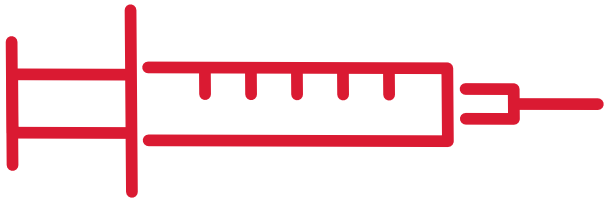
Quartz®



Quartz Medicare Advantage (HMO)

Part B Medication (Medical Benefit) **Prior Authorization Criteria**

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 (1020) Y0092_20 117_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.

Alglucosidase alfa (Myozyme, Lumizyme)
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits	Approval Limits
Alglucosidase alfa (Lumizyme, Myozyme*)	Medical Benefit-Restricted	None	None

*Myozyme is no longer available

CRITERIA FOR COVERAGE:

- Diagnosis of Pompe disease

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, Zemaria)	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

Belimumab (Benlysta)
Prior Authorization Criteria

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

CRITERIA FOR COVERAGE:

- Diagnosis of auto-antibody positive moderate to severe systemic lupus erythematosus (SLE) but not severe active lupus nephritis or 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 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.

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)*, **AND** Person has had a therapeutic failure, intolerance, or contraindication to fecal microbiota transplantation (FMT) unless FMT is not currently available

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.

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

Drug Name	Drug Status	Quantity Limit/ 28 Days	Approval Limits
Abatacept IV (Orencia)	Medical Benefit Restricted	N/A	12 months
Certolizumab (Cimzia)	Medical Benefit Restricted	N/A	12 months
Golimumab IV (Simponi Aria)	Medical Benefit Restricted	N/A	12 months
Natalizumab IV (Tysabri)	Medical Benefit Restricted	NA	12 months
Tildrakizumab (Ilumya)	Medical Benefit Restricted	None	12 months
Tocilizumab IV (Actemra)	Medical Benefit Restricted	N/A	12 months
Ustekinumab IV (Stelara)	Medical Benefit Restricted	One Infusion	12 months
Vedolizumab IV (Entyvio)	Medical Benefit Restricted	NA	12 months

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 (see DEFINITIONS below), **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, 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 MTX* **OR** Contraindication to MTX and steroids* **OR** Inability to taper corticosteroids*

4. **Hidradenitis Suppurativa (HS):**
   - Prescribed by or in consultation with a dermatologist, **AND**
   - Severe and/or refractory disease (Hurley II/Hurley III stage) with lesions despite previous treatment with topical antibiotics, systemic antibiotics, intralesional glucocorticoids, and/or surgical debridement

5. **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 (>30%) **AND** clinical failure/intolerance 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 >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), **AND**
     - Phototherapy: (e.g., broad band UVB, narrow band UVB, PUVA, excimer)

6. **Psoriatic arthritis (PsA) (moderate to severely active):**
   - 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 adequate trial of MTX (≥3 months)*

7. **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 (<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 (>6 months disease duration), reactive arthritis, or juvenile idiopathic arthritis (JIA), **AND** one of the following:
       - Documented failure with methotrexate (MTX) (≥3 months) at therapeutic doses*, **OR**
       - Persons with contraindication or intolerance to MTX therapy must fail a trial with an alternate disease modifying anti-rheumatic drug such as hydroxychloroquine, sulfasalazine, leflunomide or minocycline* (≥3 months)

8. **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 an adequate trial of corticosteroids and MTX (≥3 months)*

9. **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 (≥2-4 weeks) unless contraindicated

10. **Uveitis (non-infectious):**
   - Prescribed by or in consultation with an ophthalmologist or other eye specialist, **AND**
   - Biologic therapies are not used in combination with other biologic DMARD therapies, **AND**
   - Ongoing symptoms despite an adequate trial with BOTH topical glucocorticoids* and at least one systemic immunomodulator (e.g. oral corticosteroids, methotrexate, azathioprine, mycophenolate, or cyclosporine)*

DRUG-SPECIFIC CRITERIA FOR COVERAGE:

Abatacept (Orencia) Infusion

- Diagnosis of RA, JIA, or PsA, **AND**
- General criteria met for covered diagnosis, **AND**
- Trial & failure, contraindication, or intolerance to TWO preferred biologic DMARDs* (see Table A below), **AND**
- Failure of or inability to self-administer subcutaneous abatacept injection.*

  Note: Subcutaneous abatacept is not covered under Part B as it is considered a self-administered drug.

