"What's New" Medical Pharmaceutical Policy June 2018 Updates

MBP 22.0 Xolair (Omalizumab)- Updated policy

Xolair (Omalizumab) will be considered medically necessary when all of the following criteria are met:

1. **For Asthma:**
   - Must be prescribed by an allergist or pulmonologist **AND**
   - Insured individual must be compliant with current therapeutic regimen **AND**
   - Insured individual is at least 6 years of age **AND**
   - Physician provided documentation of a diagnosis of moderate to severe persistent asthma* with evidence of reversible airway disease [i.e. greater than 12% improvement in forced expiratory volume in one second (FEV_1) with at least 200 ml increase or at least a 20% or greater improvement in peak expiratory flow (PEF) after administration of albuterol] **AND**
   - Physician provided documentation of inadequate control or intolerance, despite a 3 month trial of: medium –high dose inhaled corticosteroids or systemic corticosteroids **and** long-acting beta agonists or leukotriene receptor antagonists **AND**
   - Physician provided documentation of an IgE level of greater than 30 IU/ml and less than 700 IU/ml for individuals age 12 and older OR IgE level of greater than 30 IU/ml and less than 1300 IU/ml for individuals age 6 through 11 **AND**
   - Physician provided documentation of evidence of a specific allergic reactivity to a perennial aeroallergen by positive skin or blood test for a specific IgE **AND**
   - Known environmental triggers within the member's control have been eliminated. **AND**
   - Medical record documentation that Xolair is not being used in combination with Fasenra (benralizumab), Nucala (mepolizumab), or Cinqair (reslizumab)

MBP 59.0 White Blood Cell Stimulating Factors - Updated policy

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Neupogen, Neulasta, Zarxio, Leukine, Granix:

The use of white blood cell stimulating factor [Neupogen (filgrastim), Neulasta (pegfilgrastim), Granix (tbo-filgrastim), Zarxio (filgrastim-sndz), or Leukine (sargramostim)] is considered medically necessary in insured individuals with a diagnosis of cancer, and when any of the following FDA labeled indications or uses supported by clinical guidelines are present:

1. Primary Prophylaxis - the prevention of febrile neutropenia (FN) when the risk of FN due to the myelosuppressive chemotherapy regimen is 20% or greater. Those regimens include but are not limited to:

- TC (paclitaxel/cisplatin, or cyclophosphamide/docetaxel or docetaxel/cisplatin or paclitaxel/carboplatin)
- MVAC (methotrexate, vinblastine, doxorubicin, cisplatin)
- AC (doxorubicin, cyclophosphamide, docetaxel)
- AT (doxorubicin, paclitaxel)
- TIC (paclitaxel, ifosfamide, mesna, cisplatin)
- VAPEC-B (vincristine, doxorubicin, prednisolone, etopside, cyclophosphamide, bleomycin)
- A(N)CVB (doxorubicin or mitoxantrone, cyclophosphamide, vindesine, bleomycin)
- DHAP (dexamethasone, cisplatin, cytarabine)

NOTE: Regimens not specified in this document must be listed on a nationally recognized guideline stating risk of FN of greater than 20%.

OR

For the prevention of FN when the risk of developing FN is less than 20%, but any other risk factor listed below is present:

- Age 65 years or greater

- Poor performance status
- Previous history of FN
- Extensive prior radiation or chemotherapy treatment
- Poor nutritional status
- Recent surgery or Open wounds or active infection
- Advanced cancer
- Persistent neutropenia
- Bone marrow involvement by tumor
- Liver dysfunction (bilirubin >2.0)
- Renal dysfunction (CrCl <50)

Neupogen, Neulasta, Zarxio, or Leukine: May also be considered medically necessary for any of the following:

2. Secondary Prophylaxis – prevention of FN when a previous cycle of chemotherapy resulted in a neutropenic complication and for which primary prophylaxis was not received, and a dose reduction will compromise disease-free or overall survival or treatment outcome.

3. Treatment of Febrile Neutropenia - as an adjunct to antibiotics in high-risk individuals with FN who are at high risk for infection related complications or when **any** of the following prognostic factors are documented:

- Age 65 years or greater
- Anticipated prolonged and profound neutropenia
- Uncontrolled primary disease
- Pneumonia
- Invasive fungal infection
- Hypotension
- Multi-organ dysfunction
- Hospitalized at the time of development of the fever

4. Dose Dense Therapy – specifically in the treatment of node positive breast cancer, small cell lung cancer, and diffuse aggressive non-Hodgkin's lymphoma.

