“What's New” Medical Pharmaceutical Policy May 2019 Updates

MBP 53.0 Eraxis (anidulafungin)- Updated policy

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

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

- The insured individual is at least 17 years of age and non-neutropenic: **AND**
- There is physician provided documentation of a diagnosis of candidemia or other *Candida* infection (*other than endocarditis, osteomyelitis, or meningitis due to Candida*) as determined by an infectious disease specialist; **OR**
- There is physician provided documentation of a diagnosis of esophageal candidiasis with failure on, intolerance to, or contraindication to fluconazole therapy as determined by an infectious disease specialist.

AUTHORIZATION DURATION: Prior Authorization will be limited to a period of 6 weeks (one course of therapy). Re-authorization for an extended treatment period (beyond the initial 6 weeks) will require documentation of a continued positive culture or documentation of a positive culture within the previous 14 days of the request. Duration of treatment should be based on the patient’s clinical response. Therapy should continue for at least 14 days after the last positive culture. Requests for re-authorization will be limited to a duration of 2 weeks for each re-authorization request.

LIMITATIONS:
Specimens for fungal culture and other relevant laboratory studies (including histopathology) should be obtained prior to therapy to isolate causative organism(s). Therapy may be instituted before the results of cultures and other laboratory studies are known. However, once these results become available, antifungal therapy should be adjusted accordingly.

MBP 57.0 Tysabri (natalizumab)- Updated policy

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.

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

1. **Relapsing Multiple Sclerosis**
   Tysabri is considered medically necessary for the treatment of relapsing forms of multiple sclerosis when the following criteria are met:
   - Medical record documentation of member being established on and responding to Tysabri for at least 60 days prior to their effective date with the plan

   OR

   - Medical record documentation of a diagnosis of a relapsing form of multiple sclerosis **AND**
   - Medical record documentation that the patient 18 years or older **AND**
   - Medical record documentation that Tysabri is being prescribed by a neurologist **AND**
   - Patient is enrolled in a risk-minimization program, called the TOUCH™ Prescribing Program, **AND**
   - Physician documentation that Tysabri is being used as monotherapy is provided. **AND**
   - Medical record documentation that the member has been tested for anti-JCV antibody prior to start of Tysabri therapy.
     - If patient is anti-JCV antibody **positive**, medical record documentation that benefits of drug outweigh the risks of progressive multifocal leukoencephalopathy (PML) and patient is aware of increased PML risk

   **AND**

   - Medical record documentation of therapeutic failure on, contraindication to, or intolerance to two formulary alternatives.

**NOTE:** According to the American Academy of Neurology recommendation, Tysabri may be considered as a first line therapy in individuals with relapsing remitting multiple sclerosis who exhibit particularly aggressive initial course of disease and in whom the potential benefit is felt to outweigh the risk. Patients with a poor
prognosis/aggressive disease include those with a heavy T2 lesion load, lesions in brain stem, cerebellum, and spinal cord.

**LIMITATIONS:**
- Cannot be used in combination with immunosuppressants (i.e. 6-mercaptopurine, azathioprine, cyclosporine, methotrexate) or inhibitors of TNF-alpha

**AUTHORIZATION DURATION:**
Initial authorization and reauthorizations for MS will be for a period of one (1) year. For re-authorization, medical record documentation of patient adherence to medication and improvement or stabilization of the multiple sclerosis disease course in signs and symptoms of multiple sclerosis while on Tysabri therapy will be required.
- For patients who were previously anti-JCV antibody negative, medical record documentation that physician has re-tested for anti-JCV antibody status within the last 12 months.
- For patients who were anti-JCV antibody positive at baseline or on re-test, medical record documentation that benefits of continuing drug outweigh risks.

**MBP 59.0 White Blood Cell Stimulating Factors- Updated policy**

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

**Neupogen, Neulasta, Nivestym, Fulphila, Udenyca, Zarfio, 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), Zarfio (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%.

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, Nivestym, Fulphila, Udenyca, 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


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 and Fulphila are considered off-label for PBPC mobilization

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. 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 and Udenyca are not indicated for radiation injury syndrome

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/mm³ on three separate occasions during a 6 month period (for Congenital or Idiopathic Neutropenia) OR five consecutive days of ANC <500 cells/mm³ 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/mm³ or greater.