Certolizumab (Cimzia)

- Diagnosis of RA, AS, or PsA **AND**
- General criteria met for covered diagnosis, **AND**
- Trial & failure, contraindication, or intolerance to TWO preferred biologic DMARDs* (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 biologic DMARDs* (see Table A below) and TWO nonpreferred biologic DMARDs* (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 vedolizumab (Entyvio) or ustekinumab (Stelara), **AND**
    - Must be used as monotherapy (without immunomodulatory therapy)

  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

Tildrakizumab (Ilumya)

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

Tocilizumab Infusion (Actemra)

- General criteria met for covered diagnosis, **AND**
- Meets all of the following:
  - Diagnosis of moderate to severely active established RA, JIA or reactive arthritis, **AND**
  - Trial & failure, contraindication, or intolerance to TWO preferred biologic DMARDs* (Table A), **AND**
  - Failure of adequate trial of self-injectable tocilizumab (subcutaneous) or inability to self-administer injection*.

  OR
- Diagnosis of giant cell arteritis, sJIA, or adult-onset Still's disease **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).

Ustekinumab (Stelara) Infusion

- Diagnosis of CD, or UC, **AND**
- General criteria met for covered diagnosis, AND
- One of the following:
    - For CD: Trial & failure, or intolerance to TWO anti-TNF medications.* If primary non-response or contraindication to anti-TNF therapy, then trial & failure, contraindication or intolerance to vedolizumab (Entyvio) or tofacitinib (Xeljanz).
    - For UC: Trial & failure, or intolerance to adalimumab (Humira)* **AND** TWO of the following: infliximab biosimilar, vedolizumab (Entyvio), tofacitinib (Xeljanz)

  AND
- Failure of or inability to self-administer subcutaneous ustekinumab injection*

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

Vedolizumab (Entyvio)

- One of the following:
    - Diagnosis of UC, or
    - Diagnosis of CD AND trial & failure, contraindication or intolerance to TWO anti-TNF therapies (i.e., adalimumab (Humira), infliximab biosimilar, certolizumab (Cimzia), etc)*

  AND
- General criteria met for covered diagnosis

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

Table A

Preferred Drug (Part D)	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	PsO
Secukinumab (Cosentyx)	Part D	PsA, PsO, AS
Tofacitinib (Xeljanz, Xeljanz XR)	Part D	RA, PsA, UC
Upadacitinib (Rinvoq)	Part D	RA

Table B

Nonpreferred Drug (Part D)	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	PsO, PsA
Tocilizumab (Actemra)	Part D	RA, PJIA
Ustekinumab (Stelara)	Part D	PsA, PsO, CD

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 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**.**

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)

High Risk in Crohn's Disease:

- Age<30 at diagnosis, extensive anatomic involvement, perianal and/or severe rectal disease, deep ulcers, prior surgical resection, stricturing and/or penetrating behavior, fistulizing disease, extraintestinal manifestations of inflammation (i.e., uveitis, erythema nodosum, pyoderma gangrenosum, spondyloarthropathy, etc)

Induction and Maintenance Therapy with Conventional Agents:

- Conventional therapy with immunomodulator therapy such as azathioprine, balsalazide, corticosteroids, mesalamine, mercaptopurine, methotrexate, sulfasalazine
- 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. 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. Dassopoulos T, Cohen RD, Scherl EJ, Schwartz RM, Kosinski L, Regueiro MD. Ulcerative Colitis Care Pathway. *Gastroenterology.* 2015;149(1):238-245.
2. Sandborn WJ. Crohn's Disease Evaluation and Treatment: Clinical Decision Tool. *Gastroenterology.* 2014;147(3):702-705.
3. Rubin, D. Anathankrishnan A, Siegel C, Sauer B. ACG Clinical Guidelines Ulcerative colitis is Adults. Am J Gastroenterol. 2019; 114 (3) Mar: 384-413.

