Quartz®
Find your spark.

Quartz Medicare Advantage (HMO)

Part B Medication (Medical Benefit) Prior Authorization Criteria

QuartzBenefits.com/MedicareAdvantage

These medication prior authorization criteria apply to Quartz Medicare Advantage members for medications when given by a health care provider (medical benefit) and billed under Medicare Part B.

GH00432_C (0822) Y0092_22 209_C

Afamelanotide (Scenesse)
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits	Approval Limits
Afamelanotide (Scenesse)	Medical benefit-Restricted	None- implant every 2 months	12 months

CRITERIA FOR COVERAGE:

- Diagnosis of Erythropoietic Protoporphyria (EPP), **AND**
- Age ≥18 years, **AND**
- History of phototoxic reactions due to free light exposure

CRITERIA FOR CONTINUATION OF THERAPY: (for renewal or new members. This criteria will be applied if the requested medication has been used in the previous 365 days)

- Initial criteria met and clinical documentation from the previous 12 months demonstrating objective improvements in pain control related to light exposure
- 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.

Agalsidase Beta (Fabrazyme)
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits	Approval Limits
Agalsidase Beta (Fabrazyme)	Medical Benefit-Restricted	1mg/kg IV infusion every two weeks	None

CRITERIA FOR COVERAGE:

- Diagnosis of Fabry's Disease, **AND**
- Prescribed by or in consultation of an expert in the treatment of Fabry's Disease, **AND**
- Will not be used in combination with migalastat.

Created: 1/1/2021
Effective: 1/1/2021

Alpha$_1$ Proteinase Inhibitor (Aralast NP, Glassia, Prolastin-C, Zemaira) Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits	Approval Limits
Alpha-1 Proteinase inhibitor (Aralast NP, Glassia, Prolastin-C, Zemaira)	Medical Benefit-Restricted	None	None

CRITERIA FOR COVERAGE:

- Alpha-1 proteinase deficient (<11 mcmol/L), **AND**
- Evidence of COPD (FEV_1 25% to 80% predicted) attributable to emphysema, **AND**
- Maximized COPD therapy based on GOLD guidelines

Created: 1/1/2021
Effective: 1/1/2021

Benralizumab (Fasenra)
Prior Authorization Criteria

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits
J0517	Benralizumab (Fasenra)	Medical Benefit- Restricted	None	None

CRITERIA FOR COVERAGE of eosinophilic asthma:

- Diagnosis of eosinophilic asthma with a documented blood eosinophil count of ≥ 150 cells/mm^3 (other causes of eosinophilia such as hyper eosinophilic syndromes, neoplastic disease, or parasitic disease must be ruled out), **AND**
- Prescribed by or in consultation with an asthma specialist (Allergist, Immunologist, Pulmonologist), **AND**
- Age ≥12 years, **AND**
- Trial and failure, contraindication, or intolerance to self-injection of benralizumab (Fasenra) or inability to self-administer benralizumab (Fasenra)*, **AND**
- One of the following:
  A. Symptoms are not well controlled or poorly controlled (Table 1) despite a 3-month trial of medium to high-dose inhaled corticosteroids in combination with a long-acting bronchodilator, long-acting muscarinic antagonist or leukotriene modifier*, **OR**
  B. Patient has intolerance to medium to high dose inhaled corticosteroids in combination with a long-acting bronchodilator or leukotriene modifier. Exceptions based on adverse effects from medium to high dose ICS or comorbid conditions increasing long-term risks of adverse effects from medium to high dose ICS or oral corticosteroids include:
    - Cataracts in patients over 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)

Note: Il-5 inhibitor drugs in combination with omalizumab will be considered on a case-by-case basis if each individual agent with combination medium to high dose ICS/LABA did not control symptoms.

* Requirement applies to members who have Part D coverage with Quartz.

CRITERIA FOR CONTINUATION OF THERAPY: (New members. This criteria will be applied if the requested medication has been used in the previous 365 days)

- 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 emergency/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
- 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
- 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 1. Outcome Measure values for uncontrolled asthma

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

Bezlotoxumab (Zinplava)
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits	Approval Limits
Bezlotoxumab (Zinplava)	Medical Benefit-Restricted	None	One dose

CRITERIA FOR COVERAGE:

- Confirmed diagnosis of current C diff infection and a positive stool test for toxigenic C difficile from a recent stool sample, **AND**
- Prescribed by or in consultation with an Infectious Disease specialist, **AND**
- Age ≥18 years, **AND**
- Has recurrent/refractory C diff infection, **AND**
- Must be currently on standard of care antibiotics for C diff (vancomycin, fidaxomicin)*

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.

* Requirement applies to members who have Part D coverage with Quartz.

Biologic Therapy for Rheumatology, Dermatology, and Gastroenterology Prior Authorization Criteria

HCPCS Code	Drug Name	Drug Status	Quantity Limit	Approval Limits
J0129	Abatacept IV (Orencia)	Medical Benefit Restricted	N/A	None
J0717	Certolizumab (Cimzia)	Medical Benefit Restricted	N/A	None
J1602	Golimumab IV (Simponi Aria)	Medical Benefit Restricted	N/A	None
J2323	Natalizumab IV (Tysabri)	Medical Benefit Restricted	N/A	None
J2327	Risankizumab IV (Skyrizi)	Medical Benefit Restricted	3 Infusions for loading dose only	3 months
J3245	Tildrakizumab (Ilumya)	Medical Benefit Restricted	N/A	None
J3262	Tocilizumab IV (Actemra)	Medical Benefit Restricted	N/A	None
J3358	Ustekinumab IV (Stelara)	Medical Benefit Restricted	1 Infusion	3 months
J3380	Vedolizumab IV (Entyvio)	Medical Benefit Restricted	N/A	None

Rituximab and infliximab biosimilars are Medical Benefit therapeutic options. They do not require prior authorization. Applicable Local Coverage Determination (LCD) requirements apply.

GENERAL CRITERIA FOR COVERAGE:

1. **Ankylosing spondylitis (AS):**
   - Prescribed by or in consultation with a rheumatologist, **AND**
   - Biologic therapies are not used in combination with other biologic DMARD therapies, **AND**
   - Condition is not controlled by a 2-month trial of scheduled prescription doses of two different NSAIDs (i.e., naproxen, nabumetone, diclofenac, etc.)*

2. **Crohn's disease (CD) (moderate to severely active):**
   - Prescribed by or in consultation with a gastroenterologist, **AND**
   - Biologic therapies are not used in combination with other biologic DMARD therapies, **AND**
   - One of the following:
     A. Individual is high risk (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)), **OR**
     B. Individual is low risk **AND** one of the following:
        - Trial & failure, contraindication, intolerance, or inadequate disease control with 2 conventional therapies (i.e., azathioprine, balsalazide, corticosteroids, mesalamine, mercaptopurine, methotrexate (MTX), sulfasalazine)*, **OR**
        - Demonstrated steroid dependence, **OR**
        - Conventional therapy clinically inappropriate based on location of disease

3. **Giant cell arteritis (GCA):**
   - Prescribed by or in consultation with a rheumatologist, **AND**
   - Biologic therapies are not used in combination with other biologic DMARD therapies, **AND**
   - Condition has relapsed despite use of corticosteroids or methotrexate* **OR** Contraindication to methotrexate and steroids* **OR** Inability to taper corticosteroids*

4. **Graft Versus Host Disease, acute (aGVHD)-**
   - Prescribed by or in consultation with a hematologist
   - Medical documentation showing patient at high risk of development of aGVHD due to use of matched unrelated donor or 1-allele mismatch donor

5. **Non-Radiographic Axial Spondyloarthropathy, Active (NR-SpA) –**
   - Prescribed by or in consultation with a rheumatologist, **AND**
   - Biologic therapies are not used in combination with other biologic DMARD therapies, **AND**
   - Condition not controlled by a 2-month trial of scheduled prescription doses of two different NSAIDS (such as naproxen, nabumetone, diclofenac, etc)

6. **Plaque psoriasis (PsO) (moderate to severe):**
   - Prescribed by or in consultation with a dermatologist, **AND**
   - Biologic therapies are not used in combination with other biologic DMARD therapies, **AND**
   - One of the following:
     A. Diagnosis of severe PsO with significant functional disability, BSA involvement at least 30% **AND** clinical failure/intolerance/contraindication to at least one prior therapy (i.e., topical therapy, oral therapy, or phototherapy), **OR**
     B. Diagnosis of moderate to severe PsO with BSA involvement at least 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
     AND
     Clinical failure of prior therapy or contraindication to:
     - Topical: (e.g., topical corticosteroids, calcipotriene, retinoids)* **AND**
     - Oral Therapy: (e.g., methotrexate (MTX), [does NOT include apremilast])*, **AND**
     - Phototherapy: (e.g., broad band UVB, narrow band UVB, PUVA, excimer)
       - 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
       - If home-based phototherapy- provision of data log recording use and dose adjustments as need for tolerability

     - *Details including phototherapy, medication, dose, potency, frequency, duration must be provided for each therapy*. 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. Contraindications to phototherapy can include skin type (Fitzpatrick type 1), history of skin cancer, and based on location (i.e. face, genitals, scalp).

7. **Psoriatic arthritis (PsA) (moderate to severely active):**
   - Prescribed by or in consultation with a rheumatologist or dermatologist, **AND**
   - Biologic therapies are not used in combination with other biologic DMARD therapies, **AND**
   - Trial & failure, contraindication or intolerance to a 3-month trial of methotrexate*

8. **Rheumatoid arthritis (RA):**
   - Prescribed by or in consultation with a rheumatologist, **AND**
   - Biologic therapies are not used in combination with other biologic DMARD therapies, **AND**
   - One of the following:
     - Early RA (less than 6 months disease duration) with one of the following features of poor prognosis
       - Functional limitations (based on HAQ or similar tool), or
       - Extraarticular disease (e.g., presence of rheumatoid nodules, RA vasculitis or Felty's syndrome (rheumatoid arthritis with splenomegaly and neutropenia)), or
       - Positive rheumatoid factor or anti-cyclic citrullinated peptide antibodies (anti-CCP antibodies), or
       - bony erosions on X-ray.

       OR
     - Moderate to severely active established RA (over 6 months disease duration), reactive arthritis, or polyarticular juvenile idiopathic arthritis (PJIA), **AND** one of the following:
       - Documented failure with a 3-month trial of methotrexate at therapeutic doses*, **OR**
       - If contraindication or intolerance to MTX therapy, must fail 3 month trial with an alternate disease modifying anti-rheumatic drug (DMARD) such as hydroxychloroquine, sulfasalazine, leflunomide or minocycline*

9. **Systemic juvenile idiopathic arthritis (sJIA) or adult-onset Still's disease:**
   - Prescribed by or in consultation with a rheumatologist, **AND**
   - Biologic therapies are not used in combination with other biologic DMARD therapies, **AND**
   - Trial & failure, contraindication or intolerance to a 3-month trial of corticosteroids and methotrexate*

10. **Systemic sclerosis-associated interstitial lung disease (SSc-ILD):**
    - Prescribed by or in consultation with a rheumatologist or pulmonologist, **AND**
    - Biologic therapies are not used in combination with other biologic DMARD therapies, **AND**
    - Medical documentation showing decline in pulmonary function despite use of at least one standard treatment (i.e., mycophenolate, cyclophosphamide or azathioprine) **OR** Contraindication to use of standard agents.

11. **Ulcerative colitis (UC) (moderate to severely active):**
    - Prescribed by or in consultation with a gastroenterologist, **AND**
    - Biologic therapies are not used in combination with other biologic DMARD therapies, **AND**
    - Individual is high risk (see DEFINITIONS below), **AND**
    - Previous failure of a short course of corticosteroids (at least 2-4 weeks) unless contraindicated*

DRUG-SPECIFIC CRITERIA FOR COVERAGE:

Abatacept (Orencia) Infusion

- Diagnosis of RA, PJIA, or PsA, **AND** general criteria met for covered diagnosis, **AND**
- Trial & failure, contraindication, or intolerance to TWO preferred drugs* (see Table A below), **AND** failure of or inability to self-administer subcutaneous abatacept injection.*, **OR**
- Age >2 years old for prevention of aGVHD when used in combination with standard immunosuppressive medications in patients at high risk of development of GVHD (e.g., matched unrelated donor or 1-allele mismatch donor).

Note: Sub-Q abatacept is not covered under Part B as it is considered a self-administered drug. Requirement applies to members who have Part D coverage with Quartz.

Certolizumab (Cimzia)

- One of the following:
  - Diagnosis of CD:
    - General criteria met for covered diagnosis, **AND**
    - Trial & failure, contraindication or intolerance to adalimumab (Humira) and risankizumab (Skyrizi)*, **AND**
    - Failure of or inability to self-administer subcutaneous certolizumab injection.*
  - Diagnosis of RA, AS, NR-SpA, PsO, or PsA:
    - General criteria met for covered diagnosis, **AND**
    - Trial & failure, contraindication or intolerance to TWO preferred drugs* (see Table A below), **AND**
    - Failure of or inability to self-administer subcutaneous certolizumab injection.*

Golimumab Infusion (Simponi Aria)

- Diagnosis of AS, PsA, RA, or PJIA **AND** general criteria met for covered diagnosis, **AND**
- Trial & failure, contraindication, or intolerance to TWO preferred drugs* (see Table A below) **AND** TWO nonpreferred drugs* (see Table B below).