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

**MBP 62.0 Remodulin IV (treprostinil sodium)- Updated policy**

**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

Remodulin IV (treprostinil sodium) will be considered medically necessary when all of the following criteria are met:

- Must be prescribed by a pulmonologist or cardiologist; and
- Physician provided documentation of a diagnosis of class 4 pulmonary arterial hypertension; or
- Physician provided documentation of a diagnosis of class 2 or 3 pulmonary arterial hypertension with therapeutic failure on, intolerance to or contraindication to Revatio; or
- Individuals who require transition from Flolan, to reduce the rate of clinical deterioration. The risks and benefits of each drug should be carefully considered prior to transition

**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.

**MBP 119.0 Keytruda (pembrolizumab)- Updated policy**

**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

Keytruda (pembrolizumab) 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 that patient is ≥ 18 years of age **AND**
   - Medical record documentation of a diagnosis of unresectable or metastatic melanoma **AND**
   - Medical record documentation of one of the following:
Unresectable or metastatic melanoma:
- A diagnosis of unresectable or metastatic melanoma AND
- Keytruda is not being used in combination with any other agents for the treatment of unresectable or metastatic melanoma.

OR

Adjuvant treatment of completely resected metastatic melanoma
- A diagnosis of metastatic melanoma with lymph node involvement, which has been completely resected AND
- Keytruda is being used in the adjuvant setting (following lymph node resection) AND
- Keytruda is being used as a single agent.

2. Metastatic Non-Small Cell Lung Cancer (NSCLS)
- 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 metastatic NSCLC meeting one of the following situations:
  - Medical record documentation of stage III NSCLC, metastatic NSCLC, OR that the member is not a candidate for surgical resection or definitive chemoradiation AND
  - Medical record documentation that Keytruda is being used as first-line treatment AND
  - Medical record documentation that tumors have high PD-L1 expression (Tumor Proportion Score (TPS)≥50% as determined by an FDA-approved test) AND
  - Medical record documentation that tumors express PD-L1 (TPS) ≥1% as determined by an FDA-approved test AND
  - Medical record documentation that tumors do not have EGFR or ALK genomic tumor aberrations

OR
  - Medical record documentation that Keytruda is being given as monotherapy AND
  - Medical record documentation that tumors express PD-L1 (TPS) ≥1% as determined by an FDA-approved test AND
  - Medical record documentation of disease progression on or after platinum-containing chemotherapy AND
  - For patients with EGFR or ALK genomic tumor aberrations: medical record documentation of disease progression on FDA-approved therapy for these aberrations prior to receiving Keytruda.

OR
  - Medical record documentation of metastatic nonsquamous NSCLC AND
  - Medical record documentation that Keytruda will be given in combination with pemetrexed AND either carboplatin or cisplatin AND
  - Medical record documentation that tumors do not have EGFR or ALK genomic tumor aberrations

OR
  - Medical record documentation that Keytruda will be given in combination with carboplatin AND either paclitaxel or nab-paclitaxel AND
  - Medical record documentation that Keytruda, carboplatin, and paclitaxel (or nab-paclitaxel) are being used as first-line treatment.

3. Head and Neck Squamous Cell 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 Head and Neck Squamous Cell Carcinoma that is recurrent or metastatic and had disease progression on or after platinum-containing chemotherapy

4. Classical Hodgkin Lymphoma
• Prescription written by a hematologist/oncologist AND
• Medical record documentation of Classical Hodgkin Lymphoma AND
• One of the following:
  a. Medical record documentation of a diagnosis of refractory Classical Hodgkin Lymphoma OR
  b. Medical record documentation of relapse following three (3) or more prior lines of therapy

5. Microsatellite Instability-High Cancer
• Prescription written by a hematologist/oncologist AND
• Medical record documentation of unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) solid tumors OR colorectal cancer AND
• For solid tumors:
  o Medical record documentation of progression following prior treatment(s) AND
  o Medical record documentation of no satisfactory alternative treatment options
• For colorectal cancer:
  o Medical record documentation of progression following treatment with fluoropyrimidine, oxaliplatin, and irinotecan

