



MEDICAL BENEFIT ONLY MEDICATION PRIOR AUTHORIZATION CRITERIA



These medication prior authorization criteria apply to persons whose Quartz benefits **ONLY** include coverage of drugs given by a health care provider (medical benefit)

March 1, 2019



**Alglucosidase-Myozyme/Lumizyme
Prior Authorization Criteria**

FORMULARY STATUS: Medical Benefit

APPROVAL LIMITS: None

QUANTITY LIMITS: None

CRITERIA FOR COVERAGE:

- Covered for persons with a diagnosis of Pompe disease

FOR BADGERCARE COVERAGE:

- Please see Forward Health for criteria or diagnosis restrictions



**Alpha₁ Proteinase Inhibitor (Aralast NP, Glassia, Prolastin-C, Zemaira)
Prior Authorization Criteria**

FORMULARY STATUS: Medical Benefit-Restricted

APPROVAL LIMITS: None

QUANTITY LIMITS: None

CRITERIA FOR COVERAGE:

- Alpha-1 proteinase deficient (< 11 mmol/L)
- Person is no longer smoking
- Evidence of COPD (FEV₁ 25% to 80% predicted) attributable to emphysema
- Maximized COPD therapy based on GOLD guidelines



| Generic Name | Brand Name | GCN | HICL | Exception/Other |
|--------------|------------|-----|-------|-----------------|
| Belimumab | Benlysta | | 37462 | |

**Belimumab (Benlysta)
Prior Authorization Criteria**

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

APPROVAL LIMITS: 12 months

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

CRITERIA FOR COVERAGE:

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

CRITERIA FOR COVERAGE (For infusion):

- Inability to self-administer weekly injection despite adequate teaching and interventions from a pharmacist and other health care providers

CRITERIA FOR COVERAGE OF QUANTITY EXCEPTIONS:

- Symptoms persist despite treatment with one injection per week and the prescriber provides an evidence-based clinical rationale for use of a dose outside of the quantity limit

CRITERIA FOR CONTINUATION OF COVERAGE:

- Clinical documentation from the previous 12 months demonstrating benefits from therapy
- Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers

IMPORTANT INFORMATION:

Should not be used in combination with other biologics or IV cyclophosphamide

Bezlotoxumab (Zinplava®) Prior Authorization Criteria

FORMULARY STATUS: Medical benefit-Restricted

APPROVAL LIMITS: One dose

QUANTITY LIMITS: None

CRITERIA FOR COVERAGE:

- Person is 18 years or older

AND

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

AND

- Has a confirmed diagnosis of current C diff infection and a positive stool test for toxigenic C difficile from a recent stool sample

AND

- Has recurrent/refractory C diff infection

AND

- Must be currently on standard of care antibiotics for C diff (vancomycin, fidaxomicin)

AND

- Person has had a therapeutic failure, intolerance, or contraindication to fecal microbiota transplantation (FMT)

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



Biologic Therapy for Dermatology Prior Authorization Criteria

| Drug Name | Benefit | Formulary Status | Quantity Limit (maintenance/28 days) |
|---|---------|------------------|--------------------------------------|
| Infliximab (Remicade, Inflectra, Renflexis) | Medical | Restricted | N/A |
| Ustekinumab (Stelara) | Medical | Restricted | N/A |

Approval Limits: None

PSORIASIS GENERAL CRITERIA FOR COVERAGE:

1. Prescribed by a Dermatologist
2. Diagnosis of moderate to severe plaque psoriasis with significant functional disability
 - a. BSA involvement (>10%)
- OR**
- b. debilitating palmar/plantar psoriasis or other vulnerable areas that are difficult to treat such as nails, hairy/scalp areas, genitals or intertriginous areas
3. Clinical failure of prior therapy or contraindication to : Details including medication, dose, potency, duration must be provided for each therapy
 - a. Topical: (e.g. topical corticosteroids, calcipotriene, retinoids) AND
 - b. Oral Therapy: (e.g. methotrexate, mycophenolate) AND
 - c. Phototherapy: (e.g. broad band UVB, narrow band UVB, PUVA, excimer)
 - i. If clinic-based phototherapy- record of phototherapy episodes provided. Adherence defined as 3 times per week for one month or if necessary, modified regimen based on required adjustments for tolerability
 - ii. If home-based phototherapy- provision of data log recording use and dose adjustments as need for tolerability

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

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

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

For infliximab

- General criteria met
- AND**
- Failure/ intolerance to two biologic DMARDs.

For ustekinumab

- General criteria met
- AND**
- Failure/ intolerance to four biologic DMARDs

HIDRADENITIS SUPPURATIVA (HS) CRITERIA FOR COVERAGE:

1. Prescribed by a Dermatologist
- AND**
2. Severe and/or refractory disease (Hurley II/Hurley III stage) with lesions despite previous treatment with topical antibiotics, systemic antibiotics, intralesional glucocorticoids, and/or surgical debridement

Therapy options:

- Infliximab

CRITERIA FOR CONTINUATION OF THERAPY:

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



Biologic Therapy for Gastroenterology Prior Authorization Criteria

| Drug Name | Benefit | Coverage Status | Quantity per month: maintenance therapy |
|---|---------|-----------------|---|
| First Line Agents: | | | |
| Infliximab (Remicade, Inflectra, Renflexis) | Medical | Restricted | NA |
| Second Line Agents: | | | |
| Vedolizumab (Entyvio) | Medical | Restricted | NA |
| Third Line Agents | | | |
| Natalizumab (Tysabri) | Medical | Restricted | NA |
| Ustekinumab (Stelara) infusion | Medical | Restricted | single dose |

Approval Limits: None

CRITERIA FOR COVERAGE:

- Prescribed by a Gastroenterologist
- Diagnosis of inflammatory bowel disease as described below.

1. **Diagnosis of moderate to severely active Crohn's disease AND**

In a **low-risk individual**: intolerance/contraindication to 2 conventional therapies **OR** inadequate disease control or inability to achieve remission after an adequate trial of 3 months with 2 conventional therapies **OR** demonstrated steroid dependence

Therapy options

- Infliximab
- Ustekinumab in adults if failure/intolerance of 2 anti-TNF trial
- Vedolizumab in adults if failure/intolerance of 2 anti-TNF trial, **OR** contraindication to anti-TNF therapy

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

Therapy options

- Infliximab
- Ustekinumab in adults IF prior failure/intolerance of 2 anti-TNF trials
- Vedolizumab IF failure or intolerance of 2 anti-TNF trials **OR** contraindication to anti-TNF therapy

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

Therapy options

- Infliximab
- Vedolizumab IF contraindication to anti-TNF therapy **OR** failure/intolerance to two anti-TNF in attempt to avoid surgical intervention
- Ustekinumab- in adults IF failure/intolerance of 2 anti-TNF trials

For natalizumab

- General criteria met for diagnosis of moderate to severely active Crohn's disease in adults

AND

- Failure of two preferred anti-TNF therapies or a contraindication to anti-TNF therapy exists **AND** failure/intolerance to vedolizumab or ustekinumab
- Must be used as monotherapy (without immunomodulatory therapy)

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

2, Diagnosis of moderate to severely active ulcerative colitis AND

In a high-risk individual

Therapy options (after short course of corticosteroids plus azathioprine unless contraindicated)

- Infliximab
- Vedolizumab IF adult patients with a failure of anti-TNF trial or contraindication to anti-TNF therapy

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

Therapy options

- Infliximab
- Vedolizumab (failure of anti-TNF trial or contraindication to anti-TNF therapy)

CRITERIA FOR CONTINUATION OF THERAPY:

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

IMPORTANT INFORMATION:

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

For persons already established on biologic therapy, consider dose escalation, addition of immunomodulator or change in biologic therapy (different anti-TNF or different class) as appropriate based on drug concentrations and antibody levels as noted below

