"What's New" Medical Pharmaceutical Policy August 2020 Updates

MBP 59.0 White Blood Cell Stimulating Factors- Updated policy

DESCRIPTION:
White blood cell stimulating factors such as granulocyte colony stimulating factors (G-CSF) [e.g., Neupogen (*filgrastim),* Neulasta (*pegfilgrastim)*, Nivestym (filgrastim-aafi), Fulphila (*pegfilgrastim-jmdb*), Udenyca *(pegfilgrastim-cbqv),* Ziextenzo *(pegfilgrastim-bmez),* Zarxio (*pegfilgrastim-sndz),* and Granix (*tbo-filgrastim)* and granulocyte-macrophage colony stimulating factor (GM-CSF) [e.g., Leukine (*sargramostim)*] are synthetic stimulants and anti-neutropenic agents administered to decrease the incidence and/or severity of infection associated with drug-related myelosuppression and to assist recovery of hematopoietic function in neutropenia.

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

Neupogen, Neulasta, Nivestym, Fulphila, Udenyca, Ziextenzo, Zarxio, Leukine, Granix:

The use of white blood cell stimulating factor [Neupogen (filgrastim), Neulasta (pegfilgrastim), Nivestym (filgrastim-aafi), Fulphila (pegfilgrastim-jmdb), Udenyca *(pegfilgrastim-cbqv),* Granix (tbo-filgrastim), Ziextenzo *(pegfilgrastim-bmez),* 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, etoposide, cyclophosphamide, 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%.*

AND

- For requests for Neulasta/Neulasta Onpro, medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Ziextenzo, Udenyca, **AND** Fulphila.

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)

AND

- For requests for Neulasta/Neulasta Onpro, medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Ziextenzo, Udenyca, **AND** Fulphila.

Neupogen, Neulasta, Nivestym, Fulphila, Udenyca, Ziextenzo, 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.

AND

- For requests for Neulasta/Neulasta Onpro, medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Ziextenzo, Udenyca, **AND** Fulphila.

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

AND

- For requests for Neulasta/Neulasta Onpro, medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Ziextenzo, Udenyca, **AND** Fulphila.

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

AND

- For requests for Neulasta/Neulasta Onpro, medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Ziextenzo, Udenyca, **AND** Fulphila.

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 leukapheresis)

Note: Neulasta, Udenyca, Ziextenzo, and Fulphila are considered off-label for PBPC mobilization

AND

- For requests for Neulasta/Neulasta Onpro, medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Ziextenzo, Udenyca, **AND** Fulphila.

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.

AND

- For requests for Neulasta/Neulasta Onpro, medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Ziextenzo, Udenyca, **AND** Fulphila.

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

AND

- For requests for Neulasta/Neulasta Onpro, medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Ziextenzo, Udenyca, **AND** Fulphila.

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

Note: Fulphila, Ziextenzo, and Udenyca are not indicated for radiation injury syndrome; however, the biosimilars are considered medically accepted for this indication by the NCCN guidelines.

AND

- For requests for Neulasta/Neulasta Onpro, medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Ziextenzo, Udenyca, **AND** Fulphila.

Neupogen, Nivestym, and 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 separate occasions during a 6 month period (for Congenital 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 clinically significant infection, fever, or oropharyngeal ulcer during the past 12 months.

Leukine: May also be considered medically necessary for the following:

10. Delayed Neutrophil Recovery or Graft Failure

- Medical record documentation that the member has had an allogeneic or autologous bone marrow transplant and neutrophil recovery* has not occurred.

  *Note to reviewer: Neutrophil engraftment is defined as the first day of three consecutive days where the neutrophil count (ANC) is 500 cells/mm^3 or greater.

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

QUANTITY LIMITS:

- **Ziextenzo**: Facets RX Count: 144 (Q5120 Units), MedAccess QL: 0.043mL per day (1 syringe per 14 days)
- **Udenyca**: Facets RX Count: 144 (Q5111 Units), MedAccess QL: 0.043mL per day (1 syringe per 14 days)
- **Fulphila**: Facets RX Count: 144 (Q5108 Units), MedAccess QL: 0.043mL per day (1 syringe per 14 days)
- **Neulasta/Neulasta Onpro**: Facets RX Count: 12 (J2505 Units), MedAccess QL: 0.043mL per day (1 syringe per 14 days)

MBP 75.0 Stelara (ustekinumab)- Updated policy

DESCRIPTION:
Stelara (ustekinumab) is a fully humanized immunoglobulin G1 monoclonal antibody that targets the p40 subunit of human IL-12 and IL-23.

