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

MBP 57.0 Tysabri (natalizumab)- Updated policy

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, including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease when the following criteria are met:
   - Medical record documentation of member being established on and responding to Tysabri
   OR
   - Medical record documentation of a diagnosis of a relapsing form of multiple sclerosis, including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease 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 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 74.0 Cimzia (certolizumab pegol)- Updated policy
6. Non-radiographic Axial Spondylarthritis

- Medical record documentation that Cimzia is written by a rheumatologist AND
- Medical record documentation of age 18 years or older AND
- Medical record documentation of non-radiographic axial spondylarthritis AND
- Medical record documentation of at least one of the following:
  - C-reactive protein (CRP) level above the upper limit of normal (10 mg/dL) OR
  - Sacroiliitis on magnetic resonance imaging (MRI)

AND

- Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on at least two (2) nonsteroidal anti-inflammatory drugs (NSAIDs) AND
- Medical record documentation that Cimzia is not being used concurrently with a TNF blocker or other biologic agent.

Quantity Limit: One-week authorization for QL of 3 kits per 28 days; Remainder of the 6-month authorization duration: QL of 1 kit per 28 days

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 signs and symptoms of non-radiographic axial spondylarthritis on six (6) months of Cimzia 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 non-radiographic axial spondylarthritis while on Cimzia therapy.

MBP 108.0 Kadcyla (ado-trastuzumab emtansine)- Updated policy

Kadcyla (ado-trastuzumab emtansine) will be considered medically necessary when all of the following criteria are met:

For Treatment of Early Breast Cancer:

- Prescribed by hematologist/oncologist AND
- Physician supplied documentation of HER2-positive early breast cancer AND
- Physician supplied documentation of neoadjuvant treatment with trastuzumab and a taxane AND
- Physician supplied documentation of residual invasive disease detected in the surgical specimen of the breast or axillary nodes after completion of neoadjuvant therapy.

AUTHORIZATION DURATION: Approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

Authorization of Kadcyla for the treatment of early breast cancer should not exceed the FDA-approved treatment duration of 14 cycles. 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.

For Treatment of Metastatic Breast Cancer:

- Prescribed by a hematologist/oncologist; and
**MBP 115.0 Cyramza (ramucirumab) - Updated policy**

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

1. Advanced or metastatic gastric or gastro-esophageal junction adenocarcinoma:
   - Prescription is written by an oncologist; **AND**
   - Medical record documentation of:
     - Advanced or metastatic gastric or gastro-esophageal junction adenocarcinoma with disease progression on or after prior fluoropyrimidine or platinum containing chemotherapy; **AND**
     - Medical record documentation of use in combination with paclitaxel **OR** for use as monotherapy **AND**
     - Absence of Grade 3 or higher gastrointestinal bleeding within the past three months; **AND**
     - Absence of arterial thromboembolic event, including myocardial infarction, unstable angina, transient ischemic attack (TIA) or cerebrovascular accident (CVA), within the past six months

2. **NSCLC:**
   - Prescription is written by an oncologist **AND**
   - Medical record documentation of metastatic non-small cell lung cancer with disease progression on or after platinum-based chemotherapy **AND**
   - Patients with EGFR or ALK genomic tumor aberrations must provide medical record documentation of disease progression on FDA-approved therapy for these aberrations prior to receiving Cyramza **AND**
   - Medical record documentation of use in combination with docetaxel

3. **Metastatic Colon or Rectal Cancer:**
   - Prescription is written by an oncologist **AND**
   - Medical record documentation of metastatic colon or rectal cancer with disease progression on or after FOLFOX, CapeOX or a regimen not previously containing irinotecan **AND**
   - Medical record documentation of use in combination with irinotecan or FOLFIRI (fluorouracil, leucovorin, and irinotecan)

4. **Hepatocellular Carcinoma (HCC):**
   - Prescription is written by an oncologist **AND**
   - Medical record documentation of a diagnosis of hepatocellular carcinoma **AND**
   - Medical record documentation of an alpha fetoprotein (AFP) level of ≥ 400ng/mL **AND**
   - Medical record documentation of disease progression on or after treatment with sorafenib (Nexavar) or an intolerance to sorafenib (Nexavar)