5. Stem Cell Transplantation- when one of the following is met:

- Bone Marrow Transplant (BMT)-
  - Documentation of a non-myeloid malignancy undergoing myeloablative chemotherapy followed by autologous or allogenic bone marrow transplant (G-CSF is given after BMT)

OR

- Peripheral Blood Progenitor Cell (Mobilization)Transplant (PBPC)
  - Used for mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis. (G-CSF is given prior to and throughout leukaphersis)

Note: Neulasta is considered off-label for PBPC mobilization

~~**5. Progenitor Cell Transplantation** – to mobilize peripheral blood progenitor cell (PBPC) administration after autologous PBPC transplant.~~
~~**Note:** Neulasta is considered off-label for this indication.~~

6. Leukemia or Myelodysplastic Syndromes – insured individuals with any of the following conditions:

- Acute myeloid leukemia (AML) receiving induction or consolidation chemotherapy
- Acute lymphoblastic leukemia (ALL) after completion of the first few days of chemotherapy of the initial induction or the first post-remission course
- Myelodysplastic syndrome with less than 15% blasts in the bone marrow, or recurrent neutropenic infections are experienced.

7. Lymphoma – Age 65 years or greater treated with curative chemotherapy, e.g., CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone)

~~**8. Non-myeloid Malignancy –** For reduction in the duration of neutropenia and related complications while undergoing myeloablative chemotherapy followed by autologous or allogenic bone marrow transplantation~~

8. Radiation therapy – with any of the following conditions

- If prolonged delays secondary to neutropenia are anticipated.
- As treatment for radiation injury secondary to doses of 3-10 Grays (Gy) or greater

Neupogen, Zarxio: May also be considered medically necessary for the following:

9. Severe Chronic Neutropenia – when the following criteria are met

- Diagnosis of Congenital, Cyclic, or Idiopathic Neutropenia AND
- Documentation of an Absolute Neutrophil Count (ANC) <500 cells/mm^3 on three seperate occasions during a 6 month period (for Congential or Idiopathic Neutropenia) OR five consecutive days of ANC <500 cells/mm^3 per cycle (for Cyclic Neutropenia) AND
- Documentation that the member experienced a clinical significant infection, fever, or oropharyngeal ulcer during the past 12 months.

AUTHORIZATION: When approved, the duration of the authorization will be for 6 months.

MBP 75.0 Stelara (ustekinumab)- Updated policy

Stelara (ustekinumab) will be considered medically necessary when all of the following criteria are met:

1. **Adult Plaque Psoriasis**
   - Prescription must be written by a dermatologist **AND**
   - Member must be at least 18 years of age **AND**
   - Medical record documentation that the prescribed dosing is appropriate for patient's weight **AND**
   - Medical record documentation of moderate to severe plaque psoriasis characterized by ≥5% of body surface area involved or disease affecting crucial body areas such as the hands, feet, face, or genitals **AND**
   - Medical record documentation that Stelara is not being used concurrently with a TNF blocker or other biologic agent **AND**
   - Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of Humira* **AND** Cosentyx*

     *Requires Prior Authorization

2. Pediatric Plaque Psoriasis

- Prescription must be written by a dermatologist **AND**
- Member must be at least 12 years of age **AND**
- Medical record documentation of a diagnosis of moderate to severe plaque psoriasis characterized by ≥5% of body surface area involved or disease affecting crucial body areas such as hands, feet, face, or genitals **AND**
- Medical record documentation of intolerance to, contraindication to, or therapeutic failure on at least two topical corticosteroids **AND**
- Medical record documentation that the prescribed dose is appropriate for the patient's weight

Dosing for plaque psoriasis:

- Patients weighing over 100kg should receive 90 mg every 12 weeks (GPID 28159)
- Patients weighing ≥60kg to ≤100kg should receive 45 mg every 12 weeks (GPID 19903 or 28158)
- Patients weighing less than 60kg should receive 0.75mg/kg every 12 weeks (via single dose vial – GPID 19903)

Quantity Limit (for plaque psoriasis):
Initial: RX count 3 for initial 6 months
Subsequent: RX count 5 for subsequent 12 months

Note: Authorizations should be approved by GPID

AUTHORIZATION DURATION:
Approval will be given for an initial duration of six (6) months. For continuation of coverage, medical record documentation of clinical improvement or lack of progression in the signs and symptoms of plaque
psoriasis at six (6) months of Stelara therapy is required.

After the initial six (6) month approval, subsequent approvals for coverage will be for a duration of one (1) year requiring medical record documentation of continued or sustained improvement in the signs and symptoms of plaque psoriasis while on Stelara therapy.