Brand Drugs with Available Biosimilars
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)	Medical Benefit Restricted	None	None
Filgrastim (Neupogen)	Medical Benefit Restricted	None	None
Epoetin Alfa (Procrit, Epogen)	Medical Benefit Restricted	None	None
Infliximab (Remicade)	Medical Benefit Restricted	None	None
Rituximab (Rituxan)	Medical Benefit Restricted	None	None

CRITERIA FOR COVERAGE:

All existing coverage restrictions from the Centers for Medicare and Medicaid Services (CMS) 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:

- Avastin – Trial and failure, contraindication or intolerance to TWO biosimilars of Avastin (Note- when administered as an intravitreal injection, Avastin does NOT require trial and failure, contraindication or intolerance to biosimilars).
- Herceptin – Trial and failure, contraindication or intolerance to TWO biosimilars of Herceptin
- Rituxan – Trial and failure, contraindication or intolerance to TWO biosimilars of Rituxan
- Neupogen – Trial and failure, contraindication or intolerance to TWO biosimilars of Neupogen
- Neulasta – Trial and failure, contraindication or intolerance to TWO biosimilars of Neulasta
- Neulasta Onpro – Trial and failure, contraindication or intolerance to TWO biosimilars of Neulasta OR cannot use biosimilar product with pre-filled syringes due to inability to return to clinic for injection AND no ability to administer self-injectable product.
- Remicade- Trial and failure, contraindication or intolerance to TWO biosimilars of Remicade
- Epogen – Trial and failure, contraindication or intolerance to ONE biosimilar of Epogen
- Procrit – Trial and failure, contraindication or intolerance to ONE biosimilar of Procrit

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 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.

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**
- Age is ≥18 years and ≤9 months postpartum, **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.

Burosumab (Crysvita)
Prior Authorization Criteria

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

CRITERIA FOR COVERAGE:

1. 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

2. 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.

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Complement Protein C5 Inhibitors
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits	Approval Limits
Ravulizumab (Ultomiris)	Medical Benefit-Restricted	None	Initial: 12 mo Renewal: indefinite

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**
- Document baseline hemoglobin (≤9 mg/dL with symptoms of anemia), lactate dehydrogenase level (LDH ≥1.5 X ULN) and/or number of transfusions in last year, **AND**
- Clinical manifestations of disease (e.g. major vascular event, transfusion dependence, renal insufficiency, disabling fatigue and/or other end organ manifestations), **AND**
- Receipt of both meningococcal vaccinations (MenACWY and MenB) at least two weeks prior to therapy initiation (or as required by REMS program).

Atypical hemolytic uremic syndrome (aHUS)
- 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**
- Receipt of both meningococcal vaccinations (MenACWY and MenB) at least two weeks prior to therapy initiation (or as required by REMS program).

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 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**.**

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

Quartz

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

Drug Name	Drug Status	Quantity Limits	Approval Limits
Eptinezumab-jjmr (Vyepti)	Medical Benefit-Restricted	Four IV infusions per year	Initial: 12 months Renewal: Indefinite

CRITERIA FOR COVERAGE:
- Diagnosis is the prevention of migraines, **AND**
- Age ≥18 years, **AND**
- Prescribed by or consultation with a provider experienced in the management of migraines, **AND**
- Person has at least 4 migraine days per month as supported by documentation, **AND**
- Failure† or intolerance to two self-administered prophylactic subcutaneous CGRP inhibitors*, **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**
- Combination therapy of two CGRP monoclonal antibody inhibitors will not be covered.

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

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

* Requirement applies to members who have Part D coverage with Quartz.
† Failure to a CGRP inhibitor is defined as an adequate trial of a CGRP and the person did not experience ONE of the following:
- Reduced frequency of at least 2 fewer migraines per month or 50% reduction from baseline,
- Reduced severity of headaches, less acute medication use, improvement in MIDAS score, or
- Improvement in the ability to participate in therapies/ADLs/work/school or fewer ER/UC visits.