6. Urothelial Carcinoma
• Prescription written by a hematologist/oncologist AND
• Medical record documentation that patient is ≥ 18 years of age AND
• Medical record documentation of locally advanced or metastatic urothelial carcinoma AND
• Medical record documentation of one of the following:
  o Disease progression during or following platinum-containing chemotherapy OR
  o Disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy OR
  o Patient is not eligible cisplatin-containing chemotherapy* AND
  o Tumors express PD-L1 (combined positive score [CPS] greater than or equal to 10) as determined by an FDA-approved test OR
  o Patient is not eligible for any platinum-containing chemotherapy (regardless of PD-L1 status)

*Note: In clinical trials, patients who were not considered cisplatin-eligible had the following characteristics: baseline creatinine clearance of <60 mL/min, ECOG performance status of 2, ECOG 2 and baseline creatinine clearance of <60 mL/min, other reasons (Class III heart failure, Grade 2 or greater peripheral neuropathy, and Grade 2 or greater hearing loss).

7. Gastric Cancer
• Prescription written by a hematologist/oncologist AND
• Medical record documentation of a diagnosis of recurrent locally advanced or metastatic gastric or gastroesophageal junction adenocarcinoma AND
• Medical record documentation that tumors express PD-L1 (combined positive score [CPS] greater than or equal to 1) as determined by an FDA-approved test AND
• Medical record documentation of disease progression on or after two or more prior lines of therapy (including fluoropyrimidine- and platinum-containing chemotherapy)* AND
• If patient has HER2-positive disease, medical record documentation of disease progression on or after HER2/neu-targeted therapy (including but not limited to trastuzumab (Herceptin))*

*Note to reviewer: Current recommendations intend Keytruda to be used as third-line treatment (i.e. patient is to have 2 prior lines of therapy, one of which must include HER2/neu-targeted therapy if the patient has HER-2 positive disease)
8. Cervical Cancer
- Prescription written by a hematologist/oncologist AND
- Medical record documentation of recurrent or metastatic cervical cancer AND
- Medical record documentation that tumors express PD-L1 (CPS≥1) AND
- Medical record documentation of disease progression after receiving at least one prior line of therapy

9. Primary Mediastinal Large B-cell Lymphoma (PMBCL)
- Prescription written by a hematologist/oncologist AND
- Medical record documentation of refractory primary mediastinal large B-cell lymphoma (PMBCL) OR
- Medical record documentation of relapse following two (2) prior lines of therapy

10. Hepatocellular Carcinoma (HCC)
- 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 hepatocellular carcinoma AND
- Medical record documentation of a therapeutic failure on or intolerance to sorafenib (Nexavar)

11. Merkel Cell Carcinoma (MCC)
- Prescription written by a hematologist/oncologist AND
- Medical record documentation of a diagnosis of Merkel Cell Carcinoma AND
- Medical record documentation of metastatic and/or recurrent disease

12. Renal Cell Carcinoma (RCC)
- 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 advanced renal cell carcinoma AND
- Medical record documentation that Keytruda is being used in combination with axitinib (Inlyta) AND
- Medical record documentation that Keytruda and axitinib (Inlyta) are being used as first-line treatment for advanced disease

   Note: In clinical trials, advanced disease included newly diagnosed or recurrent Stage IV renal cell carcinoma.

LIMITATIONS: The treatment of patients with multiple myeloma with a PD-1 or PD-L1 blocking antibody in combination with a thalidomide analogue plus dexamethasone is not recommended outside of controlled clinical trials.

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.