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

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

2. **Metastatic Non-Small Cell Lung Cancer (NSCLC)**
• 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:
  o Medical record documentation of stage III NSCLC, metastatic NSCLC, OR that the member is not a candidate for surgical resection or definitive chemoradiation AND
  o Medical record documentation that Keytruda is being used as first-line treatment AND
  o Medical record documentation that Keytruda is being given as monotherapy AND
  o Medical record documentation that tumors express PD-L1 (TPS) ≥1% as determined by an FDA-approved test AND
  o Medical record documentation that tumors do not have EGFR or ALK genomic tumor aberrations
  OR
  o Medical record documentation that Keytruda is being given as monotherapy AND
  o Medical record documentation that tumors express PD-L1 (TPS) ≥1% as determined by an FDA-approved test AND
  o Medical record documentation of disease progression on or after platinum-containing chemotherapy AND
  o 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
  o Medical record documentation of metastatic nonsquamous NSCLC AND
  o Medical record documentation that Keytruda will be given in combination with pemetrexed AND either carboplatin or cisplatin AND
  o Medical record documentation that tumors do not have EGFR or ALK genomic tumor aberrations
  OR
  o Medical record documentation that Keytruda will be given in combination with carboplatin AND either paclitaxel or nab-paclitaxel AND
  o 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.
Medical record documentation of one of the following:

- A diagnosis of Head and Neck Squamous Cell Carcinoma that is recurrent or metastatic
  AND
- Disease progression on or after platinum-containing chemotherapy AND
- Keytruda is being used as a single agent.

OR

- A diagnosis of metastatic or unresectable, recurrent Head and Neck Squamous Cell Carcinoma AND
- Keytruda is being used as a first-line treatment AND
- Keytruda is being used as a single agent AND
- Tumors express PD-L1 [Combined Positive Score (CPS) ≥ 1] as determined by an FDA-approved test.

OR

- A diagnosis of metastatic or unresectable, recurrent Head and Neck Squamous Cell Carcinoma AND
- Keytruda is being used as a first-line treatment AND
- Keytruda is being administered in combination with platinum chemotherapy and fluorouracil (FU).

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.

13. Small Cell Lung Cancer (SCLC)
- 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 small cell lung cancer (SCLC) AND
- Medical record documentation of disease progression on or after two lines of therapy, one of which must be platinum-based chemotherapy

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

MBP 132.0 Avycaz (cetfazidime/avibactam) - Updated policy

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 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
- Documentation of patient age > 18 years 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 151.0 Spinraza (nusinersen)- Updated policy

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

Spinraza (nusinersen) will be considered medically necessary when ALL of the following criteria are met:
- Prescription is being prescribed by a neurologist or pediatric neurologist AND
- Medical record documentation of a confirmed diagnosis of 5q Spinal Muscular Atrophy (SMA) by genetic testing with results showing one of the following:
  - Homozygous exon 7 gene deletion OR
  - Homozygous exon 7 conversion mutation OR
  - Compound heterozygous exon 7 mutation
- Medical record documentation of diagnostic testing confirming zero (0) SMN1 copies.
- Medical record documentation that the patient has not received prior treatment with gene therapy (e.g. Zolgensma)*

*Note: Requests for members that show decline in clinical status following treatment with Zolgensma will be reviewed on a case by case basis.

AUTHORIZATION DURATION: If determined to be medically necessary, Spinraza should be approved for an initial authorization duration of 12 months. Subsequent authorizations of Spinraza will be determined medically necessary and should be approved for an authorization duration of 12 months when the following criteria are met:
- Medical record documentation that member is compliant with prescribed nusinersen regimen.
- Medical record documentation that the patient has not received prior treatment with gene therapy (Zolgensma)*

*Note: Requests for members that show decline in clinical status following treatment with Zolgensma will be reviewed on a case by case basis.

QUANTITY LIMIT: Initial approval: One (1) injection (5ml) per fill with an RX count of 6 for a 12-month authorization duration.

Subsequent approvals: One (1) injection (5ml) per fill with an RX count of 3 for a 12-month authorization duration. Max quantity supply: 5; Max Day Supply: 365; Min Day Supply: 120

MBP 152.0 Bavencio (avelumab)- Updated policy

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

Bavencio (avelumab) will be considered medically necessary when ALL of the following criteria are met for each indication:

**Merkel Cell Carcinoma**
- Prescribed by a hematologist/oncologist AND
- Medical record documentation of a diagnosis of metastatic Merkel Cell Carcinoma (MCC) AND
- Medical record documentation of age ≥12 years
**Urothelial Carcinoma**
- Prescribed by a hematologist/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
  - Disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy

**Renal Cell Carcinoma**
- Prescribed by a hematologist/oncologist AND
- Medical record documentation of a diagnosis of advanced renal cell carcinoma (RCC) AND
- Medical record documentation that Bavencio will be given in combination with axitinib (Inlyta) AND
- Medical record documentation that Bavencio and axitinib are being used as first-line treatment

**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 155.0 Ocrevus (ocrelizumab)- 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.