3. **Psoriatic Arthritis**
   - Prescription must be written by a rheumatologist or a dermatologist **AND**
   - Member must be at least 18 years of age **AND**
   - Medical record documentation that the patient is going to receive a dose of 45 mg every 12 weeks OR medical record documentation that the patient has a co-existing diagnosis of moderate-to-severe plaque psoriasis and weighs > 100 kg. **AND**
   - Medical record documentation of a diagnosis of moderately to severely active psoriatic arthritis which must include the following:
     - Documentation of either active psoriatic lesions or a documented history of psoriasis **AND**
   - Medical record documentation that Stelara is not being used concurrently with a TNF blocker or other biologic agent **AND**
   - Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of Humira* **AND** Cosentyx*

*Requires Prior Authorization

AUTHORIZATION DURATION: Approval will be given for an initial duration of six (6) months. For continuation of coverage, medical record documentation of clinical improvement or lack of progression in the signs and symptoms of psoriatic arthritis at six (6) months of Stelara therapy is required.

After the initial six (6) month approval, subsequent approvals for coverage will be for a duration of one (1) year. Reevaluation of coverage will be every one (1) year requiring medical record documentation of continued or sustained improvement in the signs and symptoms of psoriatic arthritis while on Stelara therapy.

Quantity Limit (for psoriatic arthritis):
Initial: RX count 3 for initial 6 months
Subsequent: RX count 5 for subsequent 12 months

Note: Authorizations should be approved by GPID

4. **Crohn's Disease (CD)**
   - Prescription must be written by a gastroenterologist **AND**
   - Member must be at least 18 years of age **AND**
   - Medical record documentation of moderately to severely active Crohn's disease **AND**
   - Medical record documentation that Stelara is not being used concurrently with a TNF blocker or other biologic agent **AND**
   - Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3-month trial of three (3) of the following medications: Humira*, Cimzia*, Entyvio*, infliximab (Remicade or Inflectra) *, or Tysabri* **AND**
   - Medical record documentation of Stelara 130mg vials as IV infusion (for induction therapy) OR Stelara 90mg syringes (for maintenance therapy) being prescribed.

   *Requires Prior Authorization

   Note to reviewer: Stelara 45mg syringe is not indicated for use in Crohn's disease.

   AUTHORIZATION DURATION: If determined to be medically necessary, Stelara should be approved for an initial authorization duration of six (**6) months**. After the initial 6-month maintenance approval, subsequent approvals for coverage will be for a duration of twelve (**12) months** requiring medical record documentation of continued or sustained improvement in the signs and symptoms of Crohn's disease while on Stelara therapy.

   Quantity limit (for Crohn's disease):
   Initial Authorization:
   - One-time authorization of up to four 130mg vials for induction infusion (to be entered by medical).
   - Rx Count of two (2) 90mg syringes for remainder of the initial 6-month authorization (to be entered by pharmacy).

   Subsequent Authorizations:
   - Rx count of six (6) 90mg syringes per 12-month authorization

   Note: Authorizations should be approved by GPID (for Crohn's disease)

MBP 89.0 Xgeva (denosumab)- Updated policy

Xgeva (denosumab) will be considered medically necessary when all of the following criteria are met:

1. *Bone metastases from solid tumors*
   - Medical record documentation of use for treatment of bone metastases related to disease progression from a solid tumor (e.g. breast, prostate); **AND**
   - Member has corrected calcium if hypocalcemic prior to initiating therapy and documentation that calcium levels will be monitored and adequately supplemeted with calcium and vitamin D to achieve serum calcium levels of 8 to 11.5 mg/dL (2 to 2.9 mmol/L); **AND**
   - Member is not concurrently receiving Prolia (denosumab)

2. *Giant cell tumor of the bone*
   - Medical record documentation of use for treatment of adults and skeletally mature adolescents with giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity; **AND**

- Member has corrected calcium if hypocalcemic prior to initiating therapy and documentation that calcium levels will be monitored and adequately supplemeted with calcium and vitamin D to achieve serum calcium levels of 8 to 11.5 mg/dL (2 to 2.9 mmol/L); **AND**
- Member is not concurrently receiving Prolia (denosumab)

3. *Hypercalcemia of malignancy*
- Medical record documentation of use for treatment of hypercalcemia of malignancy that is refractory to intravenous bisphosphonate therapy (defined as an albumin-corrected calcium of > 12.5 mg/dL (3.1 mmol/L) despite treatment with intravenous bisphosphonate therapy in the previous 30 days) **AND**
- Member is not concurrently receiving Prolia (denosumab)

4. *Prevention of skeletal-related events in Multiple Myeloma*
- Medical record documentation of use for the prevention of skeletal-related events in patients with multiple myeloma **AND**
- Member has corrected calcium if hypocalcemic prior to initiating therapy and documentation that calcium levels will be monitored and adequately supplemented with calcium and vitamin D to achieve serum calcium levels of 8 to 11.5 mg/dL (2 to 2.9 mmol/L) **AND**
- Member is not concurrently receiving Prolia (denosumab) **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to zoledronic acid (Note: A creatinine clearance less than 35mL/minute is considered a contraindication to the use of zoledronic acid)