Natalizumab Infusion (Tysabri)

- One of the following:
  - Diagnosis of CD:
    - General criteria met for covered diagnosis, **AND**
    - Trial & failure, contraindication or intolerance to adalimumab (Humira)* and infliximab biosimilar, **AND**
    - Trial & failure, contraindication or intolerance to risankizumab (Skyrizi)* and one other agent (vedolizumab (Entyvio) or ustekinumab (Stelara)*), **AND**
    - Must be used as monotherapy (without immunomodulatory therapy), **AND**
    - Must have ongoing monitoring for JC virus negativity (Consider PML risk if used in patient with JC virus positivity)

  OR

  - Diagnosis of a relapsing form of multiple sclerosis:
    - Prescribed or in consultation with a neurologist or other expert in the treatment of multiple sclerosis, **AND**
    - Trial and failure, contraindication or intolerance to fingolimod (Gilenya) or dimethyl fumarate (Tecfidera)* (If intolerance or contraindication to one product, the alternative oral therapy must be trialed)

Note: For use of natalizumab (Tysabri), patient and prescriber must be enrolled in the manufacturer TOUCH Risk-Management Program. Refer to touchprogram.com for details.

Risankizumab (Skyrizi)

- Diagnosis of CD, **AND** general criteria met for covered diagnosis

  Note: infusion is only indicated for 3 doses (week 0, week 4, and week 8)

Tildrakizumab (Ilumya)

- Diagnosis of PsO, **AND** general criteria met for covered diagnosis, **AND**
- Trial & failure, contraindication or intolerance to THREE preferred drugs* (see Table A below)

Tocilizumab Infusion (Actemra)

- General criteria met for covered diagnosis, **AND**
- Meets all of the following:
  - Diagnosis of RA or PJIA, **AND**
  - Trial & failure, contraindication, or intolerance to TWO preferred drugs* (see Table A below), **AND**
  - Failure of or inability to self-administer subcutaneous tocilizumab*

  OR
- Diagnosis of GCA, sJIA, or SSc-ILD **AND** failure of adequate trial of self-injectable subcutaneous tocilizumab or inability to self-administer injection*.

  OR
- Therapy for chimeric antigen receptor (CAR) T-cell to treat T-cell–induced severe or life-threatening cytokine release syndrome (CRS) in a patient 2 years of age or older.

Ustekinumab (Stelara) Infusion

- One of the following:
  - Diagnosis of CD:
    - General criteria met for covered diagnosis, **AND**
    - Trial & failure, contraindication or intolerance to adalimumab (Humira) and risankizumab (Skyrizi)*.
  - Diagnosis of UC:
    - General criteria met for covered diagnosis, **AND**
    - Trial & failure, contraindication or intolerance to TWO preferred drugs* (see Table A below) OR ONE preferred drug and infliximab.

  Note: infusion is only indicated for inflammatory bowel disease for one dose.
  Sub-Q ustekinumab is not covered under Part B as it is considered a self-administered drug.

Vedolizumab (Entyvio)

- General criteria met for covered diagnosis, **AND**
- One of the following:
  - Diagnosis of UC, or
  - Diagnosis of CD **AND** trial & failure, contraindication or intolerance to anti-TNF therapy

* Requirement applies to members who have Part D coverage with Quartz.

Table A

Preferred Drug	Benefit	Indications
Adalimumab (Humira)	Part D	RA, PsA, PsO, AS, CD, UC, PJIA
Etanercept (Enbrel)	Part D	RA, PsA, PsO, AS, PJIA
Risankizumab (Skyrizi)	Part D	PsA, PsO, CD
Secukinumab (Cosentyx)	Part D	PsA, PsO, AS, NR-SpA
Tofacitinib (Xeljanz, Xeljanz XR)	Part D	RA, PsA, UC, AS, PJIA
Upadacitinib (Rinvoq)	Part D	RA, PsA, UC, AS

Table B

Nonpreferred Drug	Benefit	Indications
Abatacept (Orencia)	Part D	RA, PsA, PJIA
Apremilast (Otezla)	Part D	PsA, PsO
Certolizumab (Cimzia)	Part D	RA, PsA, PsO, AS, CD
Guselkumab (Tremfya)	Part D	PsA, PsO
Tocilizumab (Actemra)	Part D	RA, PJIA
Ustekinumab (Stelara)	Part D	PsA, PsO, CD

CRITERIA FOR CONTINUATION OF THERAPY: (New members. This criteria will be applied if the requested medication has been used in the previous 365 days)

- Clinical documentation from the previous 12 months that describes response as stable disease or improvement seen on therapy. Examples of improvement include:
    - For rheumatologic conditions: laboratory assessment (i.e., C-reactive protein, ESR, anemia improvement), symptomatic improvements (i.e., fatigue, function, HAQ score if available, joint pain).
    - For dermatologic conditions: improvement in PASI, PGA, TBSA affected, etc.
    - For gastrointestinal indications: 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**.**
- For patients continuing therapy on doses greater than standard baseline regimens should be assessed for remission and appropriateness for dose de-escalation. Factors to consider when evaluating for dose de-escalation include clinical remission, off corticosteroids, those with high supra-therapeutic trough levels, etc.

IMPORTANT INFORMATION:

Contraindications to therapy are based on package label and patient-specific contraindications must be documented in the request. Review the package label for black box warnings and absolute contraindications as needed.

DEFINITIONS OF TERMS:

Inadequate Disease Control:

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

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)

Induction and Maintenance Therapy with Conventional Agents:

- Conventional therapy with immunomodulator therapy such as azathioprine, balsalazide, corticosteroids, mesalamine, mercaptopurine, methotrexate, sulfasalazine as clinically appropriate based on location of disease. 5-ASA agents are less effective for ileal or ileal-colonic disease.
- Contraindications to conventional agents will be considered as noted in criteria: some specific examples include: MTX-concerns related to teratogenicity in females and effects on sperm in males, thiopurines (azathioprine, mercaptopurine) EBV negative status and lymphoma risk.

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 - ≥6 bloody stools per day, fever, tachycardia, anemia or elevated ESR or CRP

Primary non-response to anti-TNF therapy: PNR- change drug class

- 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 or class of drug.

Secondary loss of response to anti-TNF therapy: SLR-change individual drug

- 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 to different drug. When therapeutic drug levels and no detectable anti-drug antibodies exist, recommend change in drug class (mechanistic failure) When sub-therapeutic drug levels exist and high-anti-drug antibody titers exist, it would be reasonable to use same class of drug (i.e different anti-TNF).

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:

1. Feuerstein JD, Isaacs KL, Schneider Y, Siddique SM, Falck-Ytter Y, et al. AGA clinical practice guidelines on the management of moderate to severe ulcerative colitis. Gastroenterology 2020; 158:1450-1461.
2. Feuerstein JD, Ho EY, Shmidt E, Singh H, Falck-Ytter Y, Sultan S, et al. AGA clinical practice guidelines on the medical management of moderate to severe luminal and perianal fistulizing Crohn's disease. Gastroenterology, 2021; 160: 2496-2508.
3. Singh S, Proctor D, Scott FI, Falck-Ytter Y, Feuerstein. AGA technical review of moderate to severe luminal and perianal fistulizing Crohn's disease. Gastroenterology. 2021: 160: 2512-2556.
4. Feuerstein JD, Nguyen GC, Kupfer SS, Falck-Ytter Y, Singh S. AGA guideline on therapeutic drug monitoring in inflammatory bowel disease. Gastroenterol 2017; 153:827-834.
5. Menter A, Gelfand JM, Connor C, Armstrong AW, Cordoro KM, Davis D, et al. Joint American academy of dermatology-national psoriasis foundation guideline of care for the management of psoriasis with systemic nonbiologic therapies. J Am Acad Dermatol 2020; 82: 1445-1486.
6. Menter A, Strober BE, Kaplan DH, Kivelevitch D, Prater EF, Stoff B, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol 2019; 80:1029-1072.
7. Elmets CA, Korman NJ, Prater EF, Wong EB, Rupani RN, Kivelevitch D, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures. J Am Acad Dermatol 2021; 84: 432-470.

Burosumab (Crysvita)
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits	Approval Limits
Burosumab (Crysvita)	Medical Benefit-Restricted	None	12 months

CRITERIA FOR COVERAGE:

- Diagnosis of X-linked hypophosphatemia, and all of the following:
    - Age ≥1 year, **AND**
    - Low serum phosphate levels (age appropriate) despite at least six months of maximally tolerated oral phosphate* and vitamin D supplementation, **AND**
    - Clinical documentation demonstrating evidence of rickets (children) or osteomalacia-associated bone disease (adults)

  OR

- Diagnosis of tumor-induced osteomalacia
    - Low serum phosphate levels (age appropriate) despite at least six months of maximally tolerated octreotide and oral phosphate plus vitamin D supplementation
    - Clinical documentation demonstrating evidence of rickets (children) or osteomalacia-associated bone disease (adults)

CONTINUATION OF COVERAGE CRITERIA: (12-month renewal or new members. This criteria will be applied if the requested medication has been used in the previous 365 days)

- Initial criteria met, **AND**
- 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**.**

* Requirement applies to members who have Part D coverage with Quartz.

Canakinumab (Ilaris)
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits	Approval Limits
Canakinumab (Ilaris)	Medical Benefit-Restricted	None	None

CRITERIA FOR COVERAGE:

- 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**
  - Trial and Failure, contraindication or intolerance to anakinra (Kineret)*†

OR

- Diagnosis of systemic juvenile idiopathic arthritis (SJIA) or adult-onset Still's disease:
  - Trial and failure, contraindication or intolerance to prior therapies (i.e., glucocorticoids or NSAIDs)*†, **AND**
  - Trial and Failure, contraindication 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.

* Requirement applies only to members who have Part D coverage.

† Does not apply to members who have used the requested medication within the previous 12 months.

Caplacizumab (Cablivi)
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limit/Day	Approval Limits
Caplacizumab (Cablivi)	Medical Benefit-Restricted	One vial (11mg)	Duration of outpatient plasma exchange

CRITERIA FOR COVERAGE:

- Diagnosis of severe acquired thrombotic thrombocytopenic purpura (aTTP) with at least one ADAMST13 level below 20 percent, **AND**
- Age ≥18 years, **AND**
- Person has been receiving plasma exchange (PEX) and caplacizumab as an inpatient, **AND**
- PEX will be continued on an outpatient basis

CRITERIA FOR DURATION EXCEPTIONS:

- Requests for coverage on the medical benefit after the person has completed PEX will be reviewed for Medical Necessity

Cerliponase Alfa (Brineura)
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits	Approval Limits
Cerliponase Alfa (Brineura)	Medical Benefit-Restricted	None	12 months

CRITERIA FOR COVERAGE:

- Diagnosis of late infantile neuronal ceroid lipofuscinosis type 2 (CLN2), **AND**
- Age ≥3 years, **AND**
- Combined score of at least 3 on the CLN2 Clinical Rating Score

CONTINUATION OF COVERAGE CRITERIA: (12-month renewal or new members. This criteria will be applied if the requested medication has been used in the previous 365 days)

- Diagnosis of late infantile neuronal ceroid lipofuscinosis type 2 (CLN2), **AND**
- Age ≥3 years, **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.

Complement Inhibitors
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits	Approval Limits
Ravulizumab (Ultomiris)	Medical Benefit-Restricted	None	12 months
Pegcetacoplan (Empaveli)	Medical Benefit-Restricted	None	12 months

INITIAL CRITERIA FOR COVERAGE:

Paroxysmal nocturnal hemoglobinuria (PNH)
- Confirmed diagnosis of PNH by flow cytometry, **AND**
- Prescribed by or in consultation with a Hematologist or Oncologist, **AND**
- Low hemoglobin (≤9 mg/dL with symptoms of anemia), elevated lactate dehydrogenase level (LDH ≥1.5 X ULN) and/or number of transfusions in last year, **AND**
- Documentation of the clinical manifestations of disease (e.g. major vascular event, transfusion dependence, renal insufficiency, disabling fatigue and/or other end organ manifestations), **AND**
- Documentation of receipt of Advisory Committee on Immunization Practices (ACIP) recommended vaccinations at least two weeks prior to therapy initiation as outlined in drug REMS program, AND
- Age at least 18 years (pegcetacoplan only)
- Drug is not being used in combination with another complement inhibitor*

* Combination of pegcetacoplan may be considered for circumstances where all three individual complement inhibitors failed to adequately control anemia (eculizumab or ravulizumab) or there are signs of ongoing hemolysis (pegcetacoplan).