- If remission not achieved or disease relapsed on adalimumab/infliximab and subtherapeutic drug concentration with high antibody level then change to drug within the same class (i.e. Infliximab to adalimumab OR adalimumab to infliximab)
- If remission not achieved or disease relapsed on adalimumab/infliximab and subtherapeutic drug concentration with low or absent antibody level then
 - Increase adalimumab/infliximab dose
 - Decrease the dosing interval
 - Add immunomodulator to anti-TNF therapy
- If remission not achieved or disease relapsed on adalimumab/infliximab therapy based on therapeutic drug concentrations and lack of anti-drug antibodies (primary non-response or secondary loss of response) AND inflammation still present, then change to different drug class
 - Vedolizumab
 - Ustekinumab

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

High Risk in Ulcerative Colitis:

-Patient with extensive colitis, deep ulcers, age<40 years, High CRP and ESR, steroid-requiring disease, history of hospitalization, *C difficile* infection, CMV infection

OR

-Low risk patient (with limited anatomic disease or mild endoscopic disease) AND inability to achieve remission on induction and maintenance therapy with conventional agents **OR** achieved remission on induction and maintenance therapy but has relapsed after steroid taper (primary non-response or secondary loss of response)

High Risk in Crohn's Disease:

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

Induction and Maintenance Therapy with Conventional Agents:

-Conventional therapy with immunomodulator therapy such as azathioprine, balsalazide, corticosteroids, mesalamine, mercaptopurine, methotrexate, sulfasalazine

Steroid Dependence:

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

Inflammatory status: Signs/Symptoms/Labs/Endoscopy for diagnosis

-Bloody diarrhea, weight loss, tenesmus, urgency, abdominal pain, fever, joint swelling/redness, localized abdominal tenderness, anemia, cutaneous signs

-CBC, CMP, CRP, ESR, stool cultures, *C difficile* assay, fecal calprotectin

-endoscopy, colonoscopy, sigmoidoscopy

Ulcerative Colitis Disease Severity:

Based on the degree of presentation of the signs and symptoms and change in baseline inflammatory status

Moderate disease - more than four stools per day with minimal signs of toxicity, anemia, abdominal pain, low grade fever

Severe disease - more than six bloody stools per day, fever, tachycardia, anemia or elevated ESR or CRP

Primary non-response to anti-TNF therapy:

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

Secondary loss of response to anti-TNF therapy:

Re-emerging symptoms appear where they were previously controlled and are due to inflammation and not other causes. (i.e. irritable bowel disease, infection, non-inflammatory component of IBD, etc).

The inability to maintain steroid-free complete remission after achieving symptomatic response.

This can be managed by assessment of drug concentrations and antibody levels to determine if dose increase or therapy change.

Crohn's Disease Classification:

Stricturing - narrowing of bowel that may cause bowel obstruction

Penetrating - fistulae may form between bowel and other structures

Inflammatory - nonstricturing, nonpenetrating - inflammation without strictures or fistula

References:

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.

Biologic Therapy for Rheumatology Prior Authorization Criteria

| Drug Name | Benefit | Formulary Status | Quantity Limit (maintenance/28 days) |
|--|---------|------------------|--------------------------------------|
| Abatacept infusion (Orencia) | Medical | Restricted | N/A |
| Golimumab infusion (Simponi Aria) | Medical | Restricted | N/A |
| Infliximab infusion (Remicade, Inflectra, Renflexis) | Medical | Restricted | N/A |
| Tocilizumab infusion (Actemra) | Medical | Restricted | N/A |
| Ustekinumab (Stelara) | Medical | Restricted | N/A |

Approval Limits: None

RHEUMATOLOGY INDICATION GENERAL CRITERIA FOR COVERAGE:

- Prescribed by a Rheumatologist
1. **For diagnosis of** moderate to severely active established (disease duration of greater than 6 months) rheumatoid arthritis (RA), reactive arthritis, or juvenile idiopathic arthritis (JIA)
 - Documented failure with a 3 month trial of methotrexate at therapeutic doses unless contraindicated

OR

 - Persons intolerant to, or with a contraindication to MTX therapy should fail an adequate trial (3 months) with another disease modifying anti-rheumatic drugs such as hydroxychloroquine, sulfasalazine, leflunomide or minocycline
 2. **For diagnosis of** early RA (less than 6 months disease duration) with feature of poor prognosis (at least one item)
 1. Functional limitations (based on HAQ or similar tool)
 2. Extraarticular disease (e.g. presence of rheumatoid nodules, RA vasculitis or Felty's syndrome (rheumatoid arthritis with splenomegaly and neutropenia)
 3. Positive rheumatoid factor or anti-cyclic citrullinated peptide antibodies (anti-CCP antibodies)
 4. Bony erosions on X-ray.
 3. **For diagnosis of** ankylosing spondylitis (AS) not controlled by a 2 month trial of scheduled prescription doses of two different NSAIDs (such as naproxen, nabumetone, diclofenac, etc.)
 4. **For diagnosis of** moderate to severely active psoriatic arthritis (PsA) and documented failure/intolerance to adequate trial (minimum 3 months) of methotrexate therapy (unless contraindication)

DRUG-SPECIFIC CRITERIA FOR COVERAGE:

For golimumab

- General criteria met
- Failure/intolerance of three biologic DMARDs for a diagnosis of AS
- Failure/intolerance of four biologic DMARDs with a diagnosis of RA, reactive arthritis, JIA, other auto-inflammatory arthropathies, or PsA **AND** used in combination with methotrexate unless contraindicated

For infliximab

- General criteria met
- Failure/intolerance of two biologic DMARDs

For abatacept

- General criteria met
- Failure/intolerance of two biologic DMARDs **OR** Contraindication to anti-TNF therapy

For tocilizumab

- General criteria met
 - Diagnosis of moderate to severely active established RA, JIA or reactive arthritis
 - Failure/intolerance to two biologic DMARDs **OR** Contraindication to anti-TNF therapy
- OR**
- General criteria met
 - Diagnosis of systemic juvenile idiopathic arthritis or adult-onset Still's disease
 - Failure of an adequate trial (3 months) of corticosteroids and methotrexate

OR

- General criteria met
- Diagnosis of giant cell arteritis which has relapsed despite use of corticosteroids or methotrexate
- Inability to taper corticosteroids

OR

(Intravenous only) Approval of therapy for chimeric antigen receptor (CAR) T cell to treat T-cell –induced severe or life-threatening cytokine release syndrome (CRS) in patients two years of age or older

For ustekinumab

- General criteria met
- Diagnosis of PsA
- Failure/intolerance to four biologic DMARDs

CRITERIA FOR CONTINUATION OF THERAPY:

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



**Botulinum toxin (Botox, Dysport, Myobloc, Xeomin)
Prior Authorization Criteria**

FORMULARY STATUS: Medical Benefit-Restricted

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

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

CRITERIA FOR COVERAGE:

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

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

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

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



- Hyperhidrosis- when causing persistent or chronic cutaneous conditions (e.g., skin maceration, dermatitis, fungal infections)

AND

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

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

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

CRITERIA FOR REAPPROVAL/CONTINUATION OF THERAPY:

for MIGRAINE HEADACHES:

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

for all Other Diagnoses:

- For members new to the plan: must have a listed diagnosis above and the prescriber must provide clinical documentation from the previous 12 months verifying the person is established on therapy.
- Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.

CRITERIA FOR COVERAGE OF QUANTITY EXCEPTIONS for MIGRAINE HEADACHES:

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

FOR BADGERCARE COVERAGE:

- Please see Forward Health for criteria or diagnosis restrictions.