AUTHORIZATION DURATION: Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

~~**LIMITATIONS:** Xgeva is not indicated for the prevention of skeletal-related events in patients with multiple myeloma.~~

MBP 91.0 Yervoy (Ipilimumab)- Updated policy

Yervoy (Ipilimumab) will be considered medically necessary when all of the following criteria are met:

1. Melanoma
- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation of unresectable stage III or IV melanoma **AND**
- One of the following:
    - Medical record documentation of use in combination with nivolumab for first line therapy **OR**
    - Medical record documentation of use as a single agent or in combination with nivolumab as second-line or subsequent therapy for disease progression if not previously used **OR**
    - Medical record documentation of use as a single-agent reinduction therapy in select patients who experienced no significant systemic toxicity during prior ipilimumab therapy and who relapse after initial clinical response or progress after stable disease >3 months

OR

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation of use as a single agent for adjuvant therapy:
    - For Stage IIIA with metastases > 1 mm, or Stage IIIB or Stage IIIC cutaneous melanoma with nodal metastases following a complete lymph node dissection or resection **OR**
    - Following complete lymph node dissection and/or complete resection of nodal recurrence

2. Renal Cell Carcinoma

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that patient is ≥ 18 years of age **AND**
- Medical record documentation of previously untreated advanced renal cell carcinoma **AND**
- Medical record documentation that the patient is at intermediate to poor risk (defined as having 1 or more 6 prognostic risk factors as per the IMDC criteria*) **AND**
- Medical record documentation that Yervoy will be given in combination with nivolumab (Opdivo)

*IMDC Criteria risk factors include:

1. Less than one year from time of initial renal cell carcinoma diagnosis to randomization
2. Karnofsky performance status <80%
3. Hemoglobin less than the lower limit of normal
4. Corrected calcium of greater than 10 mg/dL
5. Platelet count greater than the upper limit of normal
6. Absolute neutrophil count greater than the upper limit of normal

AUTHORIZATION DURATION: ~~Initial approval will be for 6 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 6 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.~~

For Unresectable or metastatic melanoma and Advanced Renal Cell Carcinoma:
Approval will be for one (1) **6-month** authorization for the FDA-approved maximum of up to four (4) doses of Yervoy. Requests for authorization exceeding these limits will require the following:

- Medical record documentation of continued disease improvement or lack of disease progression **AND**
- Medical record documentation of peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing beyond the FDA-approved treatment duration

For Adjuvant melanoma:
Initial approval will be for **6 months**. Subsequent approvals will be for an additional **12 months** and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if the member experiences unacceptable toxicity or worsening of disease.

MBP 126.0 Opdivo (nivolumab)- Updated policy

3. *Renal Cell Carcinoma*

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that patient is ≥ 18 years of age **AND**
  - Medical record documentation of use as a single agent for relapse or for surgically unresectable advanced or metastatic renal cell carcinoma **AND**
  - Medical record documentation of a therapeutic failure on or intolerance to prior anti-angiogenic therapy, including, but not limited to, Sutent (sunitinib), Votrient (pazopanib), Inlyta (axitinib), Nexavar (sorafenib), Avastin (bevacizumab), Afinitor (everolimus), or Torisel (temsirolimus).

OR

- Medical record documentation of previously untreated advanced renal cell carcinoma **AND**
- Medical record documentation that the patient is at intermediate to poor risk (defined as having 1 or more 6 prognostic risk factors as per the IMDC criteria*) **AND**

- Medical record documentation that Opdivo will be given in combination with ipilimumab (Yervoy)

*IMDC Criteria risk factors include:
1. Less than one year from time of initial renal cell carcinoma diagnosis to randomization
2. Karnofsky performance status <80%
3. Hemoglobin less than the lower limit of normal
4. Corrected calcium of greater than 10 mg/dL
5. Platelet count greater than the upper limit of normal
6. Absolute neutrophil count greater than the upper limit of normal

MBP 128.0 Blincyto (blinatumomab)- Updated policy

Blincyto (blinatumomab) will be considered medically necessary when all of the following criteria are met per indication:

Relapsed or Refractory B-cell Precursor ALL

- Prescription written by an oncologist/hematologist **AND**
- Medical record documentation of a diagnosis of relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL)

AUTHORIZATION DURATION: Approval will be limited to one lifetime 9 cycle (20 month) course. Subsequent approval for treatment past the initial 9 cycle course will require documentation of well-controlled, peer-reviewed literature with evidence to support this request.