Atypical hemolytic uremic syndrome (aHUS) (ravulizumab)
- Diagnosis of atypical hemolytic uremic syndrome (aHUS), **AND**
- Prescribed by or in consultation with a Hematologist, Nephrologist or Oncologist, **AND**
- Document a 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, **AND**
- Documentation of receipt of Advisory Committee on Immunization Practices (ACIP) recommended vaccinations at least two weeks prior to therapy initiation as outlined in drug REMS program, AND

Mysathenia gravis (MGFA) (ravulizumab):
- Diagnosis of Myasthenia Gravis Foundation of America (MGFA) class II to IV disease
- Prescribed by or in consultation with a Neurologist.
- Positive serologic test for anti-acetylcholine receptor (AChR) antibodies.
- Baseline Myasthenia Gravis Activities of Daily Living (MG-ADL) total score ≥ 6 AND documentation of baseline levels of one or more of the following: 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.

- Trial and failure†, intolerance, or contraindication of two immunosuppressive therapies (e.g. prednisone, azathioprine, cyclophosphamide, cyclosporine, mycophenolate, tacrolimus, rituximab)* for at least 6 months
    - If intolerance occurs, a third immunosuppressive agent must be tried*
- Trial and failure†, intolerance, or contraindication to at least one of the following treatments:
    - At least 3 months of therapeutic doses of IVIG, OR
    - PLEX given at least four times per year without symptom control.
- Documentation of receipt of ACIP recommended vaccinations at least two weeks prior to therapy as outlined in drug REMS program.

†Failure to myasthenia 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.

* Requirement applies to members who have Part D coverage with Quartz.

CRITERIA FOR CONTINUATION OF COVERAGE (12-month renewal or new members)
- Initiation criteria met, **AND**
- Documentation of improvement or clinical stability, such as:
    - For PNH- improvement in hemoglobin, lactate dehydrogenase, haptoglobin level and/or number of transfusions in the last year.
    - For aHUS: improvement in lactate dehydrogenase, serum creatinine/eGFR, platelet count and/or plasma exchange (PLEX) infusion requirements).
    - For MGFA class II to IV disease: Documentation that the MG ADL score improved at least a 3-points (reduction) from baseline. Clinical documentation from the past 12 months of improvement or clinical stability (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).
- 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:

Myasthenia Gravis Foundation of America (MGFA) Abbreviated Classifications:

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

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

Created: 1/1/2021
Effective: 7/1/2022

Corticotropin Gel
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits	Approval Limits
Corticotropin Gel (Acthar HP, Cortrophin)	Medical Benefit-Restricted	None	3 months with partial fill (max 15 days/prescription)

CRITERIA FOR COVERAGE:

- Diagnosis of infantile spasm with electroencephalogram pattern consistent with hypsarrhythmia, **AND**
- Prescribed by or in consultation with a Neurologist, **AND**
- Age < 2 years

OR

- FDA approved diagnosis with evidence-based supporting literature/guideline, **AND**
- Failure, contraindication or intolerance to an adequate trial of preferred formulary medications appropriate for the condition*

* Requirement applies to members who have Part D coverage with Quartz.

CRITERIA FOR CONTINUATION OF THERAPY: (applies to renewal or new members. This criteria will be applied if the requested medication has been used in the previous 365 days)

- Provider provides an evidence-based rationale for continued use and submits clinical documentation of evidence of patient response to therapy from the previous 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.

Crizanlizumab-tmca (Adakveo)
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limit/Month	Approval Limits
Crizanlizumab-tmca (Adakveo)	Medical Benefit-Restricted	One monthly infusion after loading dose	12 months

CRITERIA FOR COVERAGE:

- Diagnosis of sickle cell disease with >1 vasoocclusive crisis within the past 12 months, despite being on a stable hydroxyurea* dose for at least 90 days (unless contraindication or intolerance), **AND**
- Prescribed by or in consultation with a hematologist or other provider with experience in the treatment of sickle cell disease, **AND**
- Person is 16 years or older, **AND**
- Not used in combination with voxelotor (Oxbryta)

CONTINUATION OF COVERAGE CRITERIA: (for renewal or new members. This criteria will be applied if the requested medication has been used in the previous 365 days)

- Clinical documentation from the previous 12 months demonstrating a response to therapy such as one of the following:
    - Decreased frequency of sickle cell hospitalizations or urgent care visits,
    - Decreased frequency of vasoocclusive crisis,
    - Reduction in use of pain medications,
    - Improved quality of life (e.g. decreased pain, fewer missed day of work/school, increase in activities, etc.)
- 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).

* Requirement applies to members who have Part D coverage with Quartz.

Disease Modifying Therapies for Multiple Sclerosis
Prior Authorization Criteria

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits
J2323	Natalizumab (Tysabri)	Medical benefit-Restricted	None	None
J0202	Alemtuzumab (Lemtrada)	Medical benefit-Restricted	None	None
J2350	Ocrelizumab (Ocrevus)	Medical benefit-Restricted	None	None
C9399 J3590	Ublituximab (Briumvi)	Medical benefit-Restricted	None	None

CRITERIA FOR COVERAGE (Ocrelizumab):

- Prescribed or in consultation with a Neurologist or other expert in the treatment of multiple sclerosis, **AND**
- One of the following:
  1. Diagnosis of a relapsing form of multiple sclerosis
     - Clinical documentation of a diagnosis of relapsing multiple sclerosis
     - Trial and failure, contraindication or intolerance to fingolimod (Gilenya) or dimethyl fumarate (Tecfidera)* (If intolerance or contraindication to one product, the alternative oral therapy must be trialed)

     OR
  2. Diagnosis of a progressive form of multiple sclerosis
     - Clinical documentation of a diagnosis of a progressive form of multiple sclerosis (secondary progressive, primary progressive, or relapsing progressive)

CRITERIA FOR COVERAGE (Alemtuzumab, Natalizumab, Ublituximab):

- Diagnosis of a relapsing form of multiple sclerosis, **AND**
- Prescribed or in consultation with a Neurologist or other expert in the treatment of multiple sclerosis, **AND**
- Trial and failure, contraindication or intolerance to fingolimod (Gilenya) or dimethyl fumarate (Tecfidera)* (If intolerance or contraindication to one product, the alternative oral therapy must be trialed)

CRITERIA FOR CONTINUATION OF THERAPY: (new members. This criteria will be applied if the requested medication has been used in the previous 365 days)

- 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).
- 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:

Natalizumab can only be administered as monotherapy. Proper wash-out periods of prior therapy are required. For criteria for coverage of natalizumab for patients with a diagnosis of inflammatory bowel disease please see the Biologic Therapies for Gastroenterology criteria.

DEFINITIONS:

- Treatment failure: clinical documentation of an acute relapse (requiring treatment) or imaging demonstrating new or enlarged lesions despite use of the prerequisite DMT
- Clinically significant side effect: side effect that prevents adherent use of the prerequisite DMT despite interventions from the pharmacist and other health care providers to minimize or mitigate the side effect.

Edaravone (Radicava)
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limit/Day	Approval Limits
Edaravone (Radicava)	Medical Benefit-Restricted	None	12 months

CRITERIA FOR COVERAGE:

- Diagnosis of definite or probable ALS based on El Escorial revised Airlie House diagnostic criteria, **AND**
- Prescribed by or in consultation with a Neurologist or other specialist in treating amyotrophic lateral sclerosis (ALS), **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
- Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage or whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers**.**

* Requirement applies to members who have Part D coverage with Quartz.

Efgartigimod alfa (Vyvgart)
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits	Approval Limits
Efgartigimod alfa (Vyvgart)	Medical Benefit Restricted	None	12 months

CRITERIA FOR COVERAGE:

- Diagnosis of Myasthenia Gravis Foundation of America (MGFA) class II to IV disease, **AND**
- Prescribed by or in consultation with a Neurologist, **AND**
- Positive serologic test for anti-acetylcholine receptor (AChR) antibodies, **AND**
- Baseline IgG level of at least 6g/L, **AND**
- Initial Myasthenia Gravis Activities of Daily Living (MG-ADL) total score ≥ 5, **AND**
- Medical notes showing at least one of the following baseline measures: Quantitative Myasthenia Gravis (QMG) score within the past 12 months, number of immune globulin (IVIG) infusions, plasma exchange (PLEX) treatments or exacerbations/hospitalizations from within the past 12 months, **AND**
- Notes indicating that efgartigimod will not be used in combination with ongoing immune globulin (IVIG) infusions (does not apply to use of IVIG for treatment of acute myasthenic crisis), **AND**
- Trial and failure, intolerance, or contraindication of a six month trial of two immunosuppressive therapies (e.g. prednisone, azathioprine, cyclophosphamide, cyclosporine, mycophenolate, tacrolimus, rituximab)*, (If intolerance occurs, a third immunosuppressive agent must be tried)
    - If intolerance to one or more immunosuppressives, then prior 3 months trial and failure of IVIG OR prior use of and failure of at least 4 PLEX treatments.

CONTINUATION/RENEWAL OF COVERAGE CRITERIA: (for renewal or new members. This criteria will be applied if the requested medication has been used in the previous 365 days)

- Initial criteria for coverage met
- Prescriber provides clinical notes from the previous 12 months documenting response to therapy compared to baseline, such as improvement in symptoms/function (i.e. decrease in MG-ADL and/or QMG score), fewer disease exacerbations (i.e. decrease in hospitalizations, PLEX treatments, steroid dosing 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

* Requirement applies to members who have Part D coverage with Quartz.

Elapegademase (Revcovi)
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits	Approval Limits
Elapegademase (Revcovi)	Medical Benefit-Restricted	None	12 months

CRITERIA FOR COVERAGE:

- Diagnosis of adenosine deaminase severe combined immune deficiency (ADA-SCID), **AND**
- Prescribed by or in consultation with an expert in the treatment of immune deficiencies

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
- 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.

Emapalumab (Gamifant)
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits	Approval Limits
Emapalumab (Gamifant)	Medical Benefit-Restricted	None	3 months

CRITERIA FOR COVERAGE:

- Prescribed by or in consultation with 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:
  - 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 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 $<100 \times 10^9$/L
  - Neutrophils $<1.0 \times 10^9$/L
  - Elevated liver enzymes (i.e. 3-times the ULN for AST, ALT, GGT or LDH)
  - Fasting triglycerides ≥3 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 renewal or new members. This criteria will be applied if the requested medication has been used in the previous 365 days)

- 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.

* Requirement applies to members who have Part D coverage with Quartz.

Created: 1/1/2021
Effective: 1/1/2021

Emicizumab (Hemlibra)
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits	Approval Limits
Emicizumab (Hemlibra)	Medical Benefit-Restricted	None	None

CRITERIA FOR 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
- Failure of self-injection (subcutaneous) or inability to self-administer emicizumab injection.*

* Requirement applies only to members who have Part D coverage.

CRITERIA FOR CONTINUATION OF THERAPY: (for new members. This criteria will be applied if the requested medication has been used in the previous 365 days)

- 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
- 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.

Esketamine Nasal Inhalation (Spravato)
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits	Approval Limits
Esketamine Nasal Inhalation (Spravato)	Medical Benefit-Restricted	None	None

CRITERIA FOR COVERAGE

- Diagnosis of one of the following:
  - Major depressive disorder (MDD) with acute suicidal ideation or behavior (thoughts of self-harm with awareness they may die as a result and intends to act on those thoughts), OR
  - Treatment-resistant depression and at least one of the following:
    - 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 2 antidepressants*, **OR**
    - Symptoms of depression continue and there is medical documentation to show treatment limiting side effects with 2 antidepressants*
- Medication is prescribed by or in consultation with a psychiatrist, **AND**
- Nasal esketamine will be used in combination with an antidepressant medication*, **AND**
- Age ≥18 years

CRITERIA FOR CONTINUATION OF THERAPY: (New members. This criteria will be applied if the requested medication has been used in the previous 365 days)

- 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

* Requirement applies to members who have Part D coverage with Quartz.

Etranacogene dezaparvovec (Hemgenix)
Prior Authorization Criteria

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits
J1411	Etranacogene dezaparvovec (Hemgenix)	Medical Benefit-Restricted	One infusion per lifetime	1 month

PRIOR AUTHORIZATION CRITERIA:

- Diagnosis of congenital hemophilia B**, AND**
- Prescribed by, or in consultation with, a Hematologist or other specialist in the treatment of hemophilia B**, AND**
- Age ≥ 18**, AND**
- Current use of Factor IX prophylaxis therapy with a history of ≥ 150 previous exposure days of prophylaxis therapy**, AND**
- One of the following is met:
    - Factor IX level less than 1 international unit (IU)/dL, **OR**
    - Factor IX level is between 1 IU/dL and 5 IU/dL with one of the following:
        - Current or historical life-threatening hemorrhage, **OR**
        - Repeated, serious spontaneous bleeding episodes
- Without evidence of any of the following:
    - History of factor IX inhibitor
    - Active inhibitors to factor IX
    - Active hepatitis C virus infection
    - Active hepatitis B virus infection
    - Current use of hepatitis B or C antiviral therapy
    - Uncontrolled HIV infection (e.g., HIV positive with CD4+ counts ≤200/µL)
    - Liver cirrhosis
    - Liver function tests* at least 2 times the upper limit of normal

*Liver function tests include aspartate transaminase (AST), Alanine transaminase (ALT), total bilirubin, and alkaline phosphatase (ALP).