Personal Therapeutic Continuous Glucose Monitors (CGM)
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limit/Day	Approval Limits
Freestyle Libre & Freestyle Libre 2 CGM systems (reader, sensors)	Covered at Pharmacy	• 1 meter per 12 months • 2 sensors per 28 days	12 months
Dexcom G6 CGM system (reader, transmitters, sensors)	Covered at Pharmacy	• 1 meter per 12 months • 1 transmitter per 90 days • 3 sensors (1 kit) per 30 days	12 months

CRITERIA FOR COVERAGE:

- Diagnosis of diabetes mellitus, **AND**
- The patient is insulin-treated with multiple (3 or more) daily injections of insulin or a Medicare-covered continuous subcutaneous insulin infusion (CSII) pump, **AND**
- The patient's insulin treatment regimen requires frequent adjustment by the patient on the basis of BGM or CGM testing results, **AND**
- Within 6 months prior to ordering the CGM, the treating practitioner has a visit with the patient to evaluate their diabetes control and determined that the criteria above are met

CRITERIA FOR CONTINUATION/RENEWAL:

- The treating practitioner has a visit with the patient within the past 12 months to assess adherence to their CGM regimen and diabetes treatment plan.
- 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.

Corticotropin Gel (Acthar HP)
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits	Approval Limits
Corticotropin Gel (Acthar HP)	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.

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.

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.

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 to members who have Part D coverage with Quartz.

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.

Quartz

Eosinophilic Conditions
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits	Approval Limits
Benralizumab (Fasenra)	Medical Benefit-Restricted	None	12 months
Mepolizumab (Nucala)	Medical Benefit-Restricted	None	**Asthma or HES:** 12 months **EGPA:** Initial: 6 months Renewal: 12 months
Reslizumab (Cinqair)	Medical Benefit-Restricted	None	12 months

CRITERIA FOR COVERAGE of eosinophilic asthma (benralizumab, mepolizumab, reslizumab):

- 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 for mepolizumab, Age ≥12 years for benralizumab, ≥18 years for reslizumab, **AND**
- One of the following:
  A. Symptoms are not well controlled or poorly controlled (Table 1) despite a ≥3-month trial of high-dose inhaled corticosteroids (Table 2) in combination with a long-acting bronchodilator or leukotriene modifier*, **OR**
  B. Patient has intolerance to high dose inhaled corticosteroids in combination with a long-acting bronchodilator or leukotriene modifier. Exceptions based on adverse effects from high dose ICS or comorbid conditions increasing long-term risks of adverse effects from high dose ICS or oral corticosteroids include:
    - Cataracts in patients >40 years of age, glaucoma, recurrent thrush, dysphonia, growth inhibition (after evaluation by Endocrine Consult), diagnosis of osteoporosis (treatment resistant to FDA approved osteoporosis treatment)

AND

- **For benralizumab (Fasenra):** Trial and failure, contraindication or intolerance to self-injection of benralizumab (Fasenra) or inability to self-administer benralizumab (Fasenra)*
- **For reslizumab (Cinqair):** Trial and failure, contraindication or intolerance to self-injection of benralizumab (Fasenra) or inability to self-administer benralizumab (Fasenra)*
- **For mepolizumab (Nucala):** Trial and failure, contraindication or intolerance to self-injection of benralizumab (Fasenra) **AND** self-injection of mepolizumab (Nucala) (or inability to self-administer these injections)*

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

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

CRITERIA FOR COVERAGE for Eosinophilic Granulomatosis with Polyangiitis (mepolizumab)

- 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**
- Failure of self-injection (subcutaneous) or inability to self-administer mepolizumab injection*, **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 (mepolizumab):

- 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**
- Failure of self-injection (subcutaneous) or inability to self-administer mepolizumab injection*

CRITERIA FOR CONTINUATION/RENEWAL for eosinophilic asthma: (for renewal or 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.

CRITERIA FOR CONTINUATION/RENEWAL of mepolizumab for EGPA: (for renewal or 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.

CRITERIA FOR CONTINUATION/RENEWAL of mepolizumab for HES: (for renewal or 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 (e.g. improvement in person-specific symptoms, decrease use of acute treatments, 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.