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

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)

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.

Quantity Limit (for plaque psoriasis):

If requesting a dose for patient weight:	Initial 6 month authorization	Subsequent 12 month authorization
Less than 60 kg	Facets RX Count: 135 MedImpact QL: One-time, one week authorization: 0.5 mL per 28 days by GPID Remainder of 6 month authorization: 0.5 mL per 84 days by GPID	Facets RX Count: 225 MedImpact QL: 0.5 mL per 84 days by GPID
Greater than or equal to 60 kg to 100 kg or less	Facets RX Count: 135 MedImpact QL: One-time, one week authorization: 0.5 mL per 28 days by GPID Remainder of 6 month authorization: 0.5 mL per 84 days by GPID	Facets RX Count: 225 MedImpact QL: 0.5 mL per 84 days by GPID
Greater than 100 kg	Facets RX Count: 270 MedImpact QL: One-time, one week authorization: 1 mL per 28 days by GPID Remainder of 6 month authorization: 1 mL per 84 days by GPID	Facets RX Count: 450 MedImpact QL: 1 mL per 84 days by GPID

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 <u>not</u> 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):

If requesting a dose for patient weight:	Initial 6 month authorization	Subsequent 12 month authorization
100 kg or less	Facets RX Count: 135 MedImpact QL: One-time, one week authorization: 0.5 mL per 28 days by GPID	Facets RX Count: 225

	Remainder of 6 month authorization: 0.5 mL per 84 days by GPID	MedImpact QL: 0.5 mL per 84 days by GPID
Greater than 100 kg	Facets RX Count: 270 MedImpact QL: One-time, one week authorization: 1 mL per 28 days by GPID Remainder of 6 month authorization: 1 mL per 84 days by GPID	Facets RX Count: 450 MedImpact QL: 1 mL per 84 days 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 (or biosimilar) *, 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: Approval will be given 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:
  - Facets Rx Count: 520 (J3358 – Ustekinumab IV)
  - MedImpact Quantity Limit: 104 mL per 56 days GPID for Stelara 130 mg vial
- Remainder of initial authorization:
  - Facets RX Count: 270 (J3357 – Ustekinumab SQ [if requested through medical])
  - MedImpact Quantity limit: 1mL per 56 days GPID for Stelara 90mg Syringe

Subsequent Authorizations:

- Facets RX Count: 630 (J3357 – Ustekinumab SQ [if requested through medical])
- MedImpact Quantity limit: 1 mL per 56 days GPID for Stelara 90mg Syringe

5. Ulcerative Colitis

- 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 ulcerative colitis **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*, Entyvio*, and infliximab (or biosimilar) * **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 ulcerative colitis.

AUTHORIZATION DURATION: Approval will be given 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 ulcerative colitis while on Stelara therapy.

Quantity limit (for ulcerative colitis):
Initial Authorization:
- One-time authorization:
  - Facets Rx Count: 520 (J3358 – Ustekinumab IV)
  - MedImpact Quantity Limit: 104 mL per 56 days GPID for Stelara 130 mg vial
- Remainder of initial authorization:
  - Facets RX Count: 270 (J3357 – Ustekinumab SQ [if requested through medical])
  - MedImpact Quantity limit: 1mL per 56 days GPID for Stelara 90mg Syringe

Subsequent Authorizations:
- Facets RX Count: 630 (J3357 – Ustekinumab SQ [if requested through medical])
- MedImpact Quantity limit: 1 mL per 56 days GPID for Stelara 90mg Syringe

MBP 91.0 Yervoy (Ipilimumab)- Updated policy

4. Hepatocellular Carcinoma (HCC)
- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation of a diagnosis of hepatocellular carcinoma (HCC) **AND**
- Medical record documentation of a therapeutic failure on or intolerance to sorafenib (Nexavar) **AND**
- Medical record documentation that Yervoy will be used in combination with nivolumab (Opdivo)

AUTHORIZATION DURATION:

For Unresectable or metastatic melanoma, colorectal cancer, ~~and~~ Advanced Renal Cell Carcinoma, and hepatocellular 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