Buprenorphine Injections Prior Authorization Criteria

FORMULARY STATUS: Medical Benefit-Restricted

PRODUCTS: Probuphine Implant
Sublocade ER injection

APPROVAL LIMITS: 12 months (two treatment cycles)- Probuphine
18 months- Sublocade

QUANTITY LIMITS: None

CRITERIA FOR COVERAGE:

- Prescriber must provide documentation that the person is actively participating in a recovery program (i.e. therapy, group sessions, counseling, psychosocial support etc.)

AND

- The person is established on transmucosal buprenorphine-containing product and achieved sustained (6 months or greater) clinical stability on doses of no more than 8mg per day. (Probuphine)
 - OR
- The person has initiated treatment with a transmucosal buprenorphine-containing product followed by dose adjustment for a minimum of seven days (Sublocade)

CRITERIA FOR DURATION EXCEPTIONS:

- Clinical rationale for use beyond two treatment cycles is provided and supplemented by published clinical evidence (Probuphine)
- For use beyond 18 months, documentation of continued active participation in counseling/therapy sessions and clinical rationale provided for continued use beyond 18 months.

CONTINUATION OF COVERAGE CRITERIA:

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

IMPORTANT INFORMATION:

- Use of buprenorphine implants beyond 12 months (two treatment cycles-one insertion in each upper arm) is not recommended.
- The use of implants is inappropriate for those new to treatment or those who have not achieved sustained clinical stability while being maintained on buprenorphine-containing product of 8mg per day or less
- Prescriber must be enrolled in the Probuphine Risk Evaluation and Mitigation Strategy (REMS) program



**Burosumab (Crysvita)
Prior Authorization Criteria**

FORMULARY STATUS: Medical Benefit-Restricted

APPROVAL LIMITS: Initial – 12 months
Renewal - indefinite

QUANTITY LIMITS: None

CRITERIA FOR COVERAGE:

- Age \geq 1 year
- Diagnosis of X-linked hypophosphatemia
- Low serum phosphate levels (age appropriate) despite at least six months of maximally tolerated oral phosphate and vitamin D supplementation
- Radiographical evidence of rickets (children) or osteomalacia-associated bone disease (adults)

CONTINUATION OF COVERAGE CRITERIA:

- Age \geq 1 year and a diagnosis of X-linked hypophosphatemia
- Documentation from the previous 12 months of normalized serum phosphorus and clinically significant improvement from baseline* in bone health (reduced Rickets Severity Score (RSS), improved Radiographic Global Impression of Change (RGI-C), improved osteomalacia-related fracture/pseudofracture counts, or decreased Osteoid volume/Bone volume)

*baseline and current values must be provided for evaluation

Note: 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**

FORMULARY STATUS: Medical Benefit-Restricted

APPROVAL LIMITS: None

QUANTITY LIMITS: None

CRITERIA FOR COVERAGE:

1. Diagnosis of Cryopyrin-associated Periodic Syndromes (CAPS) in adults and children over 4 years of age, Familial Cold Autoinflammatory Syndrome (FCAS), Muckle-Wells Syndrome (MWS), Familial Mediterranean Fever, tumor necrosis factor receptor-associated periodic syndrome or other periodic syndromes AND
 - a. Failure or intolerance to anakinra (Kineret)

OR

2. Systemic juvenile idiopathic arthritis (SJIA): AND
 - Failure or intolerance to prior therapies such as glucocorticoids or NSAIDsAND
 - Failure or intolerance to anakinra (Kineret)

CRITERIA FOR CONTINUATION OF THERAPY (SJIA only):

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

IMPORTANT INFORMATION:

Per product labeling, healthcare providers should administer Canakinumab to the patient.



Compounded Prescriptions* Prior Authorization Criteria

| | |
|--------------------------|-----------|
| FORMULARY STATUS: | Varies |
| APPROVAL LIMITS: | 12 months |
| QUANTITY LIMITS: | None |

CRITERIA FOR COVERAGE:

- Medication is not commercially available in a formulation that is suitable for the patient
- Adequate published evidence supports the use of the medication in the concentration prescribed and in the route that will be used for the patient's condition
- None of the products in the compound are otherwise excluded from coverage as defined by the person's benefit
- None of the products in the compound are experimental or limited by the FDA to investigational use only.

*See separate prior authorization criteria for compounded hormones

CRITERIA FOR COVERAGE OF DURATION EXCEPTIONS:

- Above criteria are met AND
- Prescriber provides clinical documentation from the previous 12 months that describes the person's response as stable disease or improvement seen on therapy.
- Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage



**Corticotropin Gel (Acthar HP)
Prior Authorization Criteria**

FORMULARY STATUS: Medical Benefit-Restricted

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

QUANTITY LIMITS: None

CRITERIA FOR COVERAGE:

- Age \leq 1 year
- Diagnosis of infantile spasm by a Neurologist with electroencephalogram pattern consistent with hypsarhythmia

CRITERIA FOR RE-APPROVAL/CONTINUATION OF THERAPY:

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

IMPORTANT INFORMATION:

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

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

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



Denosumab (Prolia, Xgeva) Prior Authorization Criteria

FORMULARY STATUS: Medical benefit - Restricted

APPROVAL LIMITS: None

QUANTITY LIMITS: None

CRITERIA FOR COVERAGE:

Prolia:

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

OR

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

OR

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

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

Xgeva:

Being used for **one** of the following indications:

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

AND

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

OR

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

OR

- For a different FDA labeled indication that is not addressed above



CONTINUATION OF CARE CRITERIA:

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

Important information:

Medications administered in the clinic are not included in the pharmacy benefit. They are covered by the medical benefit and must be procured by the clinic that is administering the medication.



Drugs for Eosinophilic Conditions Prior Authorization Criteria

FORMULARY STATUS:

| | |
|--------------------------|----------------------------|
| Benralizumab (Fasenra) - | Medical Benefit-Restricted |
| Mepolizumab (Nucala) - | Medical Benefit-Restricted |
| Reslizumab (Cinqair) - | Medical Benefit-Restricted |

APPROVAL LIMITS:

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

QUANTITY LIMITS:

12 visits

CRITERIA FOR COVERAGE of eosinophilic asthma:

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

AND

4. Symptoms are not well controlled or poorly controlled (Table 1) despite an adherent** \geq 3 month trial of high-dose inhaled corticosteroids (Table 2) in combination with a long-acting bronchodilator or leukotriene modifier

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

OR

- a. Patient has intolerance to high dose inhaled corticosteroids in combination with a long-acting bronchodilator or leukotriene modifier. Exceptions based on adverse effects from high dose ICS or comorbid conditions increasing long-term risks of adverse effects from high dose ICS or oral corticosteroids
 - o Cataracts in patients > 40 years of age
 - o Glaucoma
 - o Recurrent thrush
 - o Dysphonia
 - o Growth inhibition, after evaluation by Endocrine Consult
 - o Diagnosis of osteoporosis, treatment resistant to FDA approved osteoporosis treatment
5. IL-5 inhibitor in combination with omalizumab will only be considered on a case by case basis if each individual agent with combination high dose ICS/LABA did not control symptoms

CRITERIA FOR COVERAGE of mepolizumab (Nucala) for eosinophilic granulomatosis with polyangiitis (EGPA) (formerly known as Churg-Strauss Syndrome)

1. Prescribed by a provider experienced in the treatment EGPA (i.e. allergist, pulmonologist or rheumatologist)
2. Age \geq 18 years
3. Confirmed diagnosis of relapsed*or refractory† EGPA defined as:
 - a. Blood eosinophil level of \geq 10% or an absolute eosinophil count >1000 cells/ μ L with other causes ruled out (i.e. hypereosinophilic syndromes, neoplastic disease, or parasitic disease) AND
 - b. At least TWO of the following organ systems or features of EGPA disease:
 - o Histopathological evidence of
 - eosinophilic vasculitis (i.e. bleeding under skin, red rash, petechiae, fibrinoid degeneration, blood clots) OR
 - perivascular eosinophilic infiltration (i.e. inflammatory cells around blood vessels, lichenoid infiltration) OR
 - eosinophil-rich granulomatous inflammation (i.e. nodules, thick aggregation of histiocytes)

- 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]
4. Person has failed prednisone and failed[‡] a therapeutic trial (3 months) or is intolerant to at least ONE immunosuppressive agent (i.e. cyclophosphamide, azathioprine, or methotrexate).
 5. Baseline disease severity assessed with an objective measure/tool (i.e. chronic oral corticosteroid dose, number of intermittent steroid bursts, Birmingham Vasculitis Activity Score BVAS, number urgent care, emergency room visits or hospitalizations etc.)