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

Table 2. High Dose Corticosteroid

Drug	High Daily Dose (Adult)
Beclomethasone HFA 40 or 80 mcg/puff	>400 mcg
Budesonide DPI 90, 180 or 200 mcg/inhalation	>640 mcg
Ciclesonide HFA 80 or 160 mcg	> 320 mcg
Flunisolide HFA 80 mcg/puff	>640 mcg
Fluticasone HFA/MDI: 44, 110,mcg/puff DPI: 50, 100, 250 mcg/inhalation	 >500 mcg >500 mcg
Mometasone DPI 200 mcg/inhalation	>440 mcg

Esketamine Nasal Inhalation (Spravato)
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits	Approval Limits
Esketamine Nasal Inhalation (Spravato)	Medical Benefit-Restricted	None	Renewal: 12 months

CRITERIA FOR COVERAGE

- Has a diagnosis of treatment-resistant depression, **AND**
- 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, **AND**
- One of the following:
  1. Treatment was initiated during an inpatient hospitalization, **OR**
  2. Symptoms of depression continue despite an adequate trial (at or above minimum therapeutic dose for at least 4 weeks) with 3 antidepressants*, **OR**
  3. Symptoms of depression continue and there is medical documentation to show treatment limiting side effects with 3 antidepressants*

CRITERIA FOR CONTINUATION OF COVERAGE after 12 months: (for 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 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.

Quartz

Exon Skipping Drugs for Duchenne Muscular Dystrophy
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits	Approval Limits
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**.**

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).

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

Quartz

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, 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.

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**.**

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.

Quartz

Disease Modifying Therapies for Multiple Sclerosis
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits	Approval Limits
Natalizumab (Tysabri)	Medical benefit-Restricted	One infusion per month	None
Alemtuzumab (Lemtrada)	Medical benefit-Restricted	First 12 months: • 60 mg (12 mg x 5) Thereafter: • 36 mg (12 mg x 3)	None
Ocrelizumab (Ocrevus)	Medical benefit-Restricted	600 mg every six months	None
Interferon beta-1a (Avonex, Rebif)	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 or Natalizumab):

- 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 COVERAGE (Rebif):

- One of the following diagnoses:
  - Relapsing form of multiple sclerosis (includes relapsing-remitting, active secondary progressive, or relapsing-progressive disease), **OR**
  - Clinically Isolated Syndrome (CIS) with a high probability of developing Clinically Definite MS (CDMS) (i.e. ≥ 3 T2 white matter lesions or ≥ 2 GdE lesions on MRI)

  AND
- Prescribed by or in consultation with a Neurologist, **AND**
- Failure of self-injection (subcutaneous) or inability to self-administer Rebif injection*

CRITERIA FOR COVERAGE (Avonex):

- One of the following diagnoses:
  - Relapsing form of multiple sclerosis (includes relapsing-remitting, active secondary progressive, or relapsing-progressive disease), **OR**
  - Clinically Isolated Syndrome (CIS) with a high probability of developing Clinically Definite MS (CDMS) (i.e. ≥ 3 T2 white matter lesions or ≥ 2 GdE lesions on MRI)

  AND
- Prescribed by or in consultation with a Neurologist, **AND**
- Trial and failure (acute relapse or new lesion formation), contraindication or intolerance to both dimethyl fumarate AND fingolimod*, **AND**
- Failure of self-injection or inability to self-administer Avonex injection*

* 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)

- 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.