Ocrevus (ocrelizumab) will be considered medically necessary when ALL of the following criteria are met:
- Medical record documentation of age ≥ 18 years AND
- Medical record documentation Ocrevus is prescribed by a neurologist AND
- Medical record documentation of a diagnosis of primary progressive MS (PPMS) OR
  - Medical record documentation of a diagnosis of a relapsing form of multiple sclerosis, including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease AND
- For members with a diagnosis of a relapsing form of multiple sclerosis, medical record documentation of therapeutic failure on, intolerance to, or contraindication to two formulary alternatives.

**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.

**Quantity Limit:**
- Initial authorization: 12 month duration with quantity limit of 3 doses
Re-authorization: 12 month duration with quantity limit of 2 doses

**MBP 188.0 Onpattro (patisiran)- Updated policy**

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

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

- Prescription written by or in consultation with a neurologist, specialist with experience in the treatment of hereditary transthyretin-mediated amyloidosis (hATTR), or geneticist AND
- Medical record documentation of age greater than or equal to 18 years AND
- Medical record documentation of a diagnosis of hereditary transthyretin-mediated amyloidosis as confirmed by genetic testing to confirm a pathogenic mutation in TTR AND one of the following:
  - Biopsy of tissue/organ to confirm amyloid presence OR
  - A clinical manifestation typical of hATTR (Neuropathy and/or CHF) without a better alternative explanation AND
- Medical record documentation of Onpattro being used to treat polyneuropathy AND
- Medical record documentation of familial amyloid polyneuropathy (FAP) stage 1-2 and/or polyneuropathy disability score (PND) indicating the patient is not wheelchair bound or bedridden AND
- Medical record documentation that Onpattro will not be used in combination with other RNA interference treatment

**Note:**

**FAP stage:**
- 1- unimpaired ambulation
- 2- assistance with ambulation
- 3- wheelchair-bound or bedridden

**Polyneuropathy disability score:**
- I- preserved walking, sensory disturbances
- II- impaired walking without need for stick/crutches
- IIIa- walking with 1 stick/crutch
- IIIb- walking with 2 sticks/crutches
- IV-wheelchair-bound or bedridden

**Polyneuropathy disability score (used in Neuro-TTR trial for Tegsedi):**
- I- preserved walking, sensory disturbances
- II- impaired walking without need for stick/crutches
- III- walking with 1 stick/crutch
- IV- walking with 2 sticks/crutches
- V-wheelchair-bound or bedridden

**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. The medication will no longer be covered if the member progresses to FAP stage 3 and/or polyneuropathy disability score indicating the patient is wheelchair-bound or bedridden.

**QUANTITY LIMIT:** 15 mL per 21 days, Min Qty supply: 15; Max Day Supply: 21; Min Day Supply: 180
MBP 199.0 Zolgensma (onasemnogene abeparvovec-xioi)- New policy

DESCRIPTION:
Zolgensma (onasemnogene abeparvovec-xioi) is a recombinant adeno-associated virus vector-based gene therapy that delivers a normal copy of the gene encoding human survival motor neuron (SMN) protein.

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

Zolgensma (onasemnogene abeparvovec-xioi) will be considered medically necessary when ALL of the following criteria are met:

- Medical record documentation of a confirmed diagnosis of 5q Spinal Muscular Atrophy (SMA) by genetic testing with results showing one of the following:
  - Homozygous exon 7 gene deletion OR
  - Homozygous exon 7 conversion mutation OR
  - Compound heterozygous exon 7 mutation
  - Medical record documentation of diagnostic testing confirming zero (0) SMN1 copies

- Prescription is being prescribed by a neurologist or pediatric neurologist AND
- Medical record documentation that the patient will be less than 2 years of age at the time of dosing AND
- Medical record documentation that patient does not have anti-AAV9 antibody titers >1:50 as determined by ELISA (within two weeks of the anticipated infusion date) AND
- Medical record documentation that patient is not permanent ventilator-dependent AND
- Medical record documentation that patient has not received a prior dose of Zolgensma AND
- Medical record documentation that patient will not receive routine concomitant SMN modifying therapy (e.g. Spinraza) with Zolgensma (Note: Any current authorizations for SMN modifying therapy will be terminated upon Zolgensma approval)

AUTHORIZATION DURATION: 30 days (to receive the one-time infusion) or the date equivalent to the patient age of 2 years (whichever is less).
Note: Zolgensma must be administered prior to 2 years of age. If the medication is not administered during this initial month, re-review should occur to ensure patient is still eligible for the medication, particularly the anti-AAV9 antibody titers and ventilator dependence.

