12 months

QUANTITY LIMITS:
Eltrombopag: One tablet daily

PRIOR AUTHORIZATION CRITERIA:
- Prescribed by Hematology
- Eltrombopag is included as part of the Specialty Pharmaceuticals Program and must be obtained from a participating pharmacy.

AND
1. Persons with chronic ITP
   a. Platelet count < 50,000/mcL
   b. Failure of 2 prior ITP therapies (e.g. corticosteroids, rituximab, azathioprine, danzol, or splenectomy)

OR (for eltrombopag only)
2. Persons with chronic hepatitis C undergoing treatment with pegylated interferon/ribavirin*
   a. Platelet count < 75,000/mcL
   b. Must meet pegylated interferon criteria (see separate document)

OR (for eltrombopag only)
3. Treatment of severe aplastic anemia in persons who have failed to respond to immunosuppressive therapy

*Patients receiving therapy while being treated for chronic hepatitis C will only have coverage while actively undergoing antiviral treatment.

CONTINUATION OF COVERAGE CRITERIA:
- Persons new to the plan 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.
- Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.

CRITERIA FOR COVERAGE OF DURATION EXCEPTIONS:
- Prescriber presents rational, clinical reason for utilizing an extended duration
**Tobramycin for Inhalation**  
**Prior Authorization Criteria**

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Drug Status</th>
<th>Quantity Limits/Day</th>
<th>Approval Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tobramycin inhalation neb 5 mL (TOBI equiv.)</td>
<td>Preferred-Restricted</td>
<td>2 doses</td>
<td>None</td>
</tr>
</tbody>
</table>

**CRITERIA FOR COVERAGE:**
- Person with diagnosis of cystic fibrosis
- Documentation demonstrating a current culture positive for, or history of recurrent *Pseudomonas aeruginosa* lung infections
- For inhalation only

**CRITERIA FOR COVERAGE OF QUANTITY EXCEPTIONS:**
- Therapeutic failure or intolerance to a dosing regimen within the quantity limit and the prescriber provides an evidence-based clinical rationale for use of a regimen outside of the quantity limit

**CONTINUATION OF COVERAGE CRITERIA:**
- Persons new to the plan 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.
- Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.

** IMPORTANT INFORMATION:**
For chronic suppressive therapy, dosing regimen is 28 days on, 28 days off repeating.
### Prior Authorization Criteria

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Drug Status</th>
<th>Quantity Limit/Day</th>
<th>Approval Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tolvaptan (Jynarque)</td>
<td>Nonpreferred-Restricted</td>
<td>2</td>
<td>12 months</td>
</tr>
</tbody>
</table>

**CRITERIA FOR COVERAGE:**
- Age ≥ 18 years
- Diagnosis of autosomal dominant polycystic kidney disease (ADPKD)
- Prescribed by, or on the recommendation of, a Nephrologist or other expert in kidney disease
- Estimated glomerular filtration rate ≥ 25 ml/min

**CRITERIA FOR COVERAGE OF QUANTITY EXCEPTIONS:**
- Once daily dosing of the commercially available dose forms/blister pack did not control symptoms or caused side effects and the prescriber provides an evidence-based rationale for using a dose outside of the quantity limit.

**CRITERIA FOR CONTINUATION OF COVERAGE**
- Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.
- Clinical documentation that current laboratory values for liver and kidneys remain within acceptable treatment ranges.

**FOR BADGERCARE COVERAGE:**
- Medication must be billed to ForwardHealth under the pharmacy benefit. Refer to the ForwardHealth policy “Select High Cost, Orphan, and Accelerated Approval Drugs” for additional information.