MBP 118.0 Entyvio (vedolizumab)- Updated policy

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

Crohn's Disease

- Prescription written by a gastroenterologist **AND**
- Medical record documentation of age >18 years **AND**
- Medical record documentation of a diagnosis of moderate-to-severe Crohn's disease **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Humira*

Ulcerative Colitis

- Prescription written by a gastroenterologist **AND**
- Medical record documentation of age >18 years **AND**
- Medical record documentation of a diagnosis of moderate-to-severe ulcerative colitis **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to azathioprine or 6-mercaptopurine (6-MP)
- ~~Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Humira*.~~

AUTHORIZATION DURATION: After the initial 6 month approval, subsequent approvals will be for a duration of 12 months. Reevaluation of coverage will be every 12 months requiring documentation of improvement of signs and symptoms while on Entyvio.

QUANTITY LIMIT:

Initial Authorization:

- Facets RX Count: 1500 (J3380 – Vedolizumab)
- MedImpact Quantity Limit (for non-Medicare LOB): one-time 1-week authorization of 2 vials per 28 days. Remainder of initial 6 month authorization, 1 vial per 56 days

Subsequent Authorizations:

- Facets RX Count: 2100 (J3380 – Vedolizumab)
- MedImpact Quantity limit (for non-Medicare LOB): 1 vial per 56 days

MBP 126.0 Opdivo (nivolumab)- Updated policy

6. Urothelial Carcinoma

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that patient ≥ 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

AND

- Medical record documentation that Opdivo is NOT being used in combination with any other agent

7. *Hepatocellular Carcinoma (HCC)*
    - Prescription written by a hematologist/oncologist **AND**
    - Medical record documentation of a diagnosis of hepatocellular carcinoma **AND**
    - Medical record documentation of a therapeutic failure on or intolerance to sorafenib (Nexavar) **AND**
    - Medical record documentation that Opdivo will be used as a single-agent or in combination with ipilimumab (Yervoy)

MBP 132.0 Avycaz (cetfazidime/avibactam) - Updated policy

DESCRIPTION:
Avycaz (cetfazidime/avibactam) is a combination cephalosporin/beta-lactamase inhibitor indicated in combination with metronidazole, for the treatment of complicated intra-abdominal infections (cIAI) caused by the following susceptible microorganisms: *Escherichia coli, Klebsiella pneumoniae, Proteus mirabilis, Enterobacter cloacae, Klebsiella oxytoca, Citrobacter freundii* complex *and Pseudomonas aeruginosa* in patients ~~18 years~~ 3 months or older.

Avycaz is also indicated for the treatment of complicated urinary tract infections (cUTI) including pyelonephritis caused by the following susceptible microorganisms: *Escherichia coli, Klebsiella pneumoniae, Enterobacter cloacae, Citrobacter freundii* complex, *Proteus mirabilis*, and *Pseudomonas aeruginosa* in patients ~~18 years~~ 3 months or older.

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

Avycaz (cetfazidime/avibactam) will be considered medically necessary when all of the following criteria are met:

- Prescribed by or in consultation with an infectious disease specialist AND
- Medical record documentation of one of the following:
    - A diagnosis of complicated intra-abdominal infection caused by caused by the following susceptible microorganisms: *Escherichia coli, Klebsiella pneumoniae, Proteus mirabilis, Enterobacter cloacae, Klebsiella oxytoca, Citrobacter freundii* complex *and Pseudomonas aeruginosa* **OR**
    - A diagnosis of complicated urinary tract infections (cUTI) including pyelonephritis caused by the following susceptible microorganisms: *Escherichia coli, Klebsiella pneumoniae, Enterobacter cloacae, Citrobacter freundii* complex, *Proteus mirabilis*, and *Pseudomonas aeruginosa* **OR**
    - A diagnosis of Hospital-acquired Bacterial Pneumonia and Ventilator-associated Bacterial Pneumonia (HABP/VABP) caused by the following susceptible microorganisms: *Enterobacter cloacae, Escherichia coli, Haemophilus influenzae, Klebsiella pneumoniae, Proteus mirabilis, Pseudomonas aeruginosa and, Serratia marcescens*

    AND
- ~~Medical record documentation of a creatinine clearance > 50 mL/min~~ **AND**