Evinacumab (Evkeeza)
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits	Approval Limits
Evinacumab (Evkeeza)	Medical benefit-Restricted	None	Initial: 12 months Renewal: Indefinite

CRITERIA FOR COVERAGE:

- Diagnosis of homozygous familial hypercholesteremia (HoFH) with either:
  - Clinical diagnosis (LDL-C > 500 mg/dL with xanthomas or family history of both parents with LDL-C levels > 250 mg/dL), OR
  - Genetic verification of HoFH
- Prescribed by, or in consultation with, a Cardiologist or other specialist in the treatment of congenital lipid disorders, **AND**
- LDL-C level > 70 mg/dL, **AND**
- Trial and failure, contraindication, or intolerance to a proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor unless there is genetic verification of receptor negative (null-null mutation) HoFH*

CRITERIA FOR CONTINUATION OF THERAPY: (for renewal or new members. This criteria will be applied if the requested medication has been used in the previous 365 days)

- Clinical documentation of improvement in cholesterol levels from start 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.

* Requirement applies to members who have Part D coverage with Quartz.

Exon Skipping Drugs for Duchenne Muscular Dystrophy
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits	Approval Limits
Casimersen (Amondys 45)	Medical Benefit-Restricted	None	12 months
Eteplirsen (Exondys 51)	Medical Benefit-Restricted	None	12 months
Golodirsen (Vyondys 53)	Medical Benefit-Restricted	None	12 months
Viltolarsen (Viltepso)	Medical Benefit-Restricted	None	12 months

CRITERIA FOR COVERAGE:

- Diagnosis of Duchenne muscular dystrophy (DMD) with clinical documentation of a confirmed mutation of the DMD gene amendable to exon skipping by the requested drug, **AND**
- Prescribed by or in consultation with a Neurologist or other expert in the treatment of pediatric neuromuscular disorders, **AND**
- On guideline recommended steroid therapy, **AND**
- Person has a Forced Vital Capacity (FVC) ≥30% predicted, **AND**
- One of the following:
  - Can ambulate ≥180m in a 6-minute walk test (6MWT), **OR**
  - Brooke upper extremity function rating scale score ≤5

CONTINUATION OF COVERAGE CRITERIA (new to plan/renewal):

- Initial criteria met
- 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**.**

Fosdenopterin (Nulibry)
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits	Approval Limits
Fosdenopterin (Nulibry)	Medical benefit-Restricted	None	12 months

CRITERIA FOR COVERAGE:

- Diagnosis of molybdenum cofactor deficiency (MoCD) Type A, **AND**
- Prescribed by, or in consultation with, a MoCD Type A specialist (e.g. genetic, pediatrics)

CRITERIA FOR CONTINUATION OF THERAPY: (for renewal or new members. This criteria will be applied if the requested medication has been used in the previous 365 days)

- Clinical documentation from an office visit from the previous 12 months showing response to therapy (e.g. continued use, tolerability, doses adjusted for weight, 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.

Galsulfase (Naglazyme)
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits	Approval Limits
Galsulfase (Naglazyme)	Medical Benefit-Restricted	None	12 months

CRITERIA FOR COVERAGE:

- Diagnosis of mucopolysaccharidosis VI (MPS VI) (Maroteaux-Lamy syndrome) to improve walking and stair-climbing capacity

CRITERIA FOR CONTINUATION OF THERAPY: (applies to renewal or new members. This criteria will be applied if the requested medication has been used in the previous 365 days)

- Prescriber provides clinical documentation from the previous 12 months that the person has a diagnosis of mucopolysaccharidosis VI and has had improvement (or stable) in ambulation.
- 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**.**

Givosiran (Givlaari)
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits	Approval Limits
Givosiran sodium (Givlaari)	Medical benefit-Restricted	None	12 months

CRITERIA FOR COVERAGE:

- Diagnosis of acute hepatic porphyria (AHP) (i.e. acute intermittent, variegate, hereditary coproporphyria, or ALA dehydratase deficient) confirmed by appropriate laboratory testing (i.e. urine PBG, total porphyrins) or genetic testing, **AND**
- Prescribed by or in consultation with a hematologist, hepatologist or other provider with experience in the treatment of acute hepatic porphyria, **AND**
- Age ≥18 years, **AND**
- Active disease with at least 2 porphyria attacks requiring healthcare utilization within the past six months (i.e. IV hemin administration, hospitalizations) **OR** currently receiving prophylactic hemin to prevent porphyria attacks, **AND**
- Person has not had a liver transplant, does not have history of pancreatitis, and does not have an active virus infection (ex: hepatitis C, hepatitis B, etc.), **AND**
- Person will not receive concomitant prophylactic hemin treatment

CONTINUATION CRITERIA: (for renewal or new members. This criteria will be applied if the requested medication has been used in the previous 365 days)

- Initial criteria met and clinical documentation from the previous 12 months demonstrating a response to therapy such as:
  - Decreased number of porphyria hospitalizations
  - Significant reduction in hemin treatment days
  - Decrease in total number of porphyria attacks
  - Improvement in symptoms (ex: abdominal pain, nausea, vomiting, seizures, limb weakness, etc.)
- 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).

Glucosidase Alfa Enzyme Therapies
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits	Approval Limits
Alglucosidase alfa (Lumizyme)	Medical Benefit-Restricted	None	None
Avalglucosidase Alfa (Nexviazyme)	Medical Benefit-Restricted	None	None

CRITERIA FOR COVERAGE:

- Diagnosis of Pompe disease

Hereditary Angioedema Medications
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits	Approval Limits
C1 esterase inhibitor (Berinert, Cinryze, Ruconest)	Medical benefit-Restricted	None	None
Ecallantide (Kalbitor)	Medical benefit-Restricted	None	None

GENERAL CRITERIA FOR COVERAGE:

- Diagnosis of Hereditary Angioedema (HAE) with low C4 and low C1 inhibitor level or function, OR normal C1 inhibitor level and family history of HAE and high dose antihistamines ineffective, **AND**
- Prescribed by or in consultation with an Allergist or other provider with experience in the treatment of HAE, **AND**
- Discontinuation of medications that may cause angioedema (e.g. ACE inhibitors, estrogens, ARBs)

FOR TREATMENT OF ACUTE ATTACK (Berinert, Ruconest, ecallantide):

- General criteria met, **AND**
- Requested product will not be used in combination with other approved treatments for acute attacks

FOR LONG-TERM PREVENTION/PROPHYLAXIS OF ATTACKS (Cinryze):

- General criteria met, **AND**
- Requested product will not be used in combination with other approved HAE prevention treatments, **AND**
- Moderate to severe symptoms or a history of ≥2 attacks per month, **AND**
- Failure (no reduction in frequency of attacks or severity of attacks), contraindication or intolerance to Haegarda*, **AND**
- Failure (no reduction in frequency of attacks or severity of attacks), contraindication or intolerance to berotralstat (Orladeyo)*, AND lanadelumab (Takhzyro)*, **OR** age 6-12 years

CRITERIA FOR CONTINUATION: (for new members. This criteria will be applied if the requested medication has been used in the previous 365 days)

- Documentation from the previous 12 months of a clinical response with current 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.

* Requirement applies to members who have Part D coverage with Quartz.

Hereditary transthyretin (hATTR) amyloidosis treatments
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits	Approval Limits
Patisiran (Onpattro)	Medical benefit-Restricted	None	Initial: 12 months Renewal: indefinite
Vutrisiran (Amvuttra)	Medical Benefit-Restricted	None	Initial: 12 months Renewal: indefinite

CRITERIA FOR COVERAGE:

- Diagnosis of neuropathy due to hereditary transthyretin (hATTR) amyloidosis with documentation of TTR gene mutation and biopsy proven amyloid deposits, **AND**
- Prescribed by or in consultation with a Neurologist, Cardiologist, or other expert in hereditary transthyretin-mediated amyloidosis (hATTR), **AND**
- Age ≥18 years, **AND**
- Drug is not being used in combination another TTR-lowering agent (inotersen, patisiran, vutrisiran)
- Drug is not being used in combination with a TTR-stabilizing agent (diflunisal, tafamidis, tafamidis meglumine)

CRITERIA FOR CONTINUATION OF COVERAGE: (new members)

- Initiation criteria met
- The prescriber must provide clinical documentation of the person's initial response to therapy (e.g. clinical manifestation stability/improvement).
- 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: (12-month renewal)

- Clinical documentation from the previous 12 months of response to therapy or documentation of clinical 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.

HIV Pre-exposure Prophylaxis (PrEP) Injection
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits	Approval Limits
Cabotegravir injection (Apretude)	Medical benefit-Restricted	One injection every 2 months	N/A

CRITERIA FOR COVERAGE:

- Person has a high-risk of contracting HIV infection, **AND**
- One of the following:
  - Person has renal disease or has had a decline in renal function due to use of tenofovir disoproxil fumarate oral*, **OR**
  - Person unable to adhere to oral therapy PrEP regimen (tenofovir disoproxil fumarate OR tenofovir alafenamide)*

* Requirement applies to members who have Part D coverage with Quartz.

CRITERIA FOR CONTINUATION OF THERAPY: (for renewal or new members. This criteria will be applied if the requested medication has been used in the previous 365 days)

- Clinical documentation from an office visit in the preceding 12 months showing adherence to PrEP therapy requirements.
- 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.

Created: 5/17/2022
Effective: 7/1/2022

Human Chorionic Gonadotropin (HCG)
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits	Approval Limits
Human Chorionic Gonadotropin	Medical benefit-Restricted	None	None

CRITERIA FOR COVERAGE:

- Diagnosis of hypogonadotropic hypogonadism in a male

Inclisiran (Leqvio)
Prior Authorization Criteria

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits
J1306	Inclisiran (Leqvio)	Medical Benefit Restricted	Initial: 3 doses Renewal: 2 doses	12 months

CRITERIA FOR COVERAGE:

- Diagnosis of one of the following: primary hyperlipidemia (including heterozygous familial hypercholesterolemia (HeFH)), homozygous familial hypercholesterolemia (HoFH), or established cardiovascular disease†, **AND**
- LDL-C greater than or equal to 70 mg/dL, **AND**
- Prescribed by or in consultation with a cardiologist, endocrinologist, or lipidologist, **AND**
- Trial and failure, contraindication, intolerance, or inability to self-administer a formulary self-administered PCSK9 inhibitor (e.g., evolocumab)*, **AND**
- One of the following:
    - Taking a high-intensity statin (i.e., atorvastatin 40-80mg daily, rosuvastatin 20-40mg daily) for a duration of at least 8 weeks and will continue statin therapy, or
    - Cannot tolerate a high-intensity statin and is taking a maximally tolerated dose of any statin for a duration of at least 8 weeks and will continue statin therapy, or
    - Patient is considered to be statin intolerant, or
    - Has a contraindication to statin use (e.g., active liver disease or persistently elevated serum transaminases)

CONTINUATION/RENEWAL OF COVERAGE CRITERIA: (for renewal or new members. This criteria will be applied if the requested medication has been used in the previous 365 days)

- Clinical documentation from the previous 12 months demonstrating a reduction in LDL-C from baseline and continued treatment with 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 initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.

* Requirement applies to members who have Part D coverage with Quartz.

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.

Created: 3/1/2022
Effective: 7/1/2023

Inebilizumab (Uplizna)
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits	Approval Limits
Inebilizumab (Uplizna)	Medical Benefit-Restricted	None	12 months

CRITERIA FOR COVERAGE:

- Diagnosis of Neuromyelitis Optica Spectrum Disorder (NMOSD) with positive anti-aquaporin-4 (AQP4) antibody, **AND**
- Prescribed by neurologist or in consultation with a specialist in the treatment of NMOSD, **AND**
- History of ≥ 1 relapse in the past 12 months or ≥ 2 relapses in the past 24 months, **AND**
- Failure or intolerance to an adequate trial of at least one of the following rituximab, mycophenolate, or azathioprine, **AND**
- Therapy must not be used in combination with other biologic treatments for NMOSD (examples: rituximab, satralizumab, eculizumab)

CONTINUATION OF COVERAGE CRITERIA:

- Clinical documentation from the previous 12 months that describes the person's response as stable disease or improvement seen on therapy (example: reduced number of relapses, reduced number of hospitalizations, 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.