**IMPORTANT INFORMATION:**
- Because of significant drug interactions, doses may need to be adjusted with changes in other medication regimens. The authorization may need to be updated when/if dose changes occur.
### Tolvaptan (Samsca)

**Prior Authorization Criteria**

**FORMULARY STATUS:** Nonpreferred-Restricted

**APPROVAL LIMITS:** None

**QUANTITY LIMITS:**
- 15 mg tablets - One tablet per day (#30)
- 30 mg tablets - Two tablets per day (#60)

**CRITERIA FOR COVERAGE:**
- Diagnosis of hypervolemic or euvolemic hyponatremia that is severe (< 125 mEq/L) or symptomatic less severe hyponatremia (NaCL 125 mEq/L – 134 mEq/L)
- Current hospitalization for hyponatremia
- Symptoms or low serum sodium levels persist despite supervised fluid restriction and appropriate sodium supplementation

**CRITERIA FOR COVERAGE OF QUANTITY EXCEPTIONS:**
- Use of the commercial dose forms within the quantity limits did not control symptoms or caused side effects and the prescriber provides an evidence-based rationale for using a dose outside of the quantity limit
<table>
<thead>
<tr>
<th>Generic</th>
<th>Brand</th>
<th>HICL</th>
<th>GCN</th>
<th>Exception/Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>BETAMETHASONE</td>
<td>SERNIVO</td>
<td></td>
<td>40655</td>
<td></td>
</tr>
<tr>
<td>DESOXMETASONE</td>
<td>TOPICORT</td>
<td></td>
<td>34545, 6120,</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>31180, 11403</td>
<td></td>
</tr>
<tr>
<td>FLUOCINONIDE</td>
<td>VANOS</td>
<td></td>
<td>24306</td>
<td></td>
</tr>
<tr>
<td>HALOBETASOL</td>
<td>ULTRAVATE, LEXETTE, BRYHALI</td>
<td></td>
<td>40975, 45667, 45728</td>
<td>GPID ≠ 31211, 31251</td>
</tr>
<tr>
<td>AMCINONIDE</td>
<td></td>
<td></td>
<td>31490, 31500</td>
<td>GPID ≠ 31560</td>
</tr>
<tr>
<td>DIFLORASONE</td>
<td>PSORCON, APEXICON-E</td>
<td></td>
<td>31470, 67730,</td>
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<td></td>
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<tr>
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<td>HALOG OINTMENT, GENERIC CREAM</td>
<td></td>
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<td>CLOCORTOLONE</td>
<td>CLODERM</td>
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<tr>
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<tr>
<td>DESONIDE</td>
<td>DESOWEN, VERDESO</td>
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<td>31430, 31425,</td>
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<td>97254, 48971</td>
<td>GPID ≠ 99498, 99804, 99846</td>
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<tr>
<td>HYDROCORTISONE 2% LOTION</td>
<td>ALA-SCALP, SCALACORT</td>
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<td>26603</td>
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<tr>
<td>HYDROCORTISONE 2.5% SOLUTION</td>
<td>TEXACORT</td>
<td></td>
<td>9181</td>
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<tr>
<td>HYDROCORTISONE PROBUTATE</td>
<td>PANDEL</td>
<td></td>
<td>50550</td>
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<tr>
<td>CLOBETASOL PROPIONATE</td>
<td>IMPOYZ</td>
<td></td>
<td>44155</td>
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</tr>
</tbody>
</table>

**Non-Preferred Topical Steroids**

**Prior Authorization Criteria**

**FORMULARY STATUS:** Nonpreferred-Restricted

**APPROVAL LIMITS:** Indefinite
QUANTITY LIMITS: None

CRITERIA FOR COVERAGE:
• Inadequate response to or intolerance of a preferred topical steroid in comparable potency and/or formulation
<table>
<thead>
<tr>
<th>Generic</th>
<th>Brand</th>
<th>HICL</th>
<th>GCN</th>
<th>Exception/Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>NARATRIPTAN HCL</td>
<td>AMERGE</td>
<td>13266</td>
<td>50744, 50740, 5701, 5702, 26666, 26667, 5700, 50742, 24708, 50741</td>
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</tr>
<tr>
<td>SUMATRIPTAN SUCCINATE</td>
<td>IMITREX</td>
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<tr>
<td>RIZATRIPTAN BENZOATE</td>
<td>MAXALT (MLT)</td>
<td>18535</td>
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<tr>
<td>ZOLMITORPITAN</td>
<td>ZOMIG (ZMT)</td>
<td>12958</td>
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<tr>
<td>ALMOTRIPTAN MALATE</td>
<td>AXERT</td>
<td>21894</td>
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<tr>
<td>ELETRIPTAN HBR</td>
<td>RELPAX</td>
<td>23093</td>
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<td>FROVATRIPTAN SUCCINATE</td>
<td>FROVA</td>
<td>22988</td>
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</tbody>
</table>