QUANTITY LIMIT: One (1) Zolgensma infusion per lifetime

MBP 200.0 Polivy (polatuzumab vedotin-piq)- New policy

DESCRIPTION:
Polivy (polatuzumab vedotin-piq) is an antibody drug conjugate (ADC) directed at CD79b which consists of 3 components: 1) a CD79b-specific humanized IgG1 antibody; 2) a microtubule-disrupting agent, monomethylauristatin E (MMAE); and 3) a protease cleavable linker (which covalently conjugates MMAE to the polatuzumab antibody). The conjugate binds to CD79b (B-cell specific cell surface protein commonly expressed in mature B cell lymphomas, and forms a complex which is internalized within the cell and releases MMAE. MMAE binds to the tubules and disrupts the cellular microtubule network, inducing cell cycle arrest (G2/M phase) and apoptosis.

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

Polivy (polatuzumab vedotin-piq) will be considered medically necessary when ALL of the following criteria are met:
• Prescription written by an oncologist/hematologist AND
• Medical record documentation of age ≥ 18 years AND
• Medical record documentation of relapsed or refractory diffuse large B-cell lymphoma, not otherwise specified AND
• Medical record documentation that Polivy will be used in combination with bendamustine and rituximab AND
• Medical record documentation Polivy will be used as subsequent therapy after a trial of ≥ 2 prior therapies

AUTHORIZATION DURATION: Approval will be for 6 months.

Authorization for Polivy should not exceed the FDA-approved treatment duration of 6, 21 day cycles. 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.

The following policies were reviewed with no changes:

• MBP 7.0 Aldurazyme (laronidase)
• MBP 18.0 Fabrazyme (agalsidase beta)
• MBP 23.0 Velcade (bortezomib)
• MBP 29.0 Elitek (rasburicase)
• MBP 38.0 Clolar (clofarabine)
• MBP 39.0 Naglazyme (galsulfase)
• MBP 43.0 Alpha 1-Antitrypsin Inhibitor Therapy
• MBP 44.0 Elaprase (idursulfase)
• MBP 46.0 Docogen (decitabine)
• MBP 48.0 Rituxan (rituximab)
• MBP 50.0 Vectibix (panitumumab)
• MBP 58.0 Prialt (ziconotide intrathecal infusion)
• MBP 73.0 Arzerra (ofatumumab)
• MBP 78.0 Istodax (romidepsin)
• MBP 80.0 Xiaflex (collagenase clostridium histolyticum)
• MBP 88.0 Halaven (eribulin mesylate)
• MBP 91.0 Yervoy (Ipilimumab)
• MBP 97.0 Kyprolis (carfilzomib)
• MBP 110.0 Xofigo (radium Ra 223 dichloride)
• MBP 113.0 Gazyva (obinutuzumab)
• MBP 114.0 Vimizim (elosulfase alfa)
• MBP 120.0 Sylvant (siltuximab)
• MBP 121.0 Dalvance (dalbavancin)
• MBP 122.0 Sivextro (tedizolid phosphate) IV
• MBP 126.0 Opdivo (nivolumab)
• MBP 133.0 Imlygic (talimogene laherparepvec)
• MBP 137.0 Yondelis (trabectedin)
• MBP 138.0 Onivyde (irinotecan liposome injection)
• MBP 140.0 Empliciti (elotuzumab)
• MBP 142.0 Portrazza (necitumumab)
• MBP 143.0 Praxbind (idarucizumab)
• MBP 147.0 Lartruvo (olaratumab)
• MBP 148.0 Exondys 51 (eteplirsen)
• MBP 149.0 Ameluz (aminolevulinic acid)
• MBP 157.0 Brineura (cerliponase alfa)
• MBP 160.0 Besponsa (inotuzumab ozogamicin)
• MBP 161.0 Aliqopa (copanlisib)
• MBP 163.0 Mylotarg (gemtuzumab ozogamicin)
• MBP 164.0 Vyxeos (daunorubicin-cytarabine liposomal)
• MBP 182.0 Crysvita (burosumab-twza)
• MBP 183.0 Andexxa (andexanet alfa)