Infused Oncology Agents
Prior Authorization Criteria

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits
J9061	Amivantamab (Rybrevant)	Medical Benefit-Restricted	None	Up to 12 months
J9022	Atezolizumab (Tecentriq)	Medical Benefit-Restricted	None	Up to 12 months
J9023	Avelumab (Bavencio)	Medical Benefit-Restricted	None	Up to 12 months
J9037	Belantamab (Blenrep)	Medical Benefit-Restricted	None	Up to 12 months
J9118	Calaspargase (Asparlas)	Medical Benefit-Restricted	None	Up to 12 months
J9047	Carfilzomib (Kyprolis)	Medical Benefit-Restricted	None	Up to 12 months
J9119	Cemiplimab (Libtayo)	Medical Benefit-Restricted	None	Up to 12 months
J9144 J9145	Daratumumab (Darzalex, Darzalex Faspro)	Medical Benefit-Restricted	None	Up to 12 months
J9272	Dostarlimab (Jemperli)	Medical Benefit-Restricted	None	Up to 12 months
J9173	Durvalumab (Imfinzi)	Medical Benefit-Restricted	None	Up to 12 months
J9176	Elotuzumab (Empliciti)	Medical Benefit-Restricted	None	Up to 12 months
J9177	Enfortumab (Padcev)	Medical Benefit-Restricted	None	Up to 12 months
A9590	Iobenguane I-131 Therapeutic (Azedra)**	Medical Benefit-Restricted	3 doses	Up to 12 months
J9228	Ipilimumab (Yervoy)	Medical Benefit-Restricted	None	Up to 12 months
J9227	Isatuximab (Sarclisa)	Medical Benefit-Restricted	None	Up to 12 months
J9359	Loncastuximab tesirine (Zynlonta)	Medical Benefit-Restricted	None	Up to 12 months
A9607	Lu-177 vipivotide tetraxetan (Pluvicto)	Medical Benefit-Restricted	6 doses	Up to 12 months
A9223	Lurbinectedin (Zepzelca)	Medical Benefit-Restricted	None	Up to 12 months
A9513	Lutetium (Lu) 177 (Lutathera)	Medical Benefit-Restricted	4 doses	6 months
J9353	Margetuximab (Margenza)	Medical Benefit-Restricted	None	Up to 12 months
J9247	Melphalan (Pepaxto)	Medical Benefit-Restricted	None	Up to 12 months
C9146	Mirvetuximab soravtansine-GYNX (Elahere)	Medical Benefit-Restricted	None	Up to 12 months
J9204	Mogamulizumab (Poteligeo)	Medical Benefit-Restricted	None	Up to 12 months
J9399 J9999	Mosunetuzumab (Lunsumio)	Medical Benefit-Restricted	None	Up to 12 months
J9313	Moxetumomab (Lumoxiti)	Medical Benefit-Restricted	None	6 months
J9348	Naxitamab (Danyelza)	Medical Benefit-Restricted	None	Up to 12 months
J9235	Necitumumab (Portrazza)	Medical Benefit-Restricted	None	Up to 12 months
J9299	Nivolumab (Opdivo)	Medical Benefit-Restricted	None	Up to 12 months
J9298	Nivolumab/relatlimab (Opdualag)	Medical Benefit-Restricted	None	Up to 12 months
J9271	Pembrolizumab (Keytruda)	Medical Benefit-Restricted	None	Up to 12 months
J9309	Polatuzumab Vedotin (Polivy)	Medical Benefit-Restricted	None	Up to 12 months
A9606	Radium (Ra) 223 (Xofigo)	Medical Benefit-Restricted	None	6 months
J9308	Ramucirumab (Cyramza)	Medical Benefit-Restricted	None	Up to 12 months
J9317	Sacituzumab Govitecan (Trodelvy)	Medical Benefit-Restricted	None	Up to 12 months
J2860	Siltuximab (Sylvant)	Medical Benefit-Restricted	None	Up to 12 months
J9331	Sirolimus protein-bound (Fyarro)	Medical Benefit-Restricted	None	Up to 12 months
J0208	Sodium Thiosulfate (Pedmark)	Medical Benefit-Restricted	None	Up to 12 months

(continued on next page)

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits
J9349	Tafasitamab (Monjuvi)	Medical Benefit-Restricted	None	Up to 12 months
J9269	Tagraxofusp-ERZS (Elzonris)	Medical Benefit-Restricted	None	Up to 12 months
J9274	Tebentafusp-TEBN (Kimmtrak)	Medical Benefit-Restricted	None	Up to 12 months
C9148	Teclistamab-CQYV (Tecvayli)	Medical Benefit-Restricted	None	Up to 12 months
J9273	Tisotumab vedotin (Tivdak)	Medical Benefit-Restricted	None	Up to 12 months
J9352	Trabectedin (Yondelis)	Medical Benefit-Restricted	None	Up to 12 months
C9147	Tremelimumab-ACTL (Imjudo)	Medical Benefit-Restricted	None	Up to 12 months

***Also known as metaiodobenzylguanidine [MIBG], 131I-MIBG and iodine-131-labeled Iobenguane. 3 doses= 1 diagnostic, 2 therapeutic*

CRITERIA FOR COVERAGE:

- Prescribed by or in consultation with an Oncologist, Hematologist, or other specialist in the treatment of malignancy, **AND**
- One of the following:
  - 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 is supported by recognized compendia† in the specific condition of the person*

CONTINUATION/RENEWAL OF COVERAGE CRITERIA: (for renewal or new members. This criteria will be applied if the requested medication has been used in the previous 365 days)

- Initial criteria for coverage met

* Includes any relevant genetic testing, mutations, etc.

† Recognized compendia include:

- National Comprehensive Cancer Network (NCCN)
- Lexi-Drugs Web
- Micromedex DrugDex
- Clinical Pharmacology
- Clinical research in peer-reviewed medical literature (under the conditions described in the Medicare Benefit Policy Manual, Chapter 15, 50.4.5)

Inotersen (Tegsedi)
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits	Approval Limits
Inotersen (Tegsedi)	Medical Benefit-Restricted	None	Initial: 12 months Renewal: indefinite

CRITERIA FOR COVERAGE:

- Diagnosis of neuropathy due to hereditary transthyretin (hATTR) amyloidosis with documentation of TTR gene mutation and biopsy proven amyloid deposits, **AND**
- Prescribed by a Neurologist, Cardiologist, or other expert in hereditary transthyretin-mediated amyloidosis (hATTR), **AND**
- Age ≥18 years, **AND**
- Failure of self-injection (subcutaneous) or inability to self-administer inotersen injection.*

CRITERIA FOR CONTINUATION: (12-month renewal or new members. This criteria will be applied if the requested medication has been used in the previous 365 days)

- For renewal, 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.

* Requirement applies to members who have Part D coverage with Quartz.

Interferons
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits	Approval Limits
Interferon alfa-2b (Intron A)	Medical Benefit Restricted	None	12 months
Interferon alfa-n3 (Alferon N)	Medical Benefit Restricted	None	12 months

CRITERIA FOR COVERAGE (Intron A):

- Failure of self-injection (subcutaneous) or inability to self-administer Intron A injection*, **AND**
- One of the following diagnoses:
  - 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 (includes any relevant genetic testing, mutations, etc.), **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 (includes any relevant genetic testing, mutations, etc.), **OR**
  - Other FDA-labeled indications not listed above

CRITERIA FOR COVERAGE (Alferon N):

- Diagnosis of external genital or perianal warts

CRITERIA FOR CONTINUATION OF THERAPY: (for renewal or new members. This criteria will be applied if the requested medication has been used in the previous 365 days)

- Initial criteria met.
- 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**.**

Letermovir (Prevymis)
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits	Approval Limits
Letermovir (Prevymis)	Medical Benefit-Restricted	None	1 Course (up to 100 days post-transplant

CRITERIA FOR COVERAGE:

- Covered for CMV prophylaxis in adults post-allogeneic hematopoietic stem cell transplant, **AND**
- Cytomegalovirus (CMV)-seropositive recipients (R+) or have CMV positive donor (D+), **AND**
- Prescribed by or in consultation with a Hematologist, Oncologist, Infectious Disease, or Transplant specialist, **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**
- Person unable to tolerate/swallow the oral tablet of letermovir*

CONTINUATION OF COVERAGE CRITERIA: (for renewal or new members. This criteria will be applied if the requested medication has been used in the previous 365 days)

- Prescriber provides an evidence-based clinical rationale for using a duration beyond 100 days post-transplant
- 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 and not covered at this time.

* Requirement applies to members who have Part D coverage with Quartz.

Lumasiran (Oxlumo)
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits	Approval Limits
Lumasiran (Oxlumo)	Medical benefit-Restricted	None	Initial: 6 months Renewal: 12 months

CRITERIA FOR COVERAGE:

- Diagnosis of Primary Hyperoxaluria Type 1 confirmed by genetic testing (AGXT mutation) or liver biopsy, **AND**
- Prescribed by, or in consultation with, a Nephrologist, Urologist, or other related specialty, **AND**
- Has not received a liver transplant

CRITERIA FOR CONTINUATION OF THERAPY: (for renewal or new members. This criteria will be applied if the requested medication has been used in the previous 365 days)

- Clinical documentation of symptom or metabolic improvement from start 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.

Luspatercept (Reblozyl)
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits	Approval Limits
Luspatercept (Reblozyl)	Medical benefit-Restricted	None	Initial: 3 months Renewal: 12 months

CRITERIA FOR COVERAGE:

For treatment of beta thalassemia:
- Diagnosis of transfusion-dependent Beta Thalassemia (confirmed by genetic testing) requiring at least 6 RBC units per 24 weeks, **AND**
- Prescribed by or in consultation with a hematologist or other provider with experience in the treatment of beta thalassemia, **AND**
- Age ≥18 years with no history of splenectomy, **AND**
- No recent history of deep vein thrombosis (DVT) or stroke (within past six months)

For other FDA approved indications:
- Prescribed or recommended by specialist is treatment of the requested diagnosis

CRITERIA FOR COVERAGE CONTINUATION after 3 months:
- Initial criteria met, AND
- For treatment of Beta Thalassemia only, clinical documentation from the previous 3 month demonstrating at least a 33% reduction in RBC transfusions
- 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 CRITERIA: (for renewal or new members. This criteria will be applied if the requested medication has been used in the previous 365 days)
- Initial criteria met and clinical documentation from the previous 12 months demonstrating stable disease (i.e. no increase in RBC transfusion requirements)
- 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.

Nusinersen (Spinraza)
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits	Approval Limits
Nusinersen (Spinraza)	Medical benefit-Restricted	None	12 months

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**
- Prescribed by or in consultation with a 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**
- Person 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**
- Person has not received prior onasemnogene abeparvovec-xioi (Zolgensma) therapy
- Not being used in combination with risdiplam (Evrysdi)

CONTINUATION OF COVERAGE CRITERIA: (for renewal or new members. This criteria will be applied if the requested medication has been used in the previous 365 days)

- 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
    - 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,
    - For HFSME, a change of 3 or more points from baseline is considered clinically meaningful, OR
    - 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.

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-abeparvovec-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

Type	Number of copies of SMN2	Onset	Incidence
1	Two	Before 6 months	60%
2	Three or Four	6-18 months	27%
3	Three or Four	Early childhood	13%

Mepolizumab (Nucala)
Prior Authorization Criteria

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits
J2182	Mepolizumab (Nucala)	Medical Benefit- Restricted	None	None

CRITERIA FOR COVERAGE of eosinophilic asthma:

- Diagnosis of eosinophilic asthma with a documented blood eosinophil count of ≥ 150 cells/mm^3 (other causes of eosinophilia such as hyper eosinophilic syndromes, neoplastic disease, or parasitic disease must be ruled out), **AND**
- Prescribed by or in consultation with an asthma specialist (Allergist, Immunologist, Pulmonologist), **AND**
- Age ≥6 years, **AND**
- Trial and failure, contraindication, or intolerance to self-injection of mepolizumab (Nucala) (or inability to self-administer these injections)*, **AND**
- One of the following:
  A. Symptoms are not well controlled or poorly controlled (Table 1) despite a 3-month trial of medium to high-dose inhaled corticosteroids in combination with a long-acting bronchodilator, long-acting muscarinic antagonist or leukotriene modifier*, **OR**
  B. Patient has intolerance to medium to high dose inhaled corticosteroids in combination with a long-acting bronchodilator or leukotriene modifier. Exceptions based on adverse effects from medium to high dose ICS or comorbid conditions increasing long-term risks of adverse effects from medium to high dose ICS or oral corticosteroids include:
    - Cataracts in patients over 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)

Note: Il-5 inhibitor drugs in combination with omalizumab will be considered on a case-by-case basis if each individual agent with combination medium to high dose ICS/LABA did not control symptoms.