CRITERIA FOR CONTINUATION/RENEWAL for eosinophilic asthma:

1. The prescriber must provide clinical documentation from an office visit in the preceding 12 months showing response to therapy such as:
 - a. Decreased frequency of use of, or ability to lower the chronic daily dose, of oral corticosteroids to treat/prevent exacerbations
 - b. Decreased frequency of use of unscheduled emergency department/urgent care visits for exacerbations
 - c. Reduction in reported symptoms such as chest tightness, coughing, shortness of breath, or nocturnal awakenings
 - d. Sustained (at least six months) improvement in Asthma Control Test (ACT) scores
2. Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.

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

CRITERIA FOR CONTINUATION/RENEWAL of mepolizumab for EGPA:

1. The prescriber must provide clinical documentation from an office visit in the preceding 12 months showing a response to therapy based upon at least ONE objective measure such as:
 - a. Birmingham Vasculitis Activity Score (BVAS version 3) improvement from baseline (i.e. a clinically significant score improvement for vasculitis is 16 units or greater)
 - b. Reduction in the total daily dose of prednisolone/prednisone (50-75% reduction in dose from baseline) or reduction in intermittent steroid bursts
 - c. Improvement in the duration of remission or improvement in rate of relapses, urgent care, emergency room visits or hospitalizations.
2. Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.

IMPORTANT INFORMATION:

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

*Definition of relapsing EGPA; at least one confirmed EGPA relapse while the person was on prednisolone dose of ≥ 7.5 mg (or equivalent) within the past 2 years that required an increase in oral corticosteroid dose, initiation/increased immunosuppressive therapy dose, or hospitalization

†Definition of refractory EGPA: 1) failure to attain remission (BVAS = 0 and oral steroid dose \leq 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 \geq 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 (j.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 | \geq 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 \geq 2 times in the past year | Yes | Yes |
| Asthma Control Test (ACT) | 16-19 | \leq 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 | >500 mcg |
| DPI: 50, 100, 250 mcg/inhalation | >500 mcg |
| Mometasone DPI 200 mcg/inhalation | >440 mcg |

Dupilumab (Dupixent) Prior Authorization Criteria

| | |
|--------------------------|---|
| FORMULARY STATUS: | Medical Benefit-Restricted |
| APPROVAL LIMITS: | Initial: 6 months; after 6 months, 12 months |
| QUANTITY LIMITS: | Loading dose x 1 Maintenance dose: Two injections per 28 days (#2) |

CRITERIA FOR INITIAL COVERAGE:

1. Atopic Dermatitis

- Age ≥ 18 years **AND**
- Diagnosis of moderate to severe atopic dermatitis (based on body surface area (>10%), extent of disability, extent of pruritus, or impact on sleep, quality of life, current use of systemic immunomodulators) **AND**
- Clinical failure* or side effects from optimized topical treatment with either a moderate to high-potency topical steroid or a topical calcineurin inhibitor **AND**
- Clinical failure* of phototherapy, unless not indicated based on area affected,
 - If clinic-based phototherapy- record of phototherapy episodes provided. Adherence defined as 3 times per week for one month or if necessary, modified regimen based on required adjustments for tolerability
 - If home-based phototherapy- provision of data log recording use and dose adjustments as needed for tolerability

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

2. Eosinophilic Asthma

- Prescribed by an asthma specialist (e.g. Allergist, Immunologist) **AND**
- Age ≥ 12 years old **AND**
- Has a diagnosis of eosinophilic asthma with a documented blood eosinophil count of ≥ 150 cells/mm³ (other causes of eosinophilia such as hypereosinophilic syndromes, neoplastic disease, or parasitic disease must be ruled out)

AND

- Symptoms are not well controlled or poorly controlled (Table 1) despite an adherent** ≥ 3 month trial of high-dose inhaled corticosteroids (Table 2) in combination with a long-acting bronchodilator or leukotriene modifier

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

OR

- Patient has intolerance to high dose inhaled corticosteroids in combination with a long-acting bronchodilator or leukotriene modifier. Exceptions based on adverse effects from high dose ICS or comorbid conditions increasing long-term risks of adverse effects from high dose ICS or oral corticosteroids
 - Cataracts in patients > 40 years of age
 - Glaucoma

- Recurrent thrush
- Dysphonia
- Growth inhibition, after evaluation by Endocrine Consult
- Diagnosis of osteoporosis, treatment resistant to FDA approved osteoporosis treatment

CRITERIA FOR RENEWAL

- **DERMATITIS:** Clinical documentation from the previous 6-12 months of improvement, e.g. body surface area, sleep, itching, other comorbidities, etc.
- **ASTHMA:** The prescriber must provide clinical documentation from an office visit in the preceding 12 months showing response to therapy such as:
 - Decreased frequency of use of, or ability to lower the chronic daily dose, of oral corticosteroids to treat/prevent exacerbations
 - Decreased frequency of use of unscheduled emergency department/urgent care visits for exacerbations
 - Reduction in reported symptoms such as chest tightness, coughing, shortness of breath, or nocturnal awakenings
 - Sustained (at least six months) improvement in Asthma Control Test (ACT) scores

CRITERIA FOR QUANTITY EXCEPTIONS:

- Prescriber provides a clinical, evidence-based rationale for use of a dosing regimen outside of the quantity limit

Eculizumab (Soliris) Prior Authorization Criteria

FORMULARY STATUS: Medical Benefit- Restricted

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

QUANTITY LIMITS: None

CRITERIA FOR COVERAGE:

- Confirmed diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) by flow cytometry
 - Prescribed by Hematologist or Oncologist **AND**
 - Document baseline hemoglobin (≤ 9 mg/dL with symptoms of anemia), lactate dehydrogenase level (≥ 1.5 X ULN), decreased serum haptoglobin level and/or number of transfusions in last year **AND**
 - Document clinical manifestations of disease (e.g. major vascular event, transfusion dependence, renal insufficiency, disabling fatigue and/or other end organ manifestations)

OR

- Diagnosis of atypical hemolytic uremic syndrome (aHUS)
 - Prescribed by a Hematologist, Nephrologist or Oncologist **AND**
 - Document baseline level of one or more values (e.g. lactate dehydrogenase, serum creatinine/eGFR, platelet count and/or plasma exchange(PLEX)/infusion requirements). **AND**
 - Documentation states that Thrombotic Thrombocytopenic Purpura (TTP) and Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS) has been ruled out. The secondary cause of aHUS is stated if known. (eculizumab is not indicated for STEC-HUS).