Medical record documentation of culture and sensitivity showing the patient's infection is not susceptible to alternative antibiotic treatments **OR** a documented history of previous intolerance to or contraindication to other antibiotics shown to be susceptible on the culture and sensitivity

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 (UROTHELIAL CARCINOMA): 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

3. Extensive-Stage Small Cell Lung Cancer (ES-SCLC)

- 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 extensive-stage small cell lung cancer (ES-SCLC)* **AND**
- Medical record documentation that Imfinzi will be used as first-line treatment **AND**
- Medical record documentation that Imfinzi will be used in combination with etoposide and either carboplatin or cisplatin

*Note: The National Comprehensive Cancer Network (NCCN) Guidelines defines small cell lung cancer as consisting of two stages:
Limited Stage: Stage I-III (T any, N any, M0) that can be safely treated with definitive radiation doses. Excludes T3-4 due to multiple lung nodules that are too extensive or have tumor/nodal volume that is too large to be encompassed in a tolerable radiation plan.
Extensive Stage: Stage IV (T any, N any, M1a/b), or T3-4 due to multiple lung nodules that are too extensive or have tumor/nodal volume that is too large to be encompassed in a tolerable radiation plan

AUTHORIZATION DURATION (ES-SCLC): 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.

MBP 182.0 Crysvita (burosumab-twza)- Updated policy

Crysvita (burosumab-twza) will be considered medically necessary when ALL of the following criteria are met:

- Medical record documentation that the patient is at least ~~1 year~~ 6 months of age or older **AND**
- Medical record documentation that Crysvita is being prescribed by, or in consultation with, an endocrinologist, geneticist, or nephrologist **AND**
- Medical record documentation of a diagnosis of X-linked hypophosphatemia as evidenced by one of the following:
    - Reduced TmP/GFR ratio **AND** Reduced or normal plasma concentration of 1,25-dihydroxycholecalciferol (1,25-DHCC) or 25-hydroxyvitamin D [25(OH)D] **OR**
    - Genetic testing confirming a mutation in the PHEX (Phosphate regulating Endopeptidase on the X chromosome) gene

  AND
- Medical record documentation that the patient is not concurrently using vitamin D analogs or phosphate supplements.

MBP 196.0 Ultomiris (Ravulizumab-cwvz)- Updated policy

Paroxysmal Nocturnal Hemoglobinuria (PNH)

- Prescription is written by a hematologist AND
- Medical record documentation of 18 years of age or older AND
- Medical record documentation of diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) AND
- Medical record documentation of patient being vaccinated with the meningococcal vaccine
- Physician documentation of one of the following:
    - member is transfusion-dependent (i.e., has at least 1 transfusion in the 24 months prior to initiation of ravulizumab due to documented hemoglobin less than 7 g/dL in persons without anemic symptoms or less than 10 g/dL in persons with symptoms from anemia) prior to initiation of ravulizumab treatment OR
    - there is a significant adverse impact on the insured individual's health such as end organ damage or thrombosis without other cause.

AUTHORIZATION DURATION: Initial approval will be for 6 months. Subsequent authorizations will be for 6 months and will require:

- Medical record documentation:
    - Hemolysis control measured by lactic acid dehydrogenase (LDH) level less than 1.5 times the upper limit of normal (ULN) AND
    - Reduced need or elimination of transfusion requirements OR
    - Stabilization of hemoglobin levels

Atypical Hemolytic Uremic Syndrome (aHUS)

- Medical record documentation of a diagnosis of atypical hemolytic uremic syndrome (aHUS) *(Ultomiris is used to inhibit complement-mediated thrombotic microangiopathy)*

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.

MBP 210.0 Reblozyl (luspatercept-aamt)- New policy

DESCRIPTION:
Reblozyl (luspatercept-aamt) is a recombinant fusion protein that binds TGF-β superfamily ligands, diminishing Smad2/3 signaling. In mice, luspatercept-aamt promoted erythroid maturation through differentiation of late-stage erythroid precursors (normoblasts). In mice models of β-thalassemia and myelodysplastic syndromes, luspatercept-aamt decreased elevated Smad2/3 signaling and improved hematology parameters associated with ineffective erythropoiesis.

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

Reblozyl (luspatercept-aamt) will be considered medically necessary when ALL of the following criteria are met:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of diagnosis of beta thalassemia **AND**
- Medical record documentation that patient requires regular* red blood cell (RBC) transfusions **AND**
- Medical record documentation of baseline number of transfusions and red blood cell (RBC) units required for the previous six (6) months **AND**
- Medical record recommendation that Reblozyl is being dosed consistent with FDA-approved labeling**.