**Triptan Quantity Exception Criteria**

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Formulary Status</th>
<th>Quantity Limit (baseline)</th>
<th>Approval Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Naratriptan</td>
<td>Preferred</td>
<td>18 doses</td>
<td>None</td>
</tr>
<tr>
<td>Rizatriptan</td>
<td>Preferred</td>
<td>18 doses</td>
<td>None</td>
</tr>
<tr>
<td>Sumatriptan (generic tablet, injection)</td>
<td>Preferred</td>
<td>18 doses</td>
<td>None</td>
</tr>
<tr>
<td>Sumatriptan (generic nasal)</td>
<td>Preferred</td>
<td>12 doses</td>
<td>None</td>
</tr>
<tr>
<td>Almotriptan</td>
<td>Nonpreferred</td>
<td>12 doses</td>
<td>None</td>
</tr>
<tr>
<td>Eletriptan</td>
<td>Nonpreferred</td>
<td>12 doses</td>
<td>None</td>
</tr>
<tr>
<td>Frovatriptan</td>
<td>Nonpreferred</td>
<td>12 doses</td>
<td>None</td>
</tr>
</tbody>
</table>

**CRITERIA FOR COVERAGE OF QUANTITY EXCEPTIONS:**

- Diagnosis of cluster headache, menstrual migraine, transitional headache, or chronic migraine **AND**
- Currently taking migraine headache prophylaxis **OR**
- Intolerant of and/or failure of a minimum of two different classes of migraine prophylaxis medications, (e.g. a tricyclic antidepressant and a β-blocker).
Uridine triacetate (Xuriden)
Prior Authorization Criteria

FORMULARY STATUS: Nonpreferred-Restricted

APPROVAL LIMITS: 3 months, then indefinite

QUANTITY LIMITS: 4 packets (8 gm) per day (# 120)

CRITERIA FOR COVERAGE:
• Covered for persons with hereditary orotic aciduria

CONTINUATION CRITERIA FOR COVERAGE (3 months)
Prescriber provides clinical documentation of improvement from baseline in both hematologic parameters (white blood cell count, red blood cell counts, etc) and urine orotic acid levels.

CRITERIA FOR A QUANTITY EXCEPTIONS:
• Prescriber provides an evidence-based clinical rationale for using a dose outside of the quantity limit
**Restricted Vaccine Criteria**

**Criteria for Coverage**

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Drug Status</th>
<th>Quantity Limits/Series</th>
<th>Approval Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>human papillomavirus vaccine (Gardasil 9)</td>
<td>Restricted: Age Medical Benefit</td>
<td>2-3</td>
<td>One series</td>
</tr>
<tr>
<td>Zoster vaccine recombinant (Shingrix)</td>
<td>Restricted: Age Medical Benefit</td>
<td>2</td>
<td>One series</td>
</tr>
<tr>
<td>Zoster vaccine live (Zostavax)</td>
<td>Restricted: Age Medical Benefit</td>
<td>1</td>
<td>One series</td>
</tr>
</tbody>
</table>

**CRITERIA FOR COVERAGE:**

Publication of Advisory Committee on Immunization Practices (ACIP) recommendations within the CDC Morbidity and Mortality Weekly Report (MMWR)

1. Human papillomavirus vaccine:
   - Person is between the ages of 9 and 45 years at series initiation or as updated by ACIP
   - **FOR BADERCARE COVERAGE:** Please see Forward Health for criteria or diagnosis restrictions

2. Zoster vaccine live (Zostavax):
   - Person is age 60 years or older or as updated by ACIP
   - OR
   - Person with primary Medicare coverage and secondary State/Local (ETF) coverage: age 60 years or older AND less than 65 years of age (if 65 years or older, coverage for vaccine provided by Navitus)
   - OR
   - Person has managed Badgercare coverage
   - OR
   - Person with coverage with Swedish American Health System: age 55 years or older