OR

- Diagnosis of Myasthenia Gravis Foundation of America (MGFA) class II to IV disease
 - Prescribed by a Neurologist **AND**
 - Positive serologic test for anti-acetylcholine receptor (AChR) antibodies **AND**
 - Baseline Myasthenia Gravis Activities of Daily Living (MG-ADL) total score ≥ 6 **AND** document a baseline level of one or more values (e.g. number of Myasthenia Gravis exacerbations/hospitalizations in the past year, number of PLEX or intravenous immune globulin (IVIG) infusions in the past year and/or Quantitative Myasthenia Gravis (QMG) score) **AND**
 - Failure* of two immunosuppressive therapies for at least 6 months with a baseline refill pattern of at least 80% adherence. If intolerance occurs, one other immunosuppressive agent must be tried.
 - Immunosuppressive therapies include: prednisone, azathioprine, cyclophosphamide, cyclosporine, mycophenolate, tacrolimus or rituximab.
 - If all immunosuppressive agents are contraindicated or not clinically appropriate, justification must be documented, and the requirement *may be waived*.
 - AND**
 - Failure* of at least one of the following treatments:
 - Failure, intolerance, or contraindication to at least 3 months of therapeutic doses of IVIG **OR**

- Failure, intolerance or contraindication to PLEX given at least four times per year without symptom control.

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

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

CRITERIA FOR CONTINUATION OF COVERAGE

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

OR

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

OR

- Diagnosis of Myasthenia Gravis Foundation of America (MGFA) class II to IV disease
 - Initiation criteria met **AND**
 - MG ADL score must improve with at least a 3-point reduction from baseline **AND**
 - Documentation of improvement or clinical stability for renewal (e.g. number of myasthenia gravis exacerbations/hospitalizations in the past year, number of PLEX/IVIG infusions in the past year and/or QMG score)
- For members new to the plan, the prescriber must provide clinical documentation from the previous 12 months of the person’s response to therapy (e.g. clinical manifestation stability/improvement based upon the continuation criteria above).
- Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.

OTHER INFORMATION:

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

Myasthenia Gravis Foundation of America (MGFA) Abbreviated Classifications:

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

MGFA scoring tools are available here:

www.myasthenia.org/HealthProfessionals/EducationalMaterials.aspx



**Edaravone (Radicava)
Prior Authorization Criteria**

FORMULARY STATUS: Medical Benefit-Restricted

APPROVAL LIMITS: 12 months

QUANTITY LIMITS: None

CRITERIA FOR COVERAGE:

ALL OF THE FOLLOWING MUST BE MET:

- Prescribed by a Neurologist or other specialist in treating amyotrophic lateral sclerosis (ALS)
- AND**
- Diagnosis of definite or probable ALS based on El Escorial revised Airlie House diagnostic criteria
- AND**
- Independent living status (ie, Japan ALS Severity Classification Grade 1 or 2)
- AND**
- Score of ≥ 2 on all 12 items of the ALS Functional Rating Scale (ALSFRS-R) (assessed and documented within the last 3 months)
- AND**
- FVC % predicted $\geq 80\%$ (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 whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers



| Generic Name | Brand Name | GCN | HICL | Exception/Other |
|---------------|------------|-----|-------|-----------------|
| Elapegademase | Revcovi | | 45340 | |

**Elapegademase (Revcovi)
Prior Authorization Criteria**

FORMULARY STATUS: Medical Benefit-Restricted

APPROVAL LIMITS: 12 months

QUANTITY LIMITS: None

CRITERIA FOR COVERAGE:

- The drug is prescribed by an expert in the treatment of immune deficiencies

AND

Person has a diagnosis of adenosine deaminase severe combined immune deficiency (ADA-SCID)

CRITERIA FOR CONTINUATION/RENEWAL OF COVERAGE:

The prescriber provides recent clinical documentation (within the past 6 months) of a trough plasma ADA activity ≥ 30 mmol/hr/L and a trough erythrocyte dAXP level below 0.02 mmol/L



Hemophilia Factor Products Prior Authorization Criteria

| | |
|--|--|
| Factor XIII Products: | Corifact |
| Factor IX Products: | Alphanine SD, Mononine, Bebulin VH, Profilnine SD, Benefix RT, Ixinity, Idelvion, Rixubis, Aprolix, Rebinyn |
| Factor VIII Products: | Eloctate, Nuwiq, Afstyla, Adynovate, Recombinate, Kovaltry, Kogenate FS, Helixate FS, Advate, Koate, Hemofil, Monoclate-P, Xyntha, Novoeight, JIVI |
| von Willebrand Factor Products: | Wilate, Alphanate, Humate-P |
| Factor VII Products: | NovoSeven RT |
| Factor X Products: | Coagadex |
| Anti-Inhibitor Products: | Feiba NF |

FORMULARY STATUS: Medical Benefit - Restricted

APPROVAL LIMITS: None

QUANTITY LIMITS: None

CRITERIA FOR COVERAGE:

- Medication must be provided from a preferred provider
 - UW Health Specialty Pharmacy 1-866-894-3784



Gonadotropin Releasing Hormone (GNRH) Agonist Prior Authorization Criteria

| Drug Name | Brand name | Benefit | Coverage Status |
|--|----------------------------------|-------------------------------|--|
| Leuprolide acetate suspension IM injection | Lupron Depot Lupron Depot-Ped | Medical (clinic administered) | Covered unless excluded by certificate |
| Leuprolide acetate suspension Sub Q injections | Eligard, Atrigel | Medical (clinic administered) | Covered unless excluded by certificate |
| Histrelin implant yearly | Supprelin LA Vantas | Medical (clinic administered) | Covered unless excluded by certificate |

APPROVAL LIMITS: Varies by benefit

QUANTITY LIMITS: NONE

CRITERIA FOR COVERAGE:

If medication is being administered in a clinic setting by a health care provider, coverage on the pharmacy benefit is excluded. The drug must be obtained by the clinic and billed under person's medical benefit.

- Medications used for treatment of infertility are excluded from coverage unless specifically noted as covered in the certificate of coverage or included in specific state mandates.
- Medications used for the treatment of gender dysphoria are covered unless specifically excluded in the certificate of coverage.
- Medications used for all other diagnoses (ex. prostate cancer, endometriosis, dysmenorrhea, etc) are /covered and do not require prior authorization on the medical benefit.

The person's current certificate of coverage, SBC, or any related documents will be verified to assess exclusions or mandates with each request.

Human Chorionic Gonadotropin (HCG)/Clomiphene Prior Authorization Criteria

FORMULARY STATUS: Medical Benefit-Restricted

PRODUCTS INCLUDED: Novarel, Pregnyl

APPROVAL LIMITS: None

QUANTITY LIMITS: None

CRITERIA FOR COVERAGE:

1. Covered for indications that are not excluded from coverage based by the person's plan benefits (e.g. infertility). Use for hypogonadism is limited to coverage on the prescription drug benefit.

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



Hereditary Angioedema Medications Prior Authorization Criteria

FORMULARY STATUS:

| | |
|--|----------------------------|
| C1 Esterase Inhibitor (Berinert, Cinryze, Haegarda, Ruconest) | Medical Benefit-Restricted |
| Icatibant (Firazyr) | Medical Benefit-Restricted |
| Ecallantide (Kalbitor) | Medical Benefit-Restricted |

APPROVAL LIMITS: None

QUANTITY LIMITS: None

CRITERIA FOR COVERAGE:

- Diagnosis of Hereditary Angioedema (HAE)
 - Low C4 AND low C1 inhibitor level or function OR
 - Normal C1 inhibitor level AND family history of HAE AND high dose antihistamines did not work

AND

- Prescribed by an Allergist or other provider with experience in the treatment of HAE

AND

- Confirm person is not taking medications that may cause angioedema (e.g. ACE inhibitors, estrogens, ARBS)

AND

- For long term prophylaxis: history of ≥ 2 attacks per month or person's symptoms are moderate to severe

Infused Disease Modifying Therapies for Multiple Sclerosis Prior Authorization Criteria

FORMULARY STATUS:

| | |
|--------------------------|----------------------------|
| Natalizumab (Tysabri) - | Medical Benefit-Restricted |
| Alemtuzumab (Lemtrada) - | Medical Benefit-Restricted |
| Ocrelizumab (Ocrevus) - | Medical Benefit-Restricted |