CRITERIA FOR COVERAGE for Eosinophilic Granulomatosis with Polyangiitis:

- Prescribed by or in consultation with a provider experienced in the treatment EGPA (i.e., allergist, pulmonologist or rheumatologist), **AND**
- Age ≥18 years, **AND**
- Trial and failure, contraindication, or intolerance to adequate 3-month trials of prednisone and at least ONE additional immunosuppressive agent (i.e., cyclophosphamide, azathioprine, or methotrexate)*, **AND**
- Trial and failure, contraindication, or intolerance to self-injection of mepolizumab (Nucala) (or inability to self-administer these injections)*, **AND**
- 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 urgent care, emergency room visits or hospitalizations etc.), **AND**
- Confirmed diagnosis of relapsed or refractory EGPA defined as:
  - 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)
  - At least TWO of the following organ systems or features of EGPA disease:
    - Neuropathy (i.e., mono or polyneuropathy, mononeuritis multiplex)
    - Pulmonary infiltrates (i.e., asthma, chronic pneumonia, hemoptysis, cough)
    - Sino-nasal abnormality (i.e., sinusitis, allergic rhinitis, polyposis)

- Cardiomyopathy (i.e., heart failure, myocarditis, pericarditis, subendocardial fibrosis)
- Glomerulonephritis (i.e., hematuria, red cell casts, proteinuria)
- Alveolar hemorrhage (by bronchoalveolar lavage)
- Palpable purpura (i.e., skin nodules, urticarial rash, digital ischemia)
- Positive antineutrophil cytoplasmic antibody [ANCA]
- 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)

CRITERIA FOR COVERAGE of hypereosinophilic syndrome:

- Diagnosis of hypereosinophilic syndrome (HES) for ≥6 months without an identifiable non-hematologic secondary cause (i.e. cancer, imatinib-sensitive conditions, etc.), **AND**
- Prescribed by or in consultation with a hematologist, allergist or other specialist in the treatment of HES, **AND**
- Blood eosinophil count of 1,000 cells/mc on at least two occasions, **AND**
- Worsening of HES symptoms despite use of steroid-sparing preventive treatments for at least 4 week (e.g. methotrexate, hydroxyurea, interferon-alfa, azathioprine, cyclosporine, cyclophosphamide)*, **AND**
- Trial and failure, contraindication, or intolerance to self-injection of mepolizumab (Nucala) (or inability to self-administer these injections)*

CRITERIA FOR COVERAGE of Nasal Polyps:

- Diagnosis of chronic rhinosinusitis with nasal polyposis, **AND**
- Prescribed by or in consultation with a specialist experienced in the treatment of nasal polyps (ex: Otolaryngologist, Allergist), **AND**
- Documented nasal polyps by direct exam, endoscopy, or sinus CT scan, **AND**
- Persistent or worsening of nasal polyps despite being on a daily nasal steroid*, **AND**
- Inadequately controlled disease despite prior use of systemic steroids* and/or endoscopic sinus surgery, **AND**
- Will be used in combination with a nasal corticosteroid medication*, **AND**
- Trial and failure, contraindication, or intolerance to self-injection of mepolizumab (Nucala) (or inability to self-administer these injections)*

* Requirement applies to members who have Part D coverage with Quartz.

CRITERIA FOR CONTINUATION OF THERAPY FOR SEVERE ASTHMA/HES/NASAL POLYPS: (New members. This criteria will be applied if the requested medication has been used in the previous 365 days)

- 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 emergency/urgent care visits for exacerbations
  - Reduction in reported symptoms such as chest tightness, coughing, shortness of breath, nocturnal awakenings, nasal congestion, obstruction, etc.
  - Sustained (at least six months) improvement in Asthma Control Test (ACT) scores
  - Improved nasal polyposis score
- 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
- 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 THERAPY for EGPA: (New members. This criteria will be applied if the requested medication has been used in the previous 365 days)

- 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:
  - Birmingham Vasculitis Activity Score (BVAS version 3) improvement from baseline (i.e., a clinically significant score improvement for vasculitis is 16 units or greater)
  - Reduction in the total daily dose of prednisolone/prednisone (50-75% reduction in dose from baseline) or reduction in intermittent steroid bursts
  - Improvement in the duration of remission or improvement in rate of relapses, urgent care, emergency room visits or hospitalizations.
- 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:

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

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

Olipudase alfa (Xenpozyme)
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits	Approval Limits
Olipudase alfa (Xenpozyme)	Medical Benefit-Restricted	None	12 months

CRITERIA FOR COVERAGE

- Diagnosis of acid sphingomyelinase deficiency type B or type A/B with all of the following:
  - Diagnosis confirmed by enzyme assay or genetic testing, AND
  - Spleen volume ≥ 5 multiples of normal, AND
- If age ≥ 18 years: diffusion capacity of the lungs for carbon monoxide (DLco) ≤70% of predicted normal, **AND**
- Prescribed by, or in consultation with, a specialist familiar with the treatment of lysosomal storage disorders, **AND**
- Individual does not have any of the following:
  - History of major organ transplant
  - International normalized ratio (INR) >1.5
  - Require ventilatory support for >12 hours per day
  - Platelet count <60 × 103/µL,
  - Alanine aminotransferase (ALT) or aspartate aminotransferase (AST) >250 IU/L or total bilirubin >1.5 mg/dL
  - Rapidly progressing neurologic abnormalities

CRITERIA FOR CONTINUATION OF THERAPY: (for renewal or new members. This criteria will be applied if the requested medication has been used in the previous 365 days)

- Clinical documentation from the previous 12 months showing objective disease improvement or stabilization (e.g., platelet count increase, spleen volume decrease, increased percent predicted diffusion capacity of the lungs for carbon monoxide, liver volume decrease).
- 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**.**

Onasemnogene abeparvovec (Zolgensma)
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limit/Lifetime	Approval Limits/Lifetime
Onasemnogene abeparvovec (Zolgensma)	Medical benefit-Restricted	1 kit (weight-based)	1 treatment

CRITERIA FOR COVERAGE:

- Diagnosis of spinal muscle atrophy (SMA) based on documentation of gene mutation analysis with bi-allelic SMN1 mutations (5q point mutation/deletion) and has no more than 3 copies of SMN2 gene, **AND**
- Baseline antibody titers of anti AAV9 antibodies are ≤1:50 (based on ELISA), documented within one month prior to administration, **AND**
- Prescribed by or in consultation with a Neurologist or other clinician with expertise in management and treatment of SMA, **AND**
- Age <2 years at administration, **AND**
- Person does not have advanced SMA (e.g. permanent ventilatory dependence, complete limb paralysis, etc.), **AND**
- For infants established on nusinersen, will not continue nusinersen (Spinraza) post onasemnogene infusion (not studied)
- For infants established on risdiplam, will not continue risdiplam (Evrysdi) post-onasemnogene infusion (not studied)

CRITERIA FOR COVERAGE OF DURATION EXCEPTIONS:

- The prescriber provides an evidence-based clinical reason for utilizing an extended duration

CRITERIA FOR QUANTITY EXCEPTIONS:

- The requested dosing schedule cannot be met using commercially available dose forms within the quantity limit and the prescriber provides an evidence-based rationale for using a dose outside of the quantity limit

IMPORTANT INFORMATION:
Use of onasemnogene abeparvovec in combination with nusinersen or risdiplam 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.

For persons with 4 or more copies of the SMN2 gene or for other indications not listed, requests 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.

Palifermin (Kepivance)
Prior Authorization PA Criteria

Drug Name	Drug Status	Quantity Limits	Approval Limits
Palifermin (Kepivance)	Medical benefit-Restricted	6 doses per cycle	12 months

CRITERIA FOR COVERAGE:

- Person is 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), **AND**
- Prescribed by or in consultation with an Oncologist, Hematologist or other specialist in the treatment of malignancy

CRITERIA FOR CONTINUATION OF THERAPY: (for renewal or new members. This criteria will be applied if the requested medication has been used in the previous 365 days)

- Person is 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), **AND**
- Prescribed by or in consultation with an Oncologist, Hematologist or other specialist in the treatment of malignancy
- 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

Drug Name	Drug Status	Quantity Limits/Season	Approval Limits
Palivizumab (Synagis)	Medical Benefit-Restricted	5 doses	One season (November/April)

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.
- Additional doses may appropriate during periods of atypical RSV interseasonal activity for eligible patients and in cases of interseasonal activity more than 5 doses consecutive doses is reasonable
- 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.

Part B Step Therapy Program
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits	Approval Limits
Bevacizumab (Avastin)	Medical Benefit Restricted	None	None
Trastuzumab (Herceptin)	Medical Benefit Restricted	None	None
Pegfilgrastim (Neulasta, Neulasta Onpro, Nyvepria, Fulphila, Udenyca, Fylnetra, Stimufend)	Medical Benefit Restricted	None	None
Eflapegrastim (Rolvedon)	Medical Benefit Restricted	None	None
Filgrastim (Neupogen)	Medical Benefit Restricted	None	None
Epoetin Alfa (Procrit, Epogen)	Medical Benefit Restricted	None	None
Hyaluronidase products (Durolane, Gel-One, Gelsyn-3, GenVisc 850, Hyalgan, Hymovis, Orthovisc, Monovisc, Supartz FX, Synojoynt, TriVisc, Triluron, Visco-3)	Medical Benefit Restricted	None	None
Infliximab (Remicade)	Medical Benefit Restricted	None	None
Rituximab (Rituxan)	Medical Benefit Restricted	None	None

CRITERIA FOR COVERAGE:
Applicable Medicare National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and manuals also apply. For the most up-to-date Medicare policies and coverage, please search the Medicare Coverage Database. In addition, the following step therapy restrictions apply:

Drug Class / Product Name	Preferred Drug	Non-Preferred Drug
Bevacizumab *	Alymsys, Mvasi, Zirabev	Avastin (Note- when administered as an intravitreal injection, coverage of Avastin does NOT require trial and failure, contraindication, or intolerance to listed preferred drugs)
Colony Stimulating Factors (Long Acting)	Ziextenzo	Neulasta, Neulasta Onpro, Nyvepria, Fulphila, Udenyca, Fylnetra, Stimufend, Rolvedon
Colony Stimulating Factors (Short Acting)	Nivestym, Granix, Zarxio, Releuko	Neupogen
Epoetin Alfa †	Retacrit	Procrit, Epogen
Hyaluronidase products *	Euflexxa, Synvisc, Synvisc-One	Durolane, Gel-One, Gelsyn-3, GenVisc 850, Hyalgan, Hymovis, Orthovisc, Monovisc, Supartz FX, Synojoynt, TriVisc, Triluron, Visco-3
Infliximab *	Inflectra, Renflexis, Avsola, Infliximab	Remicade
Rituximab ‡	Riabni, Ruxience, Truxima	Rituxan
Trastuzumab *	Herzuma, Kanjinti, Ogivri, Ontruzant, Trazimera	Herceptin

* LCD also applies: L33394 (Drugs and Biologicals, Coverage of, for Label and Off-Label Uses)
† NCD may also apply: NCD 110.21 (Erythropoiesis Stimulating Agents (ESAs) in Cancer and Related Neoplastic Conditions)
‡ LCD also applies: L39297 (Off-label Use of Rituximab and Rituximab Biosimilars)

Bevacizumab – Non-ophthalmic uses only

- **Preferred Drug(s)-** Alymsys, Mvasi, Zirabev
- **Non-Preferred Drug(s)-** Avastin
  - **Non-Preferred Product Step Therapy Criteria-** History of trial and failure, contraindication, or intolerance to TWO of the following: Alymsys, Mvasi, Zirabev

Colony Stimulating Factors (Long Acting)

- **Preferred Drug(s)-** Ziextenzo
- **Non-Preferred Drug(s)-** Neulasta, Neulasta Onpro, Nyvepria, Fulphila, Udenyca, Fylnetra, Stimufend, Rolvedon
  - **Non-Preferred Product Step Therapy Criteria-** History of trial and failure, contraindication, or intolerance to Ziextenzo

Colony Stimulating Factors (Short Acting)

- **Preferred Drug(s)-** Nivestym, Granix, Zarxio, Releuko
- **Non-Preferred Drug(s)-** Neupogen
  - **Non-Preferred Product Step Therapy Criteria-** History of trial and failure, contraindication, or intolerance to TWO of the following: Nivestym, Granix, Zarxio, Releuko

Epoetin Alfa

- **Preferred Drug(s)-** Retacrit
- **Non-Preferred Drug(s)-** Procrit, Epogen
  - **Non-Preferred Product Step Therapy Criteria-** History of trial and failure, contraindication, or intolerance Retacrit

Hyaluronidase products

- **Preferred Drug(s)-** Euflexxa, Synvisc, Synvisc-One
- **Non-Preferred Drug(s)-** Durolane, Gel-One, Gelsyn-3, GenVisc 850**,** Hyalgan, Hymovis, Orthovisc, Monovisc, Supartz FX, Synojoynt, TriVisc, Triluron, Visco-3
  - **Non-Preferred Product Step Therapy Criteria-** History of trial and failure, contraindication, or intolerance to TWO of the following: Euflexxa, Synvisc, Synvisc-One

Infliximab

- **Preferred Drug(s)-** Avsola, Inflectra, Renflexis, Infliximab
- **Non-Preferred Drug(s)-** Remicade
  - **Non-Preferred Product Step Therapy Criteria-** History of trial and failure, contraindication, or intolerance to TWO of the following: Inflectra, Renflexis, Avsola, Infliximab

Rituximab

- **Preferred Drug(s)-** Riabni, Ruxience, Truxima
- **Non-Preferred Drug(s)-** Rituxan
  - **Non-Preferred Product Step Therapy Criteria-** History of trial and failure, contraindication, or intolerance to TWO of the following: Riabni, Ruxience, Truxima

Trastuzumab

- **Preferred Drug(s)-** Herzuma, Kanjinti, Ogivri, Ontruzant, Trazimera
- **Non-Preferred Drug(s)-** Herceptin
  - **Non-Preferred Product Step Therapy Criteria-** History of trial and failure, contraindication, or intolerance to TWO of the following: Herzuma, Kanjinti, Ogivri, Ontruzant, Trazimera

CRITERIA FOR CONTINUATION OF THERAPY:

- Documentation from the previous 365 days that shows member has received the requested medication.
- 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**.**

Created: 8/16/2022
Effective: 7/1/2023

Pegloticase (Krystexxa)
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits	Approval Limits
Pegloticase (Krystexxa)	Medical Benefit-Restricted	None	Initial: 6 months Renewal: 12 months

CRITERIA FOR COVERAGE:

- Person has frequent gout flares (at least 2 flares per year) OR has nonresolving subcutaneous tophi (at least 1 tophi, gouty arthropathy defined clinically or radiographically as joint damage due to gout) despite appropriate urate lowering therapy (as listed below) as well as appropriate colchicine, NSAIDs and glucocorticoid use for acute attacks*, **AND**
- Serum uric acid level >6 mg/dL despite an adequate trial of maximized therapeutic doses of allopurinol AND febuxostat (unless contraindication or intolerance)*, **AND**
- Drug must be prescribed or in consultation with a Rheumatologist, **AND**
- Documentation that the person does not have glucose-6-phosphate dehydrogenase (G6PD) deficiency

CRITERIA FOR CONTINUATION OF THERAPY: (12-month renewal or new members. This criteria will be applied if the requested medication has been used in the previous 365 days)

- 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.
- 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**.**

* Requirement applies to members who have Part D coverage with Quartz.