3. Zoster vaccine recombinant, adjuvanted (Shingrix):
   - Person is age 50 years or older or as updated by ACIP
   - OR
   - Person with primary Medicare coverage and secondary State/Local (ETF) coverage: age 50 years or older AND less than 65 years of age (if 65 years or older, coverage for vaccine provided by Navitus)

**IMPORTANT INFORMATION:**

For zoster vaccines (Zostavax and Shingrix):

- Those with a Medicare Select plan have coverage for the administration of the vaccine, but the vaccine itself is **NOT** covered. The vaccine is covered by the person’s Medicare part D (drug) benefit.
- Those with Medicare primary and State/Local (ETF) secondary: it is assumed all Medicare primary members have Medicare Part D. If a member has Medicare as primary but did not elect Part D then neither Quartz nor Navitus will pay for the immunization, and the member will have to pay out of pocket for them. If Quartz is primary, coverage of Zostavax will be provided by Quartz for persons 60 and older and coverage of Shingrix will be provided by Quartz for persons 50 and older.
Valbenazine (Ingrezza)
Prior Authorization Criteria

**FORMULARY STATUS:** Nonpreferred-Restricted

**APPROVAL LIMITS:** None

**QUANTITY LIMITS:** One capsule per day (#30)

**CRITERIA FOR COVERAGE:**
- The drug is prescribed by a Neurologist, Psychiatrist, or other expert in the treatment of tardive dyskinesia
- Person has a diagnosis of tardive dyskinesia
- Symptoms persist despite discontinuation of the offending dopamine receptor blocking drug
- The prescriber provides an 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
- An adequate trial of clonazepam did not control symptoms or caused significant side effects
- An adequate trial of trihexyphenidyl did not control symptoms, caused significant side effects, or is contraindicated

**CRITERIA FOR QUANTITY EXCEPTIONS:**
- Lack of symptom control or side effects with once daily dosing of the commercially available dose forms and the prescriber provides an evidence-based clinical rationale for using a dose outside of the quantity limit
<table>
<thead>
<tr>
<th>Generic</th>
<th>Brand</th>
<th>HICL</th>
<th>GCN</th>
<th>Exception/Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>CALCIFEDIOL</td>
<td>RAYALDEE</td>
<td>00998</td>
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</tr>
<tr>
<td>DOXERCALCIFEROL</td>
<td>HECTOROL</td>
<td>20533</td>
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<tr>
<td>PARICALCITOL</td>
<td>ZEMPLAR</td>
<td>18250</td>
<td></td>
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<tr>
<td>CALCITRIOL</td>
<td>VECTICAL</td>
<td>00999</td>
<td></td>
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</tr>
<tr>
<td></td>
<td>ROCALTROL</td>
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</tr>
</tbody>
</table>

**Vitamin D analogs**

**FORMULARY STATUS:**
- Calcitriol: Preferred
- Calcifediol (Rayaldee): Nonpreferred Restricted
- Doxercalciferol: Nonpreferred Restricted
- Paricalcitol: Nonpreferred Restricted

**APPROVAL LIMITS:**
- None

**QUANTITY LIMITS:**
- None

**CRITERIA FOR COVERAGE:**
- Person unable to achieve parathyroid hormone goals with calcitriol despite appropriate dose adjustments of calcitriol.
**Vorapaxar (Zontivity)**

**Prior Authorization Criteria**

**FORMULARY STATUS:** Nonpreferred-Restricted

**APPROVAL LIMITS:** None

**QUANTITY LIMITS:** One tablet per day (#30)

**CRITERIA FOR COVERAGE:**
- Persons diagnosed with peripheral arterial disease (PAD) or with a history or myocardial infarction (MI).
  
*AND*
- The prescribing Cardiologist determines they are at increased risk of thrombotic cardiovascular events despite being on combination therapy with BOTH aspirin and P2Y12 therapy (clopidogrel, ticagrelor, or prasugrel).

**CONTINUATION OF COVERAGE CRITERIA:**
- Persons new to the plan 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.
- Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.

**CRITERIA FOR COVERAGE OF QUANTITY EXCEPTIONS:**
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