MBP 125.0 Lemtrada (alemtuzumab): Updated policy

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

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

- Medical record documentation of diagnosis of relapsing form of multiple sclerosis AND
- Medical record documentation of age 17 or older AND
- Medical record documentation that patient is using Lemtrada as monotherapy AND
- Medical record documentation that Lemtrada is prescribed by a neurologist AND
- Medical record documentation that patient is receiving pre-medication w/ high dose corticosteroids and herpetic prophylaxis during therapy AND
- No medical record documentation of active/chronic infection AND
- Medical record documentation that patient is NOT receiving therapy with concomitant antineoplastic, immunosuppressive, or immune modulating therapies AND
- Medical record documentation the patient has not received any vaccines in the past 6 weeks and no plan to give any live vaccines while on therapy AND
- Medical record documentation that patient is up to date on all required vaccinations AND
- Documentation of positive antibody for varicella zoster (either physician documented diagnosis or vaccination history) AND
- Medical record documentation of therapeutic failure on, contraindication to, or intolerance to three formulary alternatives, one of which must by Tysabri.

Quantity Limits: 5 doses (60mg) for initial authorization, 3 doses (36mg) for reauthorization; max 8 doses per lifetime

AUTHORIZATION DURATION:
Initial authorization will be given for 5 doses and a duration of 1 year. Reauthorization will be given for a duration of 12 months with a quantity limit of 3 doses per 12 month duration additional 1 month for the remaining 3 doses, and will require:

- Medical record documentation that Lemtrada is being used as monotherapy AND
- Medical record documentation that patient has not started therapy with another DMT since initial 5 doses AND
- Medical record documentation that remaining 3 doses are being administered 1 year after initial 5 doses or if subsequent re-authorizations documentation that at least 12 months have passed since the last dose of any prior treatment course. AND
- Medical record documentation that patient is receiving pre-medication w/ high dose corticosteroids and herpetic prophylaxis during therapy AND
- No medical record documentation of active/chronic infection AND
- Medical record documentation that patient is NOT receiving therapy with concomitant antineoplastic, immunosuppressive, or immune modulating therapies AND
- Medical record documentation the patient has not received any vaccines in the past 6 weeks and no plan to give any live vaccines while on therapy AND
- Medical record documentation that patient is up to date on all required vaccinations
MBP 144.0 Tecentriq (atezolizumab)- Updated policy

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

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

1. **Locally Advanced or Metastatic Urothelial Carcinoma:**
   - Prescription written by an oncologist **AND**
   - Medical record documentation of a diagnosis of locally advanced or metastatic urothelial carcinoma **AND**
   - Medical record documentation of one of the following:
     - Disease progression during or following platinum-containing chemotherapy **OR**
     - Patient is not eligible for cisplatin-containing therapy **AND**
     - Tumors express PD-L1 (greater than or equal to 5%) as determined by an FDA-approved test **OR**
     - Patient is not eligible for any platinum-containing chemotherapy (regardless of PD-L1 status)

2. **Non-Small Cell Lung Cancer:**
   - Prescription written by an oncologist **AND**
   - Medical record documentation of a diagnosis of non-small cell lung cancer meeting one of the following situations:
     - Medical record documentation of disease progression during or following platinum-containing chemotherapy **OR**
     - Medical record documentation of disease progression on at least one FDA-approved therapy targeting EGFR or ALK if the patient has EGFR or ALK genomic tumor aberrations (e.g. mutation, deletion, insertion, etc.) **OR**
     - Medical record documentation of a non-squamous histologic subtype **AND**
     - Medical record documentation that Tecentriq will be given as first-line treatment **AND**
     - Medical record documentation that Tecentriq will be given in combination with bevacizumab, paclitaxel, AND carboplatin **AND**
     - Medical record documentation that the patient does not have an EGFR or ALK genomic tumor aberration.

3. **Breast Cancer:**
   - Prescription written by an oncologist **AND**
   - Medical record documentation of a diagnosis of advanced or metastatic triple negative (ER-negative, PR-negative, HER2-negative) breast cancer **AND**
   - Medical record documentation that tumors express PD-L1 (greater than or equal to 1%) as determined by an FDA-approved test **AND**
   - Medical record documentation that Tecentriq will be used in combination with protein-bound paclitaxel (Abraxane).