APPROVAL LIMITS: None

QUANTITY LIMITS:

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

CRITERIA FOR COVERAGE (Ocrelizumab):

Drug must be prescribed and monitored by a Neurologist or other expert in the treatment of multiple sclerosis

AND

1. Relapsing forms of multiple sclerosis
 - o Person with clinical documentation of a diagnosis of relapsing multiple sclerosis
 - o Treatment failure, clinically significant side effect, or labeled contraindication to:
 - A preferred oral drug (Gilenya or Tecfidera)

OR

2. Progressive forms of multiple sclerosis
 - o Person with clinical documentation of a diagnosis of a progressive form of multiple sclerosis (secondary progressive, primary progressive, or relapsing progressive)

CRITERIA FOR COVERAGE (Alemtuzumab or Natalizumab):

- Medication must be prescribed and monitored by a Neurologist or other expert in the treatment of multiple sclerosis
- Person with a diagnosis of a relapsing form of multiple sclerosis
- Person must have had a treatment failure, a clinically significant side effect, or a labeled contraindication to :
 1. a preferred oral drug (Gilenya, Tecfidera)

* if side effect or contraindication the alternative oral therapy must be trialed

CRITERIA FOR CONTINUATION OF THERAPY:

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

Note:

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

For criteria for coverage of natalizumab for patients with a diagnosis of inflammatory bowel disease please see the attached Biologic Therapies for Gastroenterology criteria.

IMPORTANT INFORMATION:

Natalizumab can only be administered as monotherapy. Proper wash-out periods of prior therapy are required.

Natalizumab, ocrelizumab, and alemtuzumab are clinic administered medications, which are covered under the medical benefit.

DEFINITIONS:

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

Clinically significant side effect: side effect that prevents adherent use of the prerequisite DMT despite interventions from the specialty pharmacist and other health care providers to minimize or mitigate the side effect



**Infused Oncology Agents
Prior Authorization Criteria**

INCLUDED DRUGS:

| Generic Name | Brand Name | Approval Limits |
|---------------------|-------------------|--|
| Atezolizumab | Tecentriq | None |
| Avelumab | Bavencio | None |
| Carfilzomib | Kyprolis | None |
| Daratumumab | Darzelex | None |
| Durvalumab | Imfinzi | None |
| Elotuzumab | Empliciti | None |
| Iobenguane iodine | Azedra | 3 doses (1 diagnostic, 2 therapeutic) |
| Ipilimumab | Yervoy | None |
| Lutetium (Lu) 177 | Lutathera | 4 doses |
| Mogamulizumab | Poteligeo | None |
| Necitumumab | Portrazza | None |
| Nivolumab | Opdivo | None |
| Pembrolizumab | Keytruda | None |
| Radium (Ra) 223 | Xofigo | 6 months |
| Ramucirumab | Cyramza | None |
| Siltuximab | Sylvant | None |
| Trabectedin | Yondelis | None |

FORMULARY STATUS: Medical Benefit - Restricted

QUANTITY LIMITS: None

CRITERIA FOR COVERAGE:

- Drug must be prescribed and monitored by an Oncologist, Hematologist, or other specialist in the treatment of malignancy

AND

- The requested drug is FDA-labeled for the treatment of the specific condition the person presents with*
OR
- The requested drug has a class 1 or 2 recommendation for use from the National Comprehensive Cancer Network (NCCN) in the specific condition of the person*
OR
- **(Minnesota plans only)** - the requested drug is recommended for use in the specific condition of the person* in either the United States Pharmacopeia Drug Information or the American Hospital Formulary Service Drug Information or one article in a major peer-reviewed medical journal recognizes the safety and efficacy of the requested drug in the person's specific condition
OR
- **(Illinois plans only)** – the requested drug is recommended for use in the specific condition of the person* in the American Hospital Formulary Service Drug Information, Thompson Micromedex's Drug Dex, Elsevier Gold Standard's Clinical Pharmacology, or two articles in peer-reviewed professional medical journals from the United States or Great Britain recognize the safety and efficacy of the requested drug in the person's specific condition.

*includes any relevant genetic testing, mutations, etc.



**Letermovir (Prevymis)
Prior Authorization Criteria**

| | |
|--------------------------|------------------------------|
| FORMULARY STATUS: | Medical Benefit-Restricted |
| APPROVAL LIMITS: | To Day # 100 post-transplant |
| QUANTITY LIMITS: | None |

CRITERIA FOR COVERAGE:

- The drug is prescribed by a Hematologist
- AND**
- Covered for the adults post-allogeneic hematopoietic stem cell transplant
- AND**
- Are cytomegalovirus (CMV)-seropositive recipients (R+)
- AND**
- Drug is initiated within the first 28 days post-transplant
- AND**
- The person does not have active CMV infection

CONTINUATION OF COVERAGE CRITERIA:

- Persons new to coverage who are established on therapy will have coverage under their drug benefit for the remainder of the current treatment course (to a maximum of Day 100 post-transplant). Restrictions to specific network pharmacies and participation in medication management programs may apply.
- Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.



**Naltrexone extended-release injectable suspension (Vivitrol)
Prior Authorization Criteria**

FORMULARY STATUS: Medical Benefit

APPROVAL LIMITS: 18 months

QUANTITY LIMITS: 380mg intramuscularly every 28 days (#1)

CRITERIA FOR COVERAGE:

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

CRITERIA FOR COVERAGE OF QUANTITY EXCEPTIONS:

- The prescriber presents an evidence-based rationale for using a dosing regimen outside of the quantity limit.

CONTINUATION OF COVERAGE CRITERIA:

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

CRITERIA FOR DURATION EXCEPTIONS:

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

FOR BADGERCARE COVERAGE:

- Please see Forward Health for criteria or diagnosis restrictions.

IMPORTANT INFORMATION:

Naltrexone ER injection is administered via intramuscular injection by a health care provider, typically at an outpatient office visit and is billed as part of the medical benefit.

When naltrexone ER injection is used, it should only be a component within a comprehensive management program that includes psychosocial support.

For details on how to locate and access a Behavioral Health or AODA provider, contact UW Behavioral Health Care Management at 800-683-2300 and ask for a consultation specialist.



| Generic Name | Brand Name | GCN | HICL | Exception/Other |
|--------------|------------|-----|------|-----------------|
| nusinersen | Spinraza | | | |

**Nusinersen (Spinraza)
Prior Authorization Criteria**

FORMULARY STATUS: Medical Benefit Restricted

APPROVAL LIMITS: 12 months

QUANTITY LIMITS: None

CRITERIA FOR COVERAGE:

- Diagnosis of Spinal muscle atrophy (SMA) based on genetic testing documenting 5q SMA (homozygous gene deletion or mutation) and having at least 2 copies of SMN2 gene.

AND

- Ordered by Neurologist or other clinician with expertise in management and treatment of SMA

AND

Age < 18 years at initiation

AND

- Medical records documentation provided to establish baseline level of function as appropriate for age and motor function (e.g. HINE, HFSME, ULM, or CHOP INTEND, based on age and motor ability)

AND

- Not dependent upon invasive ventilation or tracheostomy or requires non-invasive ventilation for less than 16 hours per day (for naps and nighttime sleep)

CONTINUATION OF COVERAGE CRITERIA-

Annual review (12 months):

- Patients that meet initial criteria above and are established on therapy

AND

- Medical record documentation of clinically significant improvement in SMA-related symptoms (improvement, stabilization or decreased decline since previous approval). Documentation should include specific scale used based on age and motor function and comparison to baseline Response is defined as improvement in more categories of motor milestones than worsening

- 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.

FOR BADGERCARE COVERAGE:

Please see Forward Health for criteria or diagnosis restrictions.