Infused Oncology Agents
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits	Approval Limits
Atezolizumab (Tecentriq)	Medical Benefit-Restricted	None	Up to 12 months
Avelumab (Bavencio)	Medical Benefit-Restricted	None	Up to 12 months
Belantamab (Blenrep)	Medical Benefit-Restricted	None	Up to 12 months
Calaspargase (Asparlas)	Medical Benefit-Restricted	None	Up to 12 months
Carfilzomib (Kyprolis)	Medical Benefit-Restricted	None	Up to 12 months
Cemiplimab (Libtayo)	Medical Benefit-Restricted	None	Up to 12 months
Daratumumab (Darzelex, Darzelex Faspro)	Medical Benefit-Restricted	None	Up to 12 months
Durvalumab (Imfinzi)	Medical Benefit-Restricted	None	Up to 12 months
Elotuzumab (Empliciti)	Medical Benefit-Restricted	None	Up to 12 months
Enfortumab (Padcev)	Medical Benefit-Restricted	None	Up to 12 months
Iobenguane I-131 Therapeutic (Azedra)**	Medical Benefit-Restricted	3 doses (1 diagnostic, 2 therapeutic)	Up to 12 months
Ipilimumab (Yervoy)	Medical Benefit-Restricted	None	Up to 12 months
Isatuximab (Sarclisa)	Medical Benefit-Restricted	None	Up to 12 months
Lurbinectedin (Zepzelca)	Medical Benefit-Restricted	None	Up to 12 months
Lutetium (Lu) 177 (Lutathera)	Medical Benefit-Restricted	4 doses	6 months
Mogamulizumab (Poteligeo)	Medical Benefit-Restricted	None	Up to 12 months
Moxetumomab (Lumoxiti)	Medical Benefit-Restricted	None	6 months
Naxitamab (Danyelza)	Medical Benefit-Restricted	None	Up to 12 months
Necitumumab (Portrazza)	Medical Benefit-Restricted	None	Up to 12 months
Pembrolizumab (Keytruda)	Medical Benefit-Restricted	None	Up to 12 months
Polatuzumab Vedotin (Polivy)	Medical Benefit-Restricted	None	Up to 12 months
Radium (Ra) 223 (Xofigo)	Medical Benefit-Restricted	None	6 months
Ramucirumab (Cyramza)	Medical Benefit-Restricted	None	Up to 12 months
Sacituzumab Govitecan (Trodelvy)	Medical Benefit-Restricted	None	Up to 12 months
Siltuximab (Sutent)	Medical Benefit-Restricted	None	Up to 12 months
Tafasitamab (Monjuvi)	Medical Benefit-Restricted	None	Up to 12 months
Trabectedin (Yondelis)	Medical Benefit-Restricted	None	Up to 12 months
Tagraxofusp-erzs (Elzonris)	Medical Benefit-Restricted	None	Up to 12 months

***Also known as metaiodobenzylguanidine [MIBG], 131I-MIBG and iodine-131-labeled Iobenguane*

CRITERIA FOR COVERAGE:

3. 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:
  - Metabolic screening (i.e. increased urinary excretion of glycolate), **OR**
  - Genetic testing, **OR**
  - Liver biopsy
- Prescribed by, or in consultation with, a Nephrologist, Urologist, or other related specialty, **AND**
- Clinical documentation of current eGFR greater than or equal to 30mL/min/1.73 m^2, **AND**
- History of kidney stones as a result of hyperoxaluria within the past 12 months

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 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%

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.
- 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.

Patisiran (Onpattro)
Prior Authorization Criteria

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

CRITERIA FOR COVERAGE:

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

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)

- For 12 month 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.

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:

8. Diagnosis of severe symptomatic tophaceous gout (chronic tophaceous gouty arthropathy in ≥ 4 joints or ≥ 1 unstable, complicated, or severe articular tophi) despite appropriate urate lowering therapy (as below) and appropriate NSAID, colchicine, and glucocorticoid use for acute attacks*, **AND**
9. Serum uric acid level >6 mg/dL despite an adequate trial of maximized therapeutic doses of allopurinol AND febuxostat (unless contraindication or intolerance)*, **AND**
10. 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.

Quartz

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.

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)*

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)
- Diagnosis of Cryopyrin-Associated Periodic Syndromes (CAPS) (including Familial Cold Auto-inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS)), **AND**
- Age ≥12 years

* 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.

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.

Quartz

Thrombopoietin Receptor Agonists
Prior Authorization Criteria

Drug Name	Drug Status	Quantity Limits	Approval Limits
Romiplostim (Nplate)	Medical Benefit-Restricted	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)

CONTINUATION OF COVERAGE CRITERIA (new to plan):
- Persons new to coverage who are established on therapy will have coverage under their drug benefit for up to 12 months. Restrictions to specific network pharmacies and participation in medication management programs may apply.

CONTINUATION OF COVERAGE/RENEWAL CRITERIA (12 month):
- 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.

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

INDEX

I

K

L

M

N

O

P

R

S

T

U

V

X

Y

Z