MRD-positive B-cell Precursor ALL

- Prescription written by an oncologist/hematologist **AND**
- Medical record documentation of a diagnosis of B-cell precursor acute lymphoblastic leukemia (ALL) in first or second remission **AND**
- Medical record documentation of a minimal residual disease (MRD) greater than or equal to 0.1%

AUTHORIZATION DURATION: Approval will be limited to one lifetime 4 cycle (6 month) course. Subsequent approval for treatment past the initial 4 cycle course will require documentation of well-controlled, peer-reviewed literature with evidence to support this request.

MBP 141.0 Nucala (mepolizumab)- Updated policy

Nucala (mepolizumab) will be considered medically necessary when all of the following criteria are met:

Severe Eosinophilic Asthma

- Documentation of patient age ≥ 12 years **AND**
- Medical record documentation of a diagnosis of severe eosinophilic asthma AND that Nucala is being used as add-on maintenance treatment **AND**
- Prescription written by an allergist or pulmonologist **AND**
- Medical record documentation of a blood eosinophil count of either ≥ 300 cells/mcL during the 12-month period before screening and/or ≥ 150 cells/mcL within 3 months of the start of therapy **AND**
- Medical record documentation of:
    - Intolerance to or not well controlled or very poorly controlled symptoms* despite at least a 3 month trial of: high-dose inhaled corticosteroids and/or oral systemic corticosteroids plus a long-acting beta agonist **OR**
    - Two or more exacerbations in the previous 12 months requiring additional medical treatment (oral corticosteroids, emergency department or urgent care visits, or

hospitalization) despite current therapy with high-dose inhaled corticosteroids plus a long-acting beta agonist **AND**

- Insured individual must be adherent with current therapeutic regimen and must demonstrate appropriate inhaler technique **AND**
- Known environmental triggers within the member's control have been eliminated **AND**
- Medical record documentation that Nucala is not being used in combination with Fasenra (benralizumab), Cinqair (reslizumab), or Xolair (omalizumab).

*****Measures of disease severity

Measure	Not Well Controlled	Very Poorly Controlled
Symptoms	> 2 days per week	Throughout the day
Nighttime awakenings	1-3x/week	≥ 4x/week
Interference with normal activity	Some limitation	Extremely limited
SABA use for symptom control (not to prevent exercise-induced bronchospasm)	> 2 days/week	Several times per day
FEV1 (% predicted) or peak flow (% personal best)	60-80%	< 60%
Asthma Control Test (ACT) Score	16-19	≤ 15

Eosinophilic Granulomatosis (EGPA)

- Prescription written by an allergist/immunologist, pulmonologist, and/or rheumatologist **AND**
- Medical record documentation that patient is ≥18 years of age **AND**
- Medical record documentation of eosinophilic granulomatosis (EGPA) confirmed by biopsy evidence of vasculitis AND at least four (4) of the following criteria:
  - Asthma (a history of wheezing or the finding of diffuse high-pitched wheezes on expiration)
  - Eosinophilia (blood eosinophil level of ≥10% or ≥1500 cells/microL on differential white blood cell count)
  - Mononeuropathy (including multiplex) or polyneuropathy
  - Migratory or transient pulmonary opacities detected radiographically
  - Paranasal sinus abnormality
  - Biopsy containing a blood vessel showing the accumulation of eosinophils in extravascular areas

  AND
- Medical record documentation of a therapeutic failure on, contraindication to, or intolerance to systemic glucocorticoid therapy AND at least one immunosuppressant therapy (cyclophosphamide, azathioprine, methotrexate)

Quantity Limit: 1 vial (100mg) per 28 days (for eosinophilic asthma), 3 vials (300mg) per 28 days (for EGPA)

AUTHORIZATION DURATION: Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

LIMITATIONS:

~~- Nucala is not indicated for treatment of other eosinophilic conditions.~~

- Nucala is not indicated for the relief of acute bronchospasm or status asthmaticus.

MBP 145.0 Cinqair (reslizumab)- Updated policy

Cinqair (reslizumab) will be considered medically necessary when all of the following criteria are met:

- Documentation of patient age ≥ 18 years **AND**
- Patient must have severe persistent eosinophilic asthma **AND**
- Cinqair is being used as add-on maintenance treatment **AND**
- Prescription written by an allergist or pulmonologist **AND**
- Medical record documentation of a blood eosinophil count of ≥ 400 cells/mcL since the time of asthma diagnosis **AND**
- Medical record documentation of:
    - Intolerance to or not well controlled or very poorly controlled symptoms* despite at least a 3 month trial of: high-dose inhaled corticosteroids and/or oral systemic corticosteroids plus a long-acting beta agonist **OR**
    - Two or more exacerbations in the previous 12 months requiring additional medical treatment (oral corticosteroids, emergency department or urgent care visits, or hospitalization) despite current therapy with high-dose inhaled corticosteroids plus a long-acting beta agonist **AND**
- Insured individual must be adherent with current therapeutic regimen and must demonstrate appropriate inhaler technique **AND**
- Known environmental triggers within the member's control have been eliminated **AND**
- Medical record documentation that Cinqair is not being used in combination with Fasenra (benralizumab), Nucala (mepolizumab), or Xolair (omalizumab). **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to the use of Nucala