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.

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% |



**Omalizumab (Xolair®)
Prior Authorization Criteria**

FORMULARY STATUS: Medical Benefit Coverage-Restricted
APPROVAL LIMITS: Urticaria: Initial: 6 months; Subsequent: 12 months
Asthma: Initial: 12 months, Subsequent: 12 months

CRITERIA FOR INITIAL COVERAGE:

1. ASTHMA

- Age ≥6
- Diagnosis of allergic asthma
- Serum IgE level ≥30 international units/mL
- Positive skin tests or *in vitro* reactivity to common aeroallergens (e.g. dust mites, pet dander, cockroaches, etc.)
- Person is a non-smoker or smoking cessation therapy has been recommended
- Moderate-to-severe persistent asthma as defined by Global Initiative for Asthma (GINA) Global Strategy for Asthma Management and Prevention Guidelines (Step 5)
- Not well controlled or poorly controlled asthma despite episodic use of systemic corticosteroids or at least 3 months of high-dose inhaled corticosteroids in combination with a trial of long acting beta₂ agonist or leukotriene modifiers
- Exceptions based on adverse effects from high dose ICS or long term risks of adverse effects from high dose ICS or oral corticosteroids
 - Cataracts in patients > 40 years of age
 - Glaucoma
 - Recurrent thrush
 - Dysphonia
 - Growth inhibition, after evaluation by Endocrine Consult
 - Diagnosis of osteoporosis, treatment resistant to FDA approved osteoporosis treatment
- Omalizumab in combination with an IL-5 inhibitor will only be considered on a case by case basis if each individual agent with combination high dose ICS/LABA did not control symptoms.

2. URTICARIA

Person with chronic (>= 3 months), refractory urticaria despite use of **ALL** of the following:

- scheduled, high dose non-sedating antihistamines
- at least one short course of corticosteroids

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

CRITERIA FOR CONTINUATION/RENEWAL:

1. ASTHMA

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

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

2. URTICARIA

- Documentation in an office visit in the preceding 12 months there was clinical improvement from prior to initiating omalizumab, including at least one of the following:



- Decrease in oral corticosteroid use
- Reduction in exacerbation frequency
- Reduction in exacerbation intensity

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

IMPORTANT INFORMATION:

If the medication is going to be administered in the clinic, the medication is not covered under the pharmacy benefit, but may be covered under the medical benefit.

Note: Requests for omalizumab for indications other than asthma and chronic urticaria will be considered experimental as defined in the Certificate of Coverage and are not covered.

Table 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 | |
|--|-----------------|-----------|
| | Child 5-11 | Adult |
| Beclomethasone HFA 40 or 80 mcg/puff | >200 mcg | >400 mcg |
| Budesonide DPI 90, 180 or 200 mcg/inhalation | >400 mcg | >640 mcg |
| Budesonide inhaled Inhalation for suspension | >1000 mcg | NA |
| Ciclesonide HFA 80 or 160 mcg | >160 mcg | > 320 mcg |
| Flunisolide HFA 80 mcg/puff | ≥640 mcg | >640 mcg |
| Fluticasone HFA/MDI: 44, 110,mcg/puff | >500 mcg | >500 mcg |
| DPI: 50, 100, 250 mcg/inhalation | >400 mcg | >500 mcg |
| Mometasone DPI 200 mcg/inhalation | ≥440 mcg | >440 mcg |



**Palifermin (Kepivance)
Prior Authorization PA Criteria**

FORMULARY STATUS:

Palifermin (Kepivance) Medical Benefit-Restricted

APPROVAL LIMITS: 12 months

QUANTITY LIMITS: 6 doses per cycle

CRITERIA FOR COVERAGE:

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

AND

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

CRITERIA FOR COVERAGE:

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

Palivizumab (Synagis®) Prior Authorization Criteria

| | |
|--------------------------|--|
| FORMULARY STATUS: | Medical benefit-Restricted |
| APPROVAL LIMITS: | One season (maximum of 5 doses from November to April) |
| QUANTITY LIMITS: | None |

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 compromises handling of respiratory tract secretions.

OR

- Infant less than 2 years of age and immunocompromised (ie. SCID, HIV infection, solid organ or hematopoietic transplant or on chemotherapy) during RSV season

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

FOR BADGERCARE COVERAGE:

Please see Forward Health for criteria or diagnosis restrictions.

IMPORTANT INFORMATION:

- The UW Health Pharmacy Benefit Management Program staff will forward requests for home administration (Home Health) to Medical Management.
- Palivizumab is a clinic administered injectable, which is covered under the medical benefit.
- Palivizumab is not effective for the treatment of RSV.
- 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**

FORMULARY STATUS: Medical Benefit-Restricted

APPROVAL LIMITS: None

QUANTITY LIMITS: None

CRITERIA FOR COVERAGE:

- Prescribed by a Neurologist, Cardiologist, or other expert in hereditary transthyretin-mediated amyloidosis (hATTR)
- Age 18 years or older
- Confirmed diagnosis of hATTR
- Documentation of polyneuropathy



**Pegfilgrastim (Fulphila, Neulasta, Udenyca)
Prior Authorization Criteria**

FORMULARY STATUS: Medical Benefit-Restricted

APPROVAL LIMITS: 12 months

QUANTITY LIMITS: One dose per copay or administration

CRITERIA FOR COVERAGE:

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

AND

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

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

QUANTITY LIMIT EXCEPTION CRITERIA:

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

Pegloticase (Krystexxa) Prior Authorization Criteria

FORMULARY STATUS: Medical Benefit - restricted

APPROVAL LIMITS: Initial – 6 months
Renewal – 12 months

QUANTITY LIMITS: None

CRITERIA FOR COVERAGE:

- Drug must be prescribed and monitored by a Rheumatologist

AND

- The person has a serum uric acid level > 6.0 mg/dL despite an adequate trial of maximized therapeutic doses of both allopurinol and febuxostat in combination with lesinurad OR allopurinol, febuxostat, and lesinurad are not tolerated

AND

- The person has severe symptomatic tophaceous gout (chronic tophaceous gouty arthropathy in ≥ 4 joints or ≥ 1 unstable, complicated, or severe articular tophi) despite appropriate urate lowering therapy (as above) and appropriate NSAID, colchicine, and glucocorticoid use for acute attacks.

AND

- Documentation that the person does not have glucose-6-phosphate dehydrogenase (G6PD) deficiency

CRITERIA FOR CONTINUATION OF THERAPY:

- Clinical documentation demonstrating the person has achieved and maintained (most recent value must be within the previous 2 months) a serum uric acid level < 6.0 mg/Dl

AND

- Clinical documentation from the previous 12 months demonstrating an objective reduction in gout symptoms such as reduction in tophi or number of acute attacks

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



Restricted Progesterone Prior Authorization Criteria

FORMULARY STATUS:

| | |
|--------------------------------|----------------------------|
| Makena (hydroxyprogesterone) | Medical Benefit Restricted |
| Hydroxyprogesterone compounded | Medical Benefit Restricted |

APPROVAL LIMITS:

see criteria below

QUANTITY LIMITS:

None

CRITERIA FOR COVERAGE:

1. Women in the 2nd trimester (6 fills for 6 months)

- Women has a singleton pregnancy **AND**
- Has a history or preterm birth
- Administration in clinic; covered under Medical Benefit. Clinic must purchase medication for administration in clinic.

2. (Illinois plans only) For the treatment of infertility (12 fills for 12 months)

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

CONTINUATION OF COVERAGE CRITERIA:

- Persons new to the plan who are established on therapy will have coverage under their drug benefit for the remainder of the current treatment course. Restrictions to specific network pharmacies and participation in medication management programs may apply.
- Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.