Created: 1/1/2021
Effective: 10/1/2021

Plasminogen (Ryplazim)
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits	Approval Limits
Plasminogen, human (Ryplazim)	Medical Benefit Restricted	None	12 months

CRITERIA FOR COVERAGE:

- Diagnosis of plasminogen deficiency type 1 or other FDA labeled indication, **AND**
- Prescribed by or in consultation with Hematologist or other specialist is the treatment of plasminogen deficiency, **AND**
- Person with refractory symptomatic lesions

CONTINUATION/RENEWAL OF COVERAGE CRITERIA: (for renewal or new members. This criteria will be applied if the requested medication has been used in the previous 365 days)

- Initiation criteria met.
- Prescriber provides clinical notes from the previous 12 months documenting response to therapy compared to baseline; such as decrease in lesion frequency or size of lesions

Positive Allosteric Modulators of $GABA_A$ Receptors
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits	Approval Limits
Brexanolone (Zulresso)	Medical Benefit-Restricted	None	One infusion per year

CRITERIA FOR COVERAGE:

- Diagnosis of moderate to severe postpartum depression, **AND**
- Postpartum within 9 months of delivery or pregnancy termination, **AND**
- Symptoms began within the third trimester and/or no later than 12 weeks after delivery, **AND**
- Person meets ONE of the following:
  1. Documentation shows potential risk of harm to self or others, **OR**
  2. 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.

Pulmonary Hypertension Drugs
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits	Approval Limits
Epoprostenol (Veletri)	Medical Benefit-Restricted	None	None
Selexipag (Uptravi)	Medical Benefit-Restricted	None	6 months
Treprostinil (Remodulin, generic)	Medical Benefit-Restricted	None	None

CRITERIA FOR COVERAGE (epoprostenol, treprostinil generic):
- Diagnosis of pulmonary arterial hypertension, **AND**
- Prescribed by, or in consultation with, a cardiologist or pulmonologist

CRITERIA FOR COVERAGE (Remodulin):
- Diagnosis of pulmonary arterial hypertension, **AND**
- Prescribed by, or in consultation with, a cardiologist or pulmonologist, **AND**
- Previous trial and failure, contraindication, or intolerance to generic treprostinil

CRITERIA FOR COVERAGE (selexipag):
- Diagnosis of pulmonary arterial hypertension, **AND**
- Prescribed by, or in consultation with, a cardiologist or pulmonologist
- Documented inability to swallow oral selexipag

Prophylactic Calcitonin Gene-Related Peptide (CGRP) Inhibitors Prior Authorization Criteria

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits
J3032	Eptinezumab-jjmr (Vyepti)	Medical Benefit-Restricted	Four infusions	None

CRITERIA FOR COVERAGE:

- Diagnosis is the prevention of migraines, **AND**
- Age ≥18 years, **AND**
- Person has at least 4 migraine days per month as supported by documentation, **AND**
- 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), **AND**
- Trial and failure, contraindication, or intolerance to two self-administered prophylactic subcutaneous CGRP inhibitors*, **AND**
- Drug is not being used in combination with another CGRP inhibitor preventative.

CRITERIA FOR CONTINUATION OF THERAPY: (New members. This criteria will be applied if the requested medication has been used in the previous 365 days)

- Clinical documents from the previous 12 months provided showing a response to therapy (specific details regarding symptom improvement such as decreased frequency or severity of headaches from baseline, reduced cluster headache frequency, improved ability to participate in therapies/ADLs, improved MIDAS score, less acute medication use, fewer ER/UC visits for migraine, ability to return to work/school, 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**.**
- Drug is not being used in combination with another CGRP inhibitor preventative

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.

* Requirement applies to members who have Part D coverage with Quartz.

Reslizumab (Cinqair)
Prior Authorization Criteria

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits
J2786	Reslizumab (Cinqair)	Medical Benefit-Restricted	None	None

CRITERIA FOR COVERAGE of eosinophilic asthma:

- Diagnosis of eosinophilic asthma with a documented blood eosinophil count of ≥ 150 cells/mm^3 (other causes of eosinophilia such as hyper eosinophilic syndromes, neoplastic disease, or parasitic disease must be ruled out), **AND**
- Prescribed by or in consultation with an asthma specialist (Allergist, Immunologist, Pulmonologist), **AND**
- Age ≥18 years, **AND**
- Trial and failure, contraindication, or intolerance to self-injection of one self-administered biologic therapy for eosinophilic asthma (or inability to self-administer injections)*, **AND**
- One of the following:
  A. Symptoms are not well controlled or poorly controlled (Table 1) despite a 3-month trial of medium to high-dose inhaled corticosteroids in combination with a long-acting bronchodilator, long-acting muscarinic antagonist or leukotriene modifier*, **OR**
  B. Patient has intolerance to medium to high dose inhaled corticosteroids in combination with a long-acting bronchodilator or leukotriene modifier. Exceptions based on adverse effects from medium to high dose ICS or comorbid conditions increasing long-term risks of adverse effects from medium to high dose ICS or oral corticosteroids include:
    - Cataracts in patients over 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)

Note: Il-5 inhibitor drugs in combination with omalizumab will be considered on a case-by-case basis if each individual agent with combination medium to high dose ICS/LABA did not control symptoms.

* Requirement applies to members who have Part D coverage with Quartz.

CRITERIA FOR CONTINUATION OF THERAPY for eosinophilic asthma: (New members. This criteria will be applied if the requested medication has been used in the previous 365 days)

- 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 emergency/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
- 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
- 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 1. Outcome Measure values for uncontrolled asthma

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

Restricted Medications with Miscellaneous Codes
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits	Approval Limits
Varies	Medical Benefit-Restricted	Varies	Up to 12 months

CRITERIA FOR COVERAGE OF RESTRICTED MEDICATIONS BILLED WITH MISCELLANEOUS HCPCS CODES (non-oncology):

- FDA approved indications*, **AND**
- Adequate trial and failure, contraindication or intolerance to clinically appropriate covered alternatives for the person's diagnosis

  *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 BILLED WITH MISCELLANEOUS HCPCS CODES:

- Prescribed by, or in consultation with, an Oncologist, Hematologist, or other provider specializing in the treatment of malignancy, **AND**
- One of the following:
  - 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

CONTINUATION/RENEWAL OF COVERAGE CRITERIA: (for renewal or new members. This criteria will be applied if the requested medication has been used in the previous 365 days)

- Initial criteria for coverage met (members established on therapy will not be required to have a trial and failure, contraindication or intolerance to alternate 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.

Restricted Progesterone
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits	Approval Limits
Hydroxyprogesterone (Makena)	Medical Benefit-Restricted	None	6 months
Hydroxyprogesterone compounded	Medical Benefit-Restricted	None	6 months

CRITERIA FOR COVERAGE:

- Woman in the 2nd trimester of a singleton pregnancy, **AND**
- Has a history of preterm birth

CONTINUATION OF COVERAGE CRITERIA: (for renewal or new members. This criteria will be applied if the requested medication has been used in the previous 365 days)

- Persons new to the plan who are established on therapy will have coverage 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**.**

Rilonacept (Arcalyst)
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits	Approval Limits
Rilonacept (Arcalyst)	Medical Benefit-Restricted	None	None

CRITERIA FOR COVERAGE:

- Diagnosis of Cryopyrin-Associated Periodic Syndromes (CAPS) (including Familial Cold Auto-inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS)), **AND**
- Prescribed by or in consultation with a Rheumatologist or Immunologist, **AND**
- Age ≥12 years, **AND**
- Trial and failure, contraindication or intolerance to an adequate trial of Kineret (Anakinra)*

OR

- Diagnosis of symptomatic recurrent pericarditis (idiopathic pericarditis or post-cardiac injury pericarditis), **AND**
- Prescribed by or in consultation with a Cardiologist

CRITERIA FOR CONTINUATION OF COVERAGE: (12-month renewal or new members. This criteria will be applied if the requested medication has been used in the previous 365 days)

- Clinical documentation from the previous 12 months demonstrating benefits from 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

* Requirement applies to members who have Part D coverage with Quartz.

Romosozumab-aqqg (Evenity)
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits	Approval Limits
Romosozumab-aqqg (Evenity)	Medical Benefit-Restricted	None	12 months

CRITERIA FOR COVERAGE:

- Medication must be administered by a health care provider, **AND**
- Total duration of treatment will not exceed 12 months over a person's lifetime, **AND**
- Person has not had a myocardial infarction or stroke within the preceding year and the benefits versus the risks in people with other cardiovascular risk factors have been considered, **AND**
- Will not be used in combination with anti-resorptive therapy or after denosumab therapy, **AND**
- For the treatment of postmenopausal women who have ONE of the following diagnoses and the associated criteria:
    1. 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 very high risk of fracture defined by **AT LEAST ONE** of the following:
        - Recent fracture (e.g. within past 12 months), fracture while on approved osteoporosis therapy, multiple fractures, fractures while on drugs causing skeletal harm (e.g. long-term glucocorticoid use), very low T-score (less than -3.0), high risk for falls, or history of injurious falls

    OR
    2. 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 with a 10-year probability of a hip fracture of at least 3% or major osteoporosis-related fracture of at least 20% **AND** at very high risk of fracture defined by **AT LEAST ONE** of the following:
        - Recent fracture (e.g. within past 12 months), fracture while on approved osteoporosis therapy, multiple fractures, fractures while on drugs causing skeletal harm (e.g. long-term glucocorticoid use), very high FRAX (major osteoporotic fracture > 30%, hip fracture > 4.5%), high risk for falls, or history of injurious falls

*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 A DURATION EXCEPTIONS:

- The prescriber provides an evidence-based clinical rationale for requesting a treatment duration outside of the FDA approved duration

CONTINUATION OF CARE CRITERIA: (12-month renewal or new members. This criteria will be applied if the requested medication has been used in the previous 365 days)

- Persons new to the plan who are established on therapy and need to complete the remainder of the current treatment course (up to 12 months total).
- 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.

Sebelipase alfa (Kanuma)
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits	Approval Limits
Sebelipase alfa (Kanuma)	Medical Benefit-Restricted	None	12 months

CRITERIA FOR COVERAGE:

- Diagnosis of 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 or in consultation with a specialist in Genetics and Metabolism

CONTINUATION OF THERAPY: (12-month renewal or new members. This criteria will be applied if the requested medication has been used in the previous 365 days)

- 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.
- 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.

Spesolimab (Spevigo)
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits	Approval Limits
Spesolimab-sbzo (Spevigo)	Medical benefit-Restricted	2- 900mg IV infusions	3 months

CRITERIA FOR COVERAGE:

- Diagnosis of generalized pustular psoriasis with a flare of moderate to severe intensity (GPPPGA total score/subscores demonstrating moderate to severe intensity) with new/worsening pustules and greater than 5% total body surface area with erythema and pustules, **AND**
- Prescribed by or in consultation with a dermatologist, **AND**
- Age ≥18 years, **AND**
- Drug is not being used in combination another systemic and topical medications for psoriasis

Sutimlimab (Enjaymo)
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limit	Approval Limits
Sutimlimab (Enjaymo)	Medical Benefit Restricted	N/A	12 months

CRITERIA FOR COVERAGE:

- Diagnosis of primary cold agglutinin disease (CAD), **AND**
- History of at least one blood transfusion within the previous six months, **AND**
- Hemoglobin level ≤ 10 g/dL, **AND**
- One or more symptoms associated with CAD (ex: anemia, acrocyanosis, etc.), **AND**
- Prior failure, intolerance, or contraindication to rituximab unless need for rapid acting therapy (ex: severe anemia, cardiac surgery, etc.), **AND**
- Not using in combination with rituximab

CRITERIA FOR CONTINUATION OF THERAPY: (for new members. This criteria will be applied if the requested medication has been used in the previous 365 days)

- Clinical documentation from the previous 12 months that describes the person's response as stable 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 and/or vouchers.