4. **Small Cell Lung Cancer (SCLC):**
   - Prescription written by an oncologist **AND**
   - Medical record documentation of a diagnosis of extensive stage small cell lung cancer (ES-SCLC) **AND**
   - Medical record documentation that Tecentriq will be used in combination with carboplatin and etoposide **AND**
   - Medical record documentation of use as first-line treatment of extensive-stage disease.
MBP 180.0 Kanuma (sebelipase alfa)- Updated policy

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

Kanuma (sebelipase alfa) will be considered medically necessary when ALL of the following criteria are met:

- Must be prescribed by a provider specializing in genetics or metabolism AND
- Medical record documentation of Lysosomal Acid Lipase deficiency as either Wolman disease OR Cholesteryl ester storage disease (CESD) AND
- Medical record documentation of confirmed diagnosis in one of three ways: Dried Blood Spot (DBS) test, leucocyte testing, or genetic testing AND
- Medical record documentation that the member will receive a weight and diagnosis appropriate dosing regimen

QUANTITY LIMITS:
- Rapidly progressing/ Wolman disease (patients initially presenting within the first 6 months of life): Patients 0-6 months of age. Kanuma will initially be approved for quantity sufficient for up to 3 mg/kg once weekly. These requests should be approved for a total of 4 visits per month.

- Late onset/ CESD: Patients 4 years of age and older will be approved for 1 mg/kg every other week. These requests should be approved for a total of 2 visits per month.

AUTHORIZATION DURATION: Initial approval will be for a period of 3 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 medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression.

MBP 185.0 Poteligeo (mogamulizumab-kpkc)- Updated policy

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

Poteligeo (mogamulizumab-kpkc) will be considered medically necessary when ALL of the following criteria are met:

- Prescription is written by a hematologist/oncologist or dermatologist AND
- Medical record documentation that patient is 18 years of age or older AND
- Medical record documentation of relapsed or refractory mycosis fungoides or Sézary syndrome AND
- Medical record documentation of resistance or intolerance to one prior therapy

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 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 195.0 Spravato (esketamine)- New policy

DESCRIPTION:
Spravato (esketamine) is a nonselective, noncompetitive N-methyl-D-aspartate (NMDA) receptor antagonist. The mechanism by which it exerts its antidepressant effect is unknown. The major circulating metabolite noresketamine demonstrated activity at the same receptor with less affinity.

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.

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

- Medical record documentation of age ≥ 18 AND
- Medical record documentation of diagnosis of major depression disorder (MDD) AND
- Medical record documentation of Spravato being used for treatment-resistant depression as defined by failure of at least two antidepressants from two different classes at an optimized dose for at least 6 weeks AND
- Medical record documentation that Spravato will be used in combination with a newly initiated antidepressant AND
- Medical record documentation of the patient’s baseline depression status using an appropriate rating scale (e.g. PHQ-9, Clinically Useful Depression Outcome Scale, Quick Inventory of Depressive Symptomatology-Self Report 16 Item, MADRS, HAM-D) AND
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to olanzapine/fluoxetine capsules

Authorization Duration:
Initial approval will be for 1 month or less if the reviewing provider feels it is medically appropriate. For continued coverage, the following criteria is required.

- Medical record documentation of clinical improvement in depression symptoms as measured by an appropriate rating scale (compared to previous measurement).

Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate. For continued coverage, the following criteria is required.

- Medical record documentation of clinical improvement or lack of progression in depression symptoms as measured by an appropriate rating scale (compared to previous measurement).

Quantity Limits:
For the initial 1 month authorization: 23 devices per 28 days
For subsequent authorizations: 12 devices per 28 days

MBP 196.0 Ultomiris (Ravulizumab-cwvz)- New policy

DESCRIPTION:
Ultomiris (Ravulizumab-cwvz) is a humanized monoclonal antibody which is a terminal complement inhibitor that specifically binds to the complement protein C5 (with high affinity), inhibiting its cleavage to C5a (the proinflammatory anaphylatoxin) and C5b (the initiating subunit of the terminal complement complex [C5b-9]) and preventing generation of the terminal complement complex C5b9. The C5 inhibition of complement-mediated hemolysis achieved by ravulizumab in patients with paroxysmal nocturnal hemoglobinuria is immediate, thorough, and sustained.