CRITERIA FOR BADGERCARE COVERAGE OF HYDROXYPROGESTERONE:

- Please see Forward Health for criteria or diagnosis restrictions.

IMPORTANT INFORMATION:

Medications will not be covered to improve libido or for sexual dysfunction



Restricted Medications with Miscellaneous Codes Prior Authorization Criteria

FORMULARY STATUS: Medical Benefit-Restricted

APPROVAL LIMITS: Drug specific

QUANTITY LIMITS: Drug specific

CRITERIA FOR COVERAGE OF RESTRICTED MEDICATIONS WITH MISCELLANEOUS CODES:

- FDA approved indications unless there are drug product specific prior authorization criteria (e.g. mepolizumab (Nucala[®]), daratumumab (Darzalex[®]), etc.); if there are drug product specific criteria those criteria apply and must be met for coverage.

OR (for oncology drugs only)

- The requested drug has a class 1 or 2 recommendation for use from the National Comprehensive Cancer Network (NCCN) in the specific condition of the person

OR

- **(Minnesota plans only)** - the requested drug is recommended for use in the specific condition of the person* in either the United States Pharmacopeia Drug Information or the American Hospital Formulary Service Drug Information or one article in a major peer-reviewed medical journal recognizes the safety and efficacy of the requested drug in the person's specific condition

OR

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

CONTINUITY OF COVERAGE CRITERIA:

- Person new to the plan who are being treated for a diagnosis that is not excluded by certificate of coverage and is established on therapy will have coverage under their medical benefit if drug product specific continuation of therapy criteria met; if no product specific criteria, with documentation of symptom improvement or disease stability.
- Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.



Restricted Vaccine Criteria Criteria for Coverage

FORMULARY STATUS:

| | |
|---|--------------------------------|
| human papillomavirus vaccine (Gardasil, Cervarix, Gardasil-9) | Medical Benefit-age restricted |
| zoster vaccine live (Zostavax) | Medical Benefit-age restricted |
| zoster vaccine recombinant, adjuvanted (Shingrix) | Medical Benefit-age restricted |

APPROVAL LIMITS:

One series

QUANTITY LIMITS:

| | |
|---|---------|
| Human papillomavirus vaccine: | 3 doses |
| Zoster vaccine live (Zostavax): | Once |
| Zoster vaccine recombinant, adjuvanted (Shingrix) | 2 doses |

CRITERIA FOR COVERAGE:

1. Human papillomavirus vaccine.
 - Person is between the ages of 9 and 26 years at series initiation
 - **FOR BADERCARE COVERAGE:** Please see Forward Health for criteria or diagnosis restrictions
2. Zoster vaccine live (Zostavax):
 - Person is age 60 years or older
OR
 - Person with primary Medicare coverage and secondary State/Local (ETF) coverage: age 60 years or older AND less than 65 years of age (if 65 years or older, coverage for vaccine provided by Navitus)
OR
 - Person has managed Badgercare coverage
OR
 - Person with coverage with Swedish American Health System: age 55 years or older
3. Zoster vaccine recombinant, adjuvanted (Shingrix):
 - Person is age 50 years or older
OR
 - Person with primary Medicare coverage and secondary State/Local (ETF) coverage: age 50 years or older AND less than 65 years of age (if 65 years or older, coverage for vaccine provided by Navitus)

IMPORTANT INFORMATION:

For zoster vaccines (Zostavax and Shingrix):

- Those with a Medicare Select plan have coverage for the administration of the vaccine, but the vaccine itself is **NOT** covered. The vaccine is covered by the person's Medicare part D (drug) benefit.
- Those with Medicare primary and State/Local (ETF) secondary: it is assumed all Medicare primary members have Medicare Part D. If a member has Medicare as primary but did not elect Part D then neither Quartz nor Navitus will pay for the immunization, and the member will have to pay out of pocket for them. If Quartz is primary, coverage of Zostavax will be provided by Quartz for persons 60 and older and coverage of Shingrix will be provided by Quartz for persons 50 and older.



**Riloncept (Arcalyst™)
Prior Authorization Criteria**

FORMULARY STATUS: Medical Benefit-Restricted

APPROVAL LIMITS: None

QUANTITY LIMITS: None

CRITERIA FOR COVERAGE:

- Diagnosis of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS) in adults and children \geq age 12
- Prescribed by a Rheumatologist or Immunologist
- Failure or intolerance to an adequate trial of Kineret (Anakinra)



**Sebelipase alfa (Kanuma)
Prior Authorization Criteria**

FORMULARY STATUS: Medical Benefit-Restricted

APPROVAL LIMITS: 12 months

QUANTITY LIMITS: None

CRITERIA FOR COVERAGE:

- Covered for persons with Lysosomal Acid Lipase (LAL) deficiency (Wolman disease or Cholesterol ester storage disease (CEST) confirmed by dried blood spot testing

AND

- Two separate elevated alanine aminotransferase levels ≥ 1.5 times the ULN

AND

- Prescribed by a specialist in Genetics and Metabolism

CONTINUATION OF THERAPY:

Clinical documentation from the previous 12 months demonstrating response to therapy such as improvements from baseline in liver function tests, cholesterol levels, or reductions in hepatic fat.

IMPORTANT INFORMATION:

Sebelipase alfa is a clinic administered medication and is not covered under the prescription drug benefit.



Testosterone Prior Authorization Criteria

FORMULARY STATUS:

| | |
|---|----------------------------|
| Testosterone injection (generics, Xyosted) | Medical Benefit-Restricted |
| Testosterone extended release injection (Aveed) | Medical Benefit-Restricted |
| Testosterone Implants (Testopel) | Medical Benefit-Restricted |

APPROVAL LIMITS: None

QUANTITY LIMITS: None

CRITERIA FOR COVERAGE:

Preferred Testosterone Injections:

- Diagnosis of gender dysphoria or transsexualism, unless excluded by certificate **OR**
- Diagnosis of primary or secondary hypogonadism or mixed hypogonadism with clinically appropriate laboratory data demonstrating androgen deficiency* **AND** are symptomatic with symptoms other than sexual dysfunction
AND
- Not for decreased libido or other sexual dysfunction

Nonpreferred Testosterone Injections (Xyosted):

- Above criteria met **AND**
- Documented intolerance to a preferred testosterone injection

For extended release injections and implants:

- Above criteria met **AND**
- Documented intolerance to topical testosterone **AND** non-extended release injections.

CRITERIA FOR CONTINUATION OF THERAPY:

- Persons new to coverage who are established on therapy will have coverage under their drug benefit for the remainder of the current treatment course. Restrictions to specific network pharmacies and participation in medication management programs may apply.
- For extended release and implant formulations: above criteria for extended-release injections and implants must be met.
- 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.



Thrombopoietin Receptor Agonists Prior Authorization Criteria

FORMULARY STATUS:

Romiplostim (Nplate)

Medical Benefit Restricted

APPROVAL LIMITS:

up to 12 months

QUANTITY LIMITS:

None

PRIOR AUTHORIZATION CRITERIA:

- Prescribed by Hematology

AND

1. Persons with chronic ITP

a. Platelet count < 50,000/mcL

b. Failure of 2 prior ITP therapy (e.g. corticosteroids, rituximab, azathioprine, danazol, or splenectomy)

CONTINUATION OF COVERAGE CRITERIA:

- Persons new to the plan who are established on therapy will have coverage under their drug benefit for the remainder of the current treatment course. Restrictions to specific network pharmacies and participation in medication management programs may apply.
- Continuation of therapy/coverage criteria will not be applied to persons who were not previously approved for coverage whose therapy was initiated using a manufacturer-sponsored free drug program, provider samples, and/or vouchers.

CRITERIA FOR COVERAGE OF DURATION EXCEPTIONS:

- Prescriber presents rational, clinical reason for utilizing an extended duration