MBP 156.0 Imfinzi (durvalumab)- Updated policy

Imfinzi (durvalumab) will be considered medically necessary when ALL of the following criteria are met:

1. Urothelial Carcinoma

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that patient is ≥ 18 years of age **AND**
- Medical record documentation of a diagnosis of locally advanced or metastatic urothelial carcinoma AND one of the following:
    - Disease progression during or following platinum-containing chemotherapy **OR**
    - Disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy

AUTHORIZATION DURATION: Initial approval will be for 6 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

2. Non-Small Cell Lung Cancer (NSCLC)

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that patient is 18 years of age or older **AND**
- Medical record documentation of a diagnosis of unresectable Stage III Non-Small Cell Lung Cancer (NSCLC) **AND**
- Medical record documentation that patient has received and has not progressed following a minimum of two cycles of concurrent platinum-based chemotherapy **AND** radiation therapy

AUTHORIZATION DURATION (NSCLC): Initial approval will be for **6 months** or less if the reviewing provider feels it is medically appropriate. One subsequent approval will be for an additional **6 months** or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

Authorization of Imfinzi for the treatment of non-small cell lung cancer should not exceed the FDA-approved treatment duration of 1 year (12 months). For requests exceeding the above limit, medical record documentation of the following is required:

- Peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing beyond the FDA-approved treatment duration

MBP 166.0 Adcetris (brentuximab vedotin)- Updated policy

Adcetris (brentuximab vedotin) will be considered medically necessary when ALL of the following criteria are met:

- Prescription written by a hematologist/oncologist AND
- Medical record documentation that patient > 18 years of age

AND

- Medical record documentation of a diagnosis of classical Hodgkin Lymphoma (cHL) AND
- Medical record documentation of failure of autologous hematopoietic stem cell transplant (auto-HSCT) OR
- Medical record documentation of failure of at least 2 multi-agent chemotherapy regimens in patients who are not candidates for auto-HSCT OR
- Medical record documentation of use as consolidation treatment following auto-HSCT in patients with high risk of relapse or progression post-auto-HSCT (high risk patients include: refractory to first line therapy, relapse within 12 months of first line therapy, presence of extranodal disease)

OR

- Medical record documentation of a diagnosis of systemic anaplastic large cell lymphoma (sALCL) AND
- Medical record documentation of failure of at least 1 prior multi-agent chemotherapy regimen

OR

- Medical record documentation of a diagnosis of primary cutaneous anaplastic large cell lymphoma (pcALCL) OR CD30-expressing mycosis fungoides (MF) AND
- Medical record documentation of failure of prior radiation or systemic therapy

OR

- Medical record documentation of previously untreated Stage III or IV classical Hodgkin Lymphoma (cHL) AND
- Medical record documentation that Adcetris will be used in combination with chemotherapy

AUTHORIZATION DURATION: ***For treatment of Stage III or IV cHL***: Initial approval will be limited to 12 doses (6 months) or less if the reviewing provider feels it is medically appropriate. Subsequent approval for treatment past the initial 12 doses will require documentation of well-controlled, peer-reviewed literature with evidence to support this request.

For all other indications: Initial approval will be for 6 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued

disease improvement or lack of disease progression. Adcetris will no longer be covered if the member experiences unacceptable toxicity or worsening of disease.

MBP 173.0 Fasenra (benralizumab)- NEW policy

DESCRIPTION:
Fasenra (benralizumab), a humanized monoclonal antibody (IgG1, kappa), is an interleukin-5 antagonist. IL-5 is the major cytokine responsible for the growth and differentiation, recruitment, activation, and survival of eosinophils (a cell type associated with inflammation and an important component in the pathogenesis of asthma). Benralizumab, by inhibiting IL-5 signaling, reduces the production and survival of eosinophils.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Fasenra (benralizumab) will be considered medically necessary when ALL of the following criteria are met:

- Prescribed by an allergist/immunologist or pulmonologist **AND**
- Patient is 12 years of age or older **AND**
- Medical record documentation of a diagnosis of severe eosinophilic asthma AND that Fasenra is being used as add-on maintenance treatment **AND**
- Medical record documentation of blood eosinophil count ≥150 cells/microL (0.15 x 10E3/uL) within the past 3 months **AND**
- Medical record documentation of:
    - Intolerance to or not well controlled or very poorly controlled symptoms* despite at least a 3-month trial of high-dose inhaled corticosteroids and/or oral systemic corticosteroids plus a long-acting beta agonist **OR**
    - Two or more exacerbations in the previous 12 months requiring additional medical treatment (oral corticosteroids, emergency department or urgent care visits, or hospitalization) despite current therapy with high-dose inhaled corticosteroids plus a long-acting beta agonist

  AND
- Medical record documentation that individual is adherent to current therapeutic regimen and must demonstrate appropriate inhaler technique **AND**
- Medical record documentation that known environmental triggers within the member's control have been eliminated **AND**
- Medical record documentation that Fasenra is not being used in combination with Xolair (omalizumab), Nucala (mepolizumab), or Cinqair (reslizumab)

Limitations:

- Fasenra is not indicated for treatment of other eosinophilic conditions.
- Fasenra is not indicated for the relief of acute bronchospasm or status asthmaticus.

*Measures of Disease Severity

Measure	Not Well Controlled	Very Poorly Controlled
Symptoms	> 2 days per week	Throughout the day
Nighttime awakenings	1-3x/week	≥ 4x/week
Interference with normal activity	Some limitation	Extremely limited
SABA use for symptom control (not to prevent exercise-induced bronchospasm)	> 2 days/week	Several times per day
FEV1 (% predicted) or peak flow (% personal best)	60-80%	< 60%
Asthma Control Test (ACT) Score	16-19	≤ 15

AUTHORIZATION DURATION: Initial approval will be for **12 months** or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional **12 months** or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of the following:

- Documentation that patient is not experiencing toxicity or worsening of disease **AND**
- Medical record documentation of at least one of the following:
    - Medical record documentation of continued disease improvement or lack of disease progression as evidenced by a reduction in asthma exacerbations (e.g. reduced use of rescue medications, reduced urgent care visits, reduced hospitalizations) **OR**
    - Medical record documentation of decreased oral corticosteroid use (if on maintenance treatment prior to Fasenra initiation)

QUANTITY LIMITS: Enter a 3-month auth for QL of 1 syringe (1mL) per 28 days. Remainder of the 12-month authorization duration and subsequent renewals, QL of 1 syringe (1mL) per 56 days.

MBP 174.0 Luxturna (voretigene-neparvovec-rzyl)- NEW policy

DESCRIPTION:
Luxturna (voretigene-neparvovec-rzyl) is an adeno-associated virus vector-based gene therapy that delivers a normal copy of the gene encoding human retinal pigment epithelial 65 kDa protein (RPE65) to retinal cells thus augmenting reduced or absent levels of biologically active RPE65. The RPE65 gene mutations lead to reduced or absent levels of RPE65 isomerohydrolase activity, blocking the visual cycle and ultimately impairing vision.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Luxturna (voretigene-neparvovec-rzyl) will be considered medically necessary when ALL of the following criteria are met:

- Prescription written by or in consultation with a retinal specialist AND
- Medical record documentation that the patient is ≥ 12 months of age AND
- Medical record documentation of diagnosis of biallelic RPE65 mutation-associated retinal dystrophy confirmed via genetic testing AND.
- Medical record documentation that the member has sufficient viable retinal cells, defined as ONE of the following:
    - An area of retina within the posterior pole of > 100 micron thickness as shown on optical coherence tomography
    - ≥ 3 disc areas of retina without atrophy or pigmentary degeneration within the posterior pole based on ophthalmoscopy
    - Remaining visual field within 30 degrees of fixation as measured by a III4e isopter or equivalent

AUTHORIZATION DURATION: One-time authorization for one (1) treatment per eye per lifetime

MBP 175.0 Mepsevii (vestronidase alfa-vjbk)- NEW policy

DESCRIPTION:
Mepsevii (vestronidase alfa-vjbk) is a recombinant human beta-glucuronidase (GUS), which provides exogenous GUS enzyme for uptake into cellular lysosomes. Mannose-6-phosphate (M6P) residues on the oligosaccharide chains allow binding of the enzyme to cell surface receptors, leading to cellular uptake of the enzyme, targeting to lysosomes and subsequent catabolism of accumulated glycosaminoglycans (GAGs) in affected tissues.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Mepsevii (vestronidase alfa-vjbk) will be considered medically necessary when ALL of the following criteria are met:

- Prescribed by or in consultation with a specialist in genetic disorders OR metabolic disorders **AND**
- Medical record documentation of a diagnosis of Mucopolysaccharidosis VII (MPS VII, Sly syndrome) confirmed by ALL of the following:
    - Elevated urinary glycosaminoglycans (GAGs) at least three times the upper limit of normal (3xULN) **AND**
    - Enzyme activity assay (beta-glucuronidase deficiency) OR genetic testing (mutation of chromosome 7q21.11) **AND**
    - At least one of the following clinical signs or symptoms: enlarged liver and spleen, joint limitations, airway obstructions or pulmonary dysfunction

  AND
- Medical record documentation of a baseline evaluation, including a standardized assessment of motor function (e.g. 6-minute walk test (6MWT)), urinary GAGs level, and pulmonary function test (PFT)

Note: Some patients may only have elevated GAGs two times the upper limit of normal (2xULN). Elevated GAGs and two mutations consistent with MPS VII are appropriate to diagnosis patients with MPS VII when diagnosed through newborn screening or sibling screening.

AUTHORIZATION DURATION: If determined to be medically necessary, Mepsevii should be approved for an initial authorization duration of **6 months**. Subsequent authorizations of Mepsevii should be approved for an authorization duration of **12 months** when the following criteria are met.

- Medical record documentation of improvement or maintenance of motor function, urinary GAGs level, pulmonary function, or other clinical signs/symptoms (i.e. decreased liver/spleen size, improvement in joint function, etc.)

MBP 177.0 Prevymis IV (letermovir)- NEW policy

DESCRIPTION:
Prevymis IV (letermovir) is an antiviral agent that inhibits cytomegalovirus (CMV) replication by targeting the CMV DNA terminase complex (pUL51, pUL56, pUL89), which is required for viral DNA processing and packaging. Letermovir affects production of genome unit lengths and alters virion maturation.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

GRANDFATHER PROVISION – Members already established on therapy are eligible for approval as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature

Prevymis IV (letermovir) will be considered medically necessary when ALL of the following criteria are met:

- Prescription written by or in consultation with a hematologist/oncologist, infectious disease, or transplant specialist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that the member is a recipient of an allogeneic hematopoietic stem cell transplant **AND**
- Medical record documentation that the member is a confirmed CMV seropositive recipient (R+) **AND**
- Medical record documentation that Prevymis is being used for CMV prophylaxis **AND**
- Medical record documentation that Prevymis is being initiated between Day 0 and Day 28 post-transplantation **AND**
- Medical record documentation that Prevymis is not being used in combination with pimozide, ergot alkaloids (ergotamine and dihydroergotamine), and/or pitavastatin and simvastatin (if co-administered with cyclosporine) **AND**
- Medical record documentation of intolerance to or contraindication to Prevymis tablets

AUTHORIZATION DURATION: If approved, a one time authorization for 100 days with a maximum of 100 doses will apply.

QUANTITY LIMIT: 100 doses per 100 days

MBP 178.0 Zilretta (triamcinolone acetonide ER injection)- NEW policy

DESCRIPTION:
Zilretta (triamcinolone acetonide ER injection) is an extended-release intra-articular injection of triamcinolone that is indicated for the management of osteoarthritis pain of the knee. It is a long acting corticosteroid with minimal sodium-retaining potential. Decreases inflammation by suppression of migration of polymorphonuclear leukocytes and reversal of increased capillary permeability.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Zilretta (triamcinolone acetonide ER injection) will be considered medically necessary when ALL of the following criteria are met:

- Prescribed by a rheumatologist or orthopedic specialist **AND**
- Patient is 18 years of age or older **AND**
- Medical record documentation of a diagnosis of osteoarthritic pain of the knee **AND**
- Medical record documentation that patient has not received a previous administration of Zilretta to the requested knee **AND**
- Medical record documentation that non-pharmacologic modalities (e.g. Weight loss, aerobic/resistance land-based exercise or aquatic exercise, other physical therapy modalities or exercises) have not promoted satisfactory symptomatic relief.
- Medical record documentation that there has been no significant improvement following a 10-12 week trial of full-dose nonsteroidal anti-inflammatory drug (NSAID) therapy, with or without supplemental acetaminophen **OR** if NSAIDs are contraindicated, a failure of daily acetaminophen regimen over a 4 to 6 week period **AND**
- Medical record documentation of a therapeutic failure on or intolerance to two different intra-articular steroid injections (e.g. triamcinolone, methylprednisolone, betamethasone, dexamethasone).

AUTHORIZATION DURATION: One injection per knee per lifetime

Notes:

- The safety and efficacy of repeat administrations of Zilretta have not been studied.
- The safety and efficacy of Zilretta for management of osteoarthritis pain in joints other than the knee have not been studied.
- Zilretta is for intra-articular use only and should not be administered by epidural, intrathecal, intravenous, intraocular, intramuscular, intradermal, or subcutaneous routes.