AUTHORIZATION DURATION: Approval will be given for an **initial duration of six (6) months** or less if the reviewing provider feels it is medically appropriate. After the initial six (6) month approval, subsequent approvals will be for a **duration of six (6) months** or less if the reviewing provider feels it is medically appropriate, requiring medical record documentation of:

- a decrease in red blood cell (RBC) transfusion burden from baseline **AND**
- Reblozyl being dosed consistent with the FDA-approved labeling**

Ongoing subsequent approvals will be for a **duration of six (6) months** or less if the reviewing provider feels it is medically appropriate, requiring medical record documentation of:

- a sustained reduction of red blood cell (RBC) transfusion burden from baseline **AND**
- Reblozyl being dosed consistent with the FDA-approved labeling**

LIMITATIONS: Reblozyl will no longer be covered if the patient does not experience a decrease in transfusion burden after nine (9) weeks of treatment (administration of three (3) doses) at the maximum dose level or if unacceptable toxicity occurs at any time.

NOTES:
*In clinical trials, “regular red blood cell transfusions” was considered to be 6 to 20 red blood cell units per 24 weeks with no transfusion-free period greater than 35 days.

**Per current labeling: 1mg/kg every 3 weeks increasing to a maximum of 1.25mg/kg every 3 weeks after two doses if a reduction in transfusion burden is not seen. Dose should not exceed 1.25mg/kg every 3 weeks

MBP 211.0 Givlaari (givosiran)- New policy

DESCRIPTION:
Givlaari (givosiran) is a double-stranded small interfering RNA that causes degradation of aminolevulinate synthase 1 (ALAS1) mRNA in hepatocytes through RNA interference, reducing the elevated levels of liver ALAS1 mRNA. The reduction of ALAS1 mRNA decreases circulating levels of neurotoxic intermediates aminolevulinic acid (ALA) and porphobilinogen (PBG), which are factors associated with attacks and other

disease manifestations of acute hepatic porphyria (AHP).

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

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

- Medical record documentation that Givlaari is prescribed by a specialist with experience managing porphyrias (including but not limited to a hematologist, hepatologist, or gastroenterologist) **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of acute hepatic porphyria (AHP) [including acute intermittent porphyria (AIP), hereditary coproporphyria (HCP), variegate porphyria (VP), and aminolevulinic acid dehydratase (ALAD) porphyria (ADP)] by at least one of the following:
    - Elevated urinary or plasma aminolevulinic acid (ALA) **OR**
    - Elevated urinary or plasma porphobilinogen (PBG) **OR**
    - Genetic testing confirming a mutation associated with acute hepatic porphyria (AHP)

  AND
- Medical record documentation of the baseline number of porphyria attacks requiring hospitalization, urgent healthcare visit, or IV hemin treatment within the previous 6 months **AND**
- Medical record documentation of active disease with at least two documented porphyria attacks within the previous 6 months.

AUTHORIZATION DURATION: Approval will be given for an initial duration of six (6) months or less if the reviewing provider feels it is medically appropriate. After the initial six (6) month approval, subsequent approvals will be for a duration of twelve (12) months or less if the reviewing provider feels it is medically appropriate, and will require:

- Medical record documentation of a clinically significant positive response to Givlaari treatment as evidenced by:
    - a reduction in the number of porphyria attacks requiring hospitalization, urgent healthcare visit, or IV hemin treatment within the previous 6 months from baseline OR
    - decreased severity in the symptoms of acute hepatic porphyria OR
    - a reduction in the baseline levels of urinary or plasma aminolevulinic acid (ALA) OR urinary or plasma porphobilinogen (PBG)

MBP 212.0 Adakveo (crizanlizumab-tmca)- New policy

DESCRIPTION:
Adakveo (crizanlizumab-tmca) is a humanized monoclonal antibody, which binds to P-selectin and blocks interaction with ligands, including P-selectin glycoprotein ligand 1. Normally, the translocation of P-selectin to the activated endothelial cell surface results in adhesion of sickle erythrocytes to vessels and the development of vascular occlusion. By binding to P-selectin, Adakveo inhibits interactions between endothelial cells, platelets, red blood cells, and leukocytes, which results in decreased platelet aggregation, maintenance of blood flow, and minimized sickle cell-related crises.