Systemic Lupus Erythematosus (SLE) treatments
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits	Approval Limits
Belimumab (Benlysta)	Medical Benefit-Restricted	None	12 months
Anifrolumab (Saphnelo)	Medical Benefit-Restricted	None	12 months

CRITERIA FOR COVERAGE (belimumab infusion):

- Diagnosis of active lupus nephritis or active systemic lupus erythematosus (SLE) but not severe active central nervous system lupus, **AND**
- Prescribed by or in consultation with a Rheumatologist or other expert in the treatment of SLE, **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**
- Inability to self-administer weekly belimumab injection despite adequate teaching and interventions from a pharmacist and other health care providers*

CRITERIA FOR COVERAGE (anifrolumab infusion):

- Diagnosis of auto-antibody positive moderate to severe SLE but not severe active lupus nephritis or severe active central nervous system lupus
- Prescribed by, or in consultation with, a Rheumatologist or other expert in the treatment of SLE
- 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.
- Belimumab and anifrolumab combination therapy will not be covered

CRITERIA FOR CONTINUATION OF COVERAGE: (12-month renewal or new members. This criteria will be applied if the requested medication has been used in the previous 365 days):

- Clinical documentation from the previous 12 months demonstrating benefits from 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:
Should not be used in combination with other biologics or IV cyclophosphamide

* Requirement applies to members who have Part D coverage with Quartz.

Teplizumab (Tzield)
Prior Authorization Criteria

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits
C9149	Teplizumab (Tzield)	Medical Benefit-Restricted	None	14 days

CRITERIA FOR COVERAGE OF EOSINOPHILIC ASTHMA:

- Diagnosis of Stage 2 type 1 diabetes with presence of two or more pancreatic islet autoantibodies† and evidence of dysglycemia‡, **AND**
- Prescribed by or in consultation with an Endocrinologist or other specialist in the treatment of Type 1 Diabetes, **AND**
- Age≥8

† Pancreatic autoantibodies include: glutamic acid decarboxylase 65 (GAD) autoantibodies, Insulin autoantibody (IAA), Insulinoma-associated antigen 2 autoantibody (IA-2A), Zinc transporter 8 autoantibody (ZnT8A), Islet cell autoantibody (ICA).

‡ Dysglycemia is defined by the American Diabetes Association as:

- A fasting plasma glucose between 100 mg/dL and 125 mg/dL (5.6–6.9 mmol/L)
- 2 hour post prandial plasma glucose between 140mg/dL and 199 mg/dL (7.8–11.0 mmol/L)
- A1C 5.7–6.4% (39–47 mmol/mol) or ≥10% increase in A1C

Teprotumumab-trbw (Tepezza)
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits	Approval Limits
Teprotumumab (Tepezza)	Medical Benefit-Restricted	None	1 course (8 doses)

CRITERIA FOR COVERAGE:

- Diagnosis of thyroid-associated ophthalmopathy (Graves' orbitopathy) with moderate-to-severe symptoms such as:
  - Lid retraction ≥ 2 mm
  - Proptosis ≥ 3 mm
  - Intermittent diplopia
  - Clinical activity score (CAS) ≥ 4, **AND**
- Medical or surgical reversal of hyperthyroidism, **AND**
- Trial and failure, contraindication, or intolerance to an adequate 4-week trial of high-dose oral steroids (30-40 mg/day)*

CONTINUATION OF COVERAGE CRITERIA (new to the plan):

- Persons new to coverage who are established on therapy will have coverage 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 DURATION EXCEPTIONS:

- The prescriber provides published evidence to support the safety and efficacy of a treatment regimen beyond 8 doses.

* Requirement applies to members who have Part D coverage with Quartz.

Testosterone (Implant and ER injection)
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits	Approval Limits
Testosterone extended-release injection (Aveed)	Medical Benefit-Restricted	None	None
Testosterone implant (Testopel)	Medical Benefit-Restricted	None	None

CRITERIA FOR COVERAGE:

- Diagnosis of primary or secondary hypogonadism or mixed hypogonadism with clinically appropriate laboratory data demonstrating androgen deficiency*, **AND**
- Person is symptomatic with symptoms other than sexual dysfunction, **AND**
- Not for decreased libido or other sexual dysfunction, **AND**
- Documented intolerance to topical testosterone† AND non-extended release injections.

CRITERIA FOR CONTINUATION OF THERAPY: (For new members this criteria will be applied if the requested medication has been used in the previous 365 days)

- Diagnosis of primary or secondary hypogonadism or mixed hypogonadism with clinically appropriate laboratory data demonstrating androgen deficiency*, **AND**
- Person is symptomatic with symptoms other than sexual dysfunction, **AND**
- Not for decreased libido or other sexual dysfunction
- 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.

† Requirement applies to members who have Part D coverage with Quartz.

Tezepelumab (Tezspire)
Prior Authorization Criteria

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits
J2356	Tezepelumab (Tezspire)	Medical Benefit-Restricted	None	None

CRITERIA FOR COVERAGE OF EOSINOPHILIC ASTHMA:

- Diagnosis of eosinophilic asthma with a documented blood eosinophil count of ≥ 150 cells/mm^3 (other causes of eosinophilia such as hyper eosinophilic syndromes, neoplastic disease, or parasitic disease must be ruled out), **AND**
- Prescribed by or in consultation with an asthma specialist (Allergist, Immunologist, Pulmonologist), **AND**
- Age ≥12 years, **AND**
- Trial and failure or intolerance to at least two self-administered biologic therapies for eosinophilic asthma (i.e., dupilumab, benralizumab, mepolizumab)*, **AND**
- One of the following:
  A. Symptoms are not well controlled or poorly controlled (Table 1) despite a 3-month trial of medium to high-dose inhaled corticosteroids in combination with a long-acting bronchodilator, long-acting muscarinic antagonist or leukotriene modifier*, **OR**
  B. Patient has intolerance to medium to high dose inhaled corticosteroids in combination with a long-acting bronchodilator or leukotriene modifier. Exceptions based on adverse effects from medium to high dose ICS or comorbid conditions increasing long-term risks of adverse effects from medium to high dose ICS or oral corticosteroids include:
    - Cataracts in patients over 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)

CRITERIA FOR COVERAGE OF ALLERGIC ASTHMA:

- Diagnosis of moderate-to-severe persistent allergic asthma as defined by Global Initiative for Asthma (GINA) Global Strategy for Asthma Management and Prevention Guidelines (Step 5), **AND**
- Serum IgE level ≥30 international units/mL, **AND**
- Positive skin tests or in vitro reactivity to common aeroallergens (e.g. dust mites, pet dander, cockroaches, etc.), **AND**
- Prescribed by or in consultation with an asthma specialist (Allergist, Immunologist, Pulmonologist), **AND**
- Age ≥12 years, **AND**
- Trial and failure or intolerance to at least one self-administered biologic therapies for eosinophilic asthma (i.e., omalizumab)*, **AND**
- One of the following:
  A. Symptoms are not well controlled or poorly controlled (Table 1) despite a 3-month trial of medium to high-dose inhaled corticosteroids in combination with a long-acting bronchodilator, long-acting muscarinic antagonist or leukotriene modifier*, **OR**

B. Patient has intolerance to medium to high dose inhaled corticosteroids in combination with a long-acting bronchodilator or leukotriene modifier. Exceptions based on adverse effects from medium to high dose ICS or comorbid conditions increasing long-term risks of adverse effects from medium to high dose ICS or oral corticosteroids include:
    - Cataracts in patients over 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)

CRITERIA FOR COVERAGE OF SEVERE ASTHMA:

- Diagnosis of severe asthma with all of the following:
    - History of ≥2 asthma exacerbations requiring systemic corticosteroids within the past 12 months OR one asthma exacerbation requiring hospitalization in the past 12 months
    - Asthma is non-eosinophilic (example: blood eosinophil counts of <150 cells/uL)
    - Asthma is non-allergic (example: Serum IgE level <30 international units/mL, negative skin tests or in vitro reactivity to common aeroallergens)
    - For oral corticosteroid dependent asthma (requiring daily oral steroids): trial and failure or intolerance to at least one self-administered biologic therapy for corticosteroid dependent asthma (i.e., dupilumab) *
- Prescribed by or in consultation with an asthma specialist (Allergist, Immunologist, Pulmonologist), **AND**
- Age ≥12 years, **AND**
- One of the following:
    C. Symptoms are not well controlled or poorly controlled (Table 1) despite a 3-month trial of medium to high-dose inhaled corticosteroids in combination with a long-acting bronchodilator, long-acting muscarinic antagonist or leukotriene modifier*, **OR**
    D. Patient has intolerance to medium to high dose inhaled corticosteroids in combination with a long-acting bronchodilator or leukotriene modifier. Exceptions based on adverse effects from medium to high dose ICS or comorbid conditions increasing long-term risks of adverse effects from medium to high dose ICS or oral corticosteroids include:
        - Cataracts in patients over 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)

* Requirement applies to members who have Part D coverage with Quartz.

NOTE: Tezepelumab, in combination with other biologics, has not been studied and coverage is not allowed except in extenuating circumstances (applies to both eosinophilic or non-eosinophilic asthma populations).

CRITERIA FOR CONTINUATION OF THERAPY: (New members. This criteria will be applied if the requested medication has been used in the previous 365 days)

- 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 emergency/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

- 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 1. Outcome Measure values for uncontrolled asthma

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

Thrombopoietin Receptor Agonists
Prior Authorization Criteria

HCPCS Code	Drug Name	Drug Status	Quantity Limits	Approval Limits
J2796	Romiplostim (Nplate)	Medical Benefit-Restricted	For acute radiation injury: 1 dose All other indications: None	12 months

PRIOR AUTHORIZATION CRITERIA:

- Diagnosis of chronic immune thrombocytopenia (ITP) with a platelet count <50,000/mcL, **AND**
- Prescribed by or in consultation with Hematology, **AND**
- Trial and failure, contraindication or intolerance to adequate trials of ≥ 2 prior ITP therapies (e.g. corticosteroids, rituximab, azathioprine, danazol, or splenectomy)

OR

- Medical documentation of acute hematopoietic radiation injury and request is for 1 dose

CRITERIA FOR CONTINUATION OF THERAPY: (for renewal or new members. This criteria will be applied if the requested medication has been used in the previous 365 days)

- Diagnosis of chronic immune thrombocytopenia (ITP)
- Untreated platelet count was <50,000/mcL
- Prescribed by or in consultation with Hematology
- 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**.**

Trilaciclib (Cosela)
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits	Approval Limits
Trilaciclib (Cosela)	Medical benefit-Restricted	None	Initial: 6 months Renewal: 12 months

CRITERIA FOR COVERAGE:

- Treatment diagnosis and regimen follow FDA-labeled indication OR National Comprehensive Cancer Network (NCCN) category 1 or 2 recommendations, **AND**
- Prescribed by, or in consultation with, a hematologist or oncologist

CRITERIA FOR CONTINUATION OF THERAPY: (for renewal or new members. This criteria will be applied if the requested medication has been used in the previous 365 days)

- Clinical documentation of symptom or metabolic improvement from start 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.

Trilaciclib (Cosela)
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits	Approval Limits
Trilaciclib (Cosela)	Medical benefit-Restricted	None	12 months

CRITERIA FOR COVERAGE:

- Treatment diagnosis and regimen follow FDA-labeled indication OR National Comprehensive Cancer Network (NCCN) category 1 or 2 recommendations, **AND**
- Prescribed by, or in consultation with, a hematologist or oncologist

CRITERIA FOR CONTINUATION OF THERAPY: (for renewal or new members. This criteria will be applied if the requested medication has been used in the previous 365 days)

- Initial criteria for coverage met
- 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.

Voretigene Neparovec (Luxturna)
Prior Authorization Criteria

Drug Name	Formulary Status	Quantity Limits	Approval Limits
Voretigene neparovec (Luxturna)	Medical Benefit-Restricted	None	One treatment per eye

CRITERIA FOR COVERAGE:

- Confirmed diagnosis of inherited retinal dystrophy with biallelic RPE65 gene mutations, **AND**
- Visual acuity of ≤ 20/60 and/or visual field ≤ 20 degrees in both eyes, **AND**
- Clinical documentation to support evidence of sufficient viable retinal cells (such as retinal thickness > 100 microns within the posterior pole on spectral domain optical coherence tomography)

CRITERIA FOR DURATION EXCEPTIONS:

- Prescriber provides an evidence-based clinical rationale based on sufficient published literature to support retreatment