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

Ultomiris (Ravulizumab-cwvz) will be considered medically necessary when ALL of the following criteria are met:

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

MBP 197.0 Elzonris (Tagraxofusp-erzs)- New policy

DESCRIPTION:
Elzonris (Tagraxofusp-erzs) is a CD123-directed fusion protein which is composed of human interleukin-3
(IL-3) and truncated diphtheria toxin (DT). After binding to CD123, tagraxofusp is internalized, leading to
inhibition of protein synthesis and cell death

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

Elzonris (Tagraxofusp-erzs) will be considered medically necessary when ALL of the following criteria are
met:

• Prescription being written by hematologist/oncologist AND
• Medical record documentation of age ≥ 2 years AND
• Medical record documentation of diagnosis of Blastic plasmacytoid dendritic cell neoplasm
  (BPDCN)

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 198.0 Gamifant (emapalumab-lzsg)- New policy

DESCRIPTION:
Gamifant (emapalumab-lzsg) is an interferon gamma (IFNy) blocking monoclonal antibody. IFNy is
hypersecreted in hemophagocytic lymphohistiocytosis (HLH); emapalumab binds to IFNy and neutralizes
it.

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

Gamifant (emapalumab-lzsg) will be considered medically necessary when ALL of the following criteria are
met:
• Prescription written by or in consultation with a hematologist or oncologist AND
• Medical record documentation of a diagnosis of primary hemophagocytic lymphohistiocytosis (HLH) based on one of the following:
  o A molecular diagnosis (HLH gene mutations) OR
  o A family history consistent with primary HLH (X-linked lymphoproliferative syndrome) OR
  o 5 out of the following 8 criteria fulfilled:
    ▪ Fever ≥ 38.5°C
    ▪ Splenomegaly
    ▪ Cytopenias affecting 2 of 3 lineages in the peripheral blood; hemoglobin <9 g/dL, platelets <100 x 10⁹/L, neutrophils <1 x 10⁹/L
    ▪ Hypertriglyceridemia (fasting triglycerides > 3 mmol/L or ≥ 265 mg/dL) and/or hyperfibrinogenemia (≤1.5 g/dL)
    ▪ Hemophagocytosis in bone marrow, spleen, or lymph nodes with no evidence of malignancy
    ▪ Low or absent NK-cell activity
    ▪ Ferritin ≥ 500 mcg/L
    ▪ Soluble CD25 level (i.e. soluble IL-2 receptor) of ≥ 2,400 U/mL or standard deviations above age-adjusted laboratory-specific norms

AND
• Medical record documentation of refractory, recurrent or progressive disease or intolerance with conventional HLH therapy (e.g. etoposide, dexamethasone, cyclosporine A, intrathecal methotrexate)

Authorization Duration (for members without a confirmed molecular diagnosis): Initial approval will be for 4 weeks or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of a diagnosis of primary hemophagocytic lymphohistiocytosis based on molecular diagnosis (HLH gene mutations). Subsequent approvals will be for an additional 6 months of less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement (e.g. improvement in hemoglobin/lymphocyte/platelet counts, afebrile, normalization of inflammatory factors/markers) or lack of disease progression. The medication will no longer be covered if the member experiences unacceptable toxicity or received a hematopoietic stem cell transplantation.

Authorization Duration (for members with a confirmed molecular diagnosis): 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 (e.g. improvement in hemoglobin/lymphocyte/platelet counts, afebrile, normalization of inflammatory factors/markers) or lack of disease progression. The medication will no longer be covered if the member experiences unacceptable toxicity or received a hematopoietic stem cell transplantation.

The following policies were reviewed with no changes:
• MBP 2.0 Synagis (palivizumab)
• MBP 15.0 Zevalin (Ibritumomab)
• MBP 36.0 Abraxane (paclitaxel protein bound particles)
• MBP 68.0 Nplate (romiplostim)
• MBP 82.0 Jevtana (cabazitaxel)
• MBP 132.0 Avycaz (cetfazidime and avibactam)
• MBP 134.0 Cresentiva IV (isavuconazonium sulfate)
• MBP 135.0 Unituxin (dinutuximab)
• MBP 139.0 Darzalex (daratumumab)
• MBP 154.0 Radicava (edaravone)