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

Adakveo (crizanlizumab-tmca) will be considered medically necessary when ALL of the following criteria are met:

- Prescription written by or in consultation with a hematologist **AND**
- Medical record documentation of the member being greater than or equal to 16 years of age **AND**
- Medical record documentation of diagnosis of sickle cell disease **AND**

- Medical record documentation of number of vasoocclusive crises in the previous 12 months **AND**
- Medical record documentation of intolerance to, or contraindication to, or therapeutic failure on a minimum 3-month trial of generic hydroxyurea **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Endari

AUTHORIZATION DURATION: Each treatment period is defined as 12 months. Re-review will occur every 12 months. The following criteria is required for reauthorization:

- Medical record documentation of continued or sustained improvement in the acute complications of sickle cell disease (i.e. number of vasoocclusive crises, hospitalizations, and number of ACS occurrences)

MBP 213.0 Sarclisa (isatuximab-irfc)- New policy

DESCRIPTION:
Sarclisa (isatuximab-irfc) is a CD38-directed monoclonal antibody that binds to CD38 expressed on the surface of hematopoietic and tumor cells (including multiple myeloma cells). After binding, Sarclisa induces apoptosis the cells and activates immune effector mechanisms via antibody-dependent cell-mediated cytotoxicity (ADCC), antibody-dependent cellular phagocytosis (ADCP), and complement dependent cytotoxicity (CDC). The combination of Sarclisa and pomalidomide enhanced ADCC activity and direct tumor cell killing compared to that of Sarclisa alone in vitro, and enhanced antitumor activity compared to the activity of Sarclisa or pomalidomide alone in human multiple myeloma xenograft model.

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

Sarclisa (isatuximab-irfc) will be considered medically necessary when ALL of the following criteria are met:

- Medical record documentation that Sarclisa is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of diagnosis of multiple myeloma **AND**
- Medical record documentation of prior treatment with at least two lines of therapy, which included lenalidomide (Revlimid)* AND a proteasome inhibitor (including but not limited to Velcade (bortezomib)*, Kyprolis (carfilzomib)*, or Ninlaro (ixazomib)*) **AND**
- Medical record documentation that Sarclisa will be used in combination with pomalidomide (Pomalyst)* and dexamethasone

*Prior authorization required

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 the member experiences unacceptable toxicity or worsening of disease.

MBP 214.0 Vyondys 53 (golodirsen)- New policy

DESCRIPTION:
Vyondys 53 (golodirsen) is an antisense oligonucleotide which binds exon 53 of dystrophin pre-mRNA, which results in exclusion of exon 53 during mRNA processing in patients with genetic mutations that are amenable to exon 53 skipping. Exon 53 skipping causes production of a truncated dystrophin protein in these patients. Vyondys 53 is indicated in the treatment of Duchenne muscular dystrophy (DMD) in

patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping.

This indication is approved under accelerated approval based on an increase in dystrophin production in skeletal muscle observed in patients treated with Vyondys 53. Continued approval for this indication may be contingent
upon verification of a clinical benefit in confirmatory trials.

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

Vyondys 53 (golodirsen) will be considered medically necessary when ALL of the following criteria are met:

- Medical record documentation of interdisciplinary team involvement including, at a minimum, neurology, cardiology, pulmonology, and a genetic specialist (e.g. geneticist, genetic counselor, etc.) **AND**
- Medical record documentation of Duchenne's Muscular Dystrophy (DMD) confirmed by genetic testing **AND**
- Medical record documentation that the member has a confirmed mutation of the DMD gene that is amenable to exon 53 skipping confirmed by a genetic counselor **AND**
- Medical record documentation of a baseline evaluation, including a standardized assessment of motor function by a neurologist with experience treating Duchenne muscular dystrophy **AND**
- Medical record documentation that Vyondys 53 is being given concurrently with oral corticosteroids unless intolerant or contraindicated **AND**
- Medical record documentation that patient will receive a dose consistent with the FDA approved labeling (maximum dose of 30mg/kg infused once weekly)

Note: Exon Deletions* on the Duchenne Muscular Dystrophy Gene Theoretically Amenable to Exon 53 Skipping

3-52	4-52	5-52	6-52	9-52					
10-52	11-52	13-52	14-52	15-52	16-52	17-52	19-52		
21-52	23-52	24-52	25-52	26-52	27-52	28-52	29-52		
30-52	31-52	32-52	33-52	34-52	35-52	36-52	37-52	38-52	39-52
40-52	41-52	42-52	43-52	45-52	47-52	48-52	49-52		
50-52	52	54-58	54-61	54-63	54-64	54-66	54-76	54-77	

*The first number represents the first exon deleted. The last number is the last exon deleted. The dash (-) represents all exons in between the first and last exon deleted.

Note: In clinical trials, stable cardiac function was defined as left ventricular ejection fraction ≥50% based on screening echocardiogram and QTc<450 ms based on screening electrocardiogram and stable pulmonary function was defined as percent predicted forced vital capacity of at least 50% and no requirement for nocturnal ventilation.

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 the following:

- Medical record documentation that the member continues to benefit from treatment with golodirsen **AND**
- Medical record documentation of an annual evaluation, including an assessment of motor function ability, by a neurologist with experience treating Duchenne muscular dystrophy **AND**
- Medical record documentation that Vyondys 53 continues to be given concurrently with oral corticosteroids unless intolerant or contraindicated **AND**

- Medical record documentation that the patient will continue to receive a dose consistent with the FDA approved labeling (maximum dose of 30mg/kg infused once weekly)

MBP 215.0 Recarbrio (imipenem/cilastatin/relebactam)- New policy

DESCRIPTION:
Recarbrio (imipenem/cilastatin/relebactam) is a carbapenem antimicrobial that contains imipenem, which inhibits penicillin-binding proteins and leads to the disruption of bacterial cell wall synthesis. Recarbio also contains cilastatin, which is a renal dehydropeptidase inhibitor that limits the renal metabolism of imipenem, and relebactam, which is a beta-lactamase inhibitor that protects imipenem from degradation by beta-lactamases.

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

Recarbrio (imipenem/cilastatin/relebactam) will be considered medically necessary when ALL of the following criteria are met:

- Prescription is written by or in consultation with Infectious Disease **AND**
- Medical record documentation that the member is greater than or equal to 18 years of age **AND**
- Medical record documentation of one of the following:
    - Diagnosis of Complicated Urinary Tract Infection (including Pyelonephritis) (cUTI) caused by the following susceptible gram-negative microorganisms: Enterobacter cloacae, Escherichia coli, Klebsiella aerogenes, Klebsiella pneumoniae, and Pseudomonas aeruginosa **OR**
    - Diagnosis of Complicated Intra-abdominal Infection (cIAI) caused by the following susceptible gram-negative microorganisms: Bacteroides caccae, Bacteroides fragilis, Bacteroides ovatus, Bacteroides stercoris, Bacteroides thetaiotaomicron, Bacteroides uniformis, Bacteroides vulgatus, Citrobacter freundii, Enterobacter cloacae, Escherichia coli, Fusobacterium nucleatum, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae, Parabacteroides distasonis, and Pseudomonas aeruginosa

  AND
- Medical record documentation of a culture and sensitivity showing the patient's infection is not susceptible to preferred alternative antibiotic treatments OR a documented history of previous intolerance to or contraindication to three (3) preferred alternative antibiotics shown to be susceptible on the culture and sensitivity **AND**
- Medical record documentation of a therapeutic failure on imipenem/cilastatin OR medical rationale of why imipenem/cilastatin cannot be used.

AUTHORIZATION DURATION: If approved, Recarbrio will be authorized for up to 14 days.

QUANTITY LIMITS: 4 vials per day (Facets RX Count of 7000 units)

MBP 218.0 Vyepti (eptinezumab-jjmr)- New policy

DESCRIPTION:
Vyepti (eptinezumab-jjmr) is a humanized monoclonal antibody that binds to calcitonin gene-related peptide (CGRP) ligand and blocks its binding to the receptor.

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

Vyepti (eptinezumab-jjmr) will be considered medically necessary when ALL of the following criteria are met:

- Prescription written by or in consultation with a neurologist or headache specialist AND
- Medical record documentation of the patient age greater than or equal to 18 years AND
- Medical record documentation of a diagnosis of migraine with or without aura, based on the ICHD-III diagnostic criteria AND
- Medical record documentation of the number of baseline migraine or headache days per month AND
- Medical record documentation of the patient experiencing 4 or more migraines per month AND
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Aimovig and Emgality AND
- If the request is for Vyepti 300 mg every 3 months, medical record documentation of therapeutic failure on Vyepti 100 mg every 3 months AND
- If the request is for use in combination with Botox, all of the following must be met:
    - Medical record documentation of therapeutic failure on a minimum 3 month trial of at least one calcitonin gene-related peptide (CGRP) receptor antagonist without the concomitant use of Botox AND
    - Medical record documentation of therapeutic failure on a minimum 6 month trial of Botox without the concomitant use of calcitonin gene-related peptide (CGRP) receptor antagonist AND
- Medical record documentation that Vyepti will not be used concomitantly with another calcitonin gene-related peptide (CGRP) receptor antagonist indicated for the preventive treatment of migraine (e.g. Aimovig, Ajovy, Emgality)

ICHD-III Diagnostic Criteria [4]

Migraine without Aura:	**Migraine with Aura:**
A) At least five (5) attacks fulfilling criteria B through D below:	A) At least two (2) attacks fulfilling criteria B through C below:
B) Headache lasting 4 to 72 hours (untreated or unsuccessfully treated)	B) One (1) or more of the following fully reversible aura symptoms: o Visual o Sensory o Speech and/or language o Motor o Brainstem o Retinal
C) Headache with at least two (2) of the following characteristics: o unilateral location o pulsating quality o moderate to severe pain intensity o aggravation by or causing avoidance of routine physical activity (e.g. walking or climbing stairs)	C) At least three (3) of the following: o at least one (1) aura symptom spreads over 5 or more minutes o two (2) or more aura symptoms occur in succession o each individual aura symptom lasts 5 to 60 minutes[1] o at least one (1) aura symptom is unilateral[2] o at least one (1) aura symptom is positive[3] o the aura is accompanied, or followed within 60 minutes, by a headache
D) At least one of the following during the headache: o nausea and/or vomiting o photophobia and phonophobia	D) Not better accounted for by another ICHD-3 diagnosis
E) Not better accounted for by another ICHD-3 diagnosis	

AUTHORIZATION DURATION: Initial approval will be for three (3) months and subsequent approvals will be for twelve (12) months.

Reauthorization Criteria:

- Medical record documentation of continued or sustained reduction in migraine or headache frequency AND
- If the request is for Vyepti 300 mg every 3 months, medical record documentation of therapeutic failure on Vyepti 100 mg every 3 months AND
- If the request is for use in combination with Botox, all of the following must be met:
    - Medical record documentation of therapeutic failure on a minimum 3 month trial of at least one calcitonin gene-related peptide (CGRP) receptor antagonist without the concomitant use of Botox AND
    - Medical record documentation of therapeutic failure on a minimum 6 month trial of Botox without the concomitant use of calcitonin gene-related peptide (CGRP) receptor antagonist AND
- Medical record documentation that Vyepti will not be used concomitantly with another calcitonin gene-related peptide (CGRP) receptor antagonist indicated for the preventive treatment of migraine (e.g. Aimovig, Ajovy, Emgality)

QUANTITY LIMITS:

If request is for 100 mg every 3 months:
Initial 3 months: Facets Rx count: 100 (C9063); Medimpact 1 vial per 90 days; max qty supply:1; min day supply: 84; max day supply: 90
Subsequent 12 months: Facets Rx count: 400 (C9063); Medimpact 1 vial per 90 days; max qty supply:1; min day supply: 84; max day supply: 90

If the request is for 300 mg every 3 months:
Initial 3 months: Facets Rx count: 300 (C9063); Medimpact 3 vial per 90 days; max qty supply:1; min day supply: 84; max day supply: 90
Subsequent 12 months: Facets Rx count: 1,200 (C9603); Medimpact 3 vial per 90 days; max qty supply:1; min day supply: 84; max day supply: 90

The following policies were reviewed with no changes:

- MBP 108.0 Kadcyla (ado-trastuzumab emtansine)
- MBP 115.0 Cyramza (ramucirumab)
- MBP 151.0 Spinraza (nusinersen)
- MBP 152.0 Bavencio (avelumab)
- MBP 199.0 Zolgensma (onasemnogene abeparvovec-xioi)
- MBP 200.0 Polivy (polatuzumab vedotin-piiq)