“What’s New” Medical Pharmaceutical Policy March 2019 Updates

MBP 187.0 Zemdri (plazomicin)- New policy

DESCRIPTION:
Zemdri (plazomicin) is an aminoglycoside, which acts by binding to bacterial 30S ribosomal subunit, inhibiting protein synthesis.

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

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

- Prescribed by or in consultation with an infectious disease specialist AND
- Age of 18 years or greater AND
- Medical record documentation of a diagnosis of complicated urinary tract infections (cUTI) including pyelonephritis caused by the following susceptible microorganisms: *Escherichia coli, Klebsiella pneumoniae, Proteus mirabilis*, and *Enterobacter cloacae* AND
- Medical record documentation of culture and sensitivity showing the patient’s infection is not susceptible to ALL alternative antibiotic treatments OR a documented history of previous intolerance to or contraindication to ALL other antibiotics shown to be susceptible on the culture and sensitivity OR
- If initiated during an inpatient stay: Medical record documentation of a 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

AUTHORIZATION DURATION: Up to a maximum of 7 days

MBP 188.0 Onpattro (patisiran)- New policy

DESCRIPTION:
Onpattro (patisiran) is a double-stranded small interfering ribonucleic acid (siRNA) that causes degradation of mutant and wild-type transthyretin (TTR) mRNA through RNA interference, which results in a reduction of serum TTR protein and TTR protein deposits in tissues. Serum TTR is a carrier of retinol binding protein, which is involved in the transport of vitamin A in the blood.

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 at a hereditary transthyretin-mediated amyloidosis treatment center, or geneticist AND
- Medical record documentation of age greater than or equal to 18 years AND
- Medical record documentation of diagnosis of hereditary transthyretin-mediated amyloidosis as confirmed by all of the following:
  - Biopsy of tissue/organ to confirm amyloid presence AND
  - Immunohistochemistry or mass spectroscopy to differentiate ATTR amyloidosis from amyloid light-chain amyloidosis AND
  - Genetic testing to differentiate between hereditary and wild-type ATTR amyloidosis 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 of I, II, IIIA, or IIIB 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

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 IV (wheelchair-bound or bedridden).

QUANTITY LIMIT: 15 mL per 21 days

MBP 189.0 Lumoxiti (moxetumomab pasudotox-tdfk)- New policy

DESCRIPTION:
Lumoxiti (moxetumomab pasudotox-tdfk) is a CD22-directed cytotoxin composed of a recombinant murine immunoglobulin genetically fused to truncated Pseudomonas exotoxin (PE38). Moxetumomab pasudotox-tdfk binds CD22 on the cell surface of B-cells and is internalized. Moxetumomab pasudotox-tdfk internalization results in ADP-ribosylation of elongation factor 2, inhibition of protein synthesis, and apoptotic cell death.

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

Lumoxiti (moxetumomab pasudotox-tdfk) will be considered medically necessary when ALL of the following criteria are met:

Hairy Cell Leukemia
- Prescription is written by a hematologist/oncologist AND
- Medical record documentation that member is 18 years of age or older AND
- Medical record documentation of a diagnosis of relapsed or refractory hairy cell leukemia (HCL) AND
- Medical record documentation that member has received at least two prior systemic therapies, one of which must be a purine nucleoside analog (e.g., cladribine, pentostatin (Nipent), etc.)

AUTHORIZATION DURATION: Initial approval will be limited to 6 cycles (6 months) or less if the reviewing provider feels it is medically necessary. Subsequent approval for treatment past 6 cycles (6 months) will require documentation of well-controlled, peer-reviewed literature with evidence to support this request.

Note: FDA recommended treatment duration is for a maximum of 6 cycles (The recommended dose of Lumoxiti is 0.04 mg/kg administered as a 30-minute intravenous infusion on Days 1, 3, and 5 of each 28-day cycle)
**MBP 190.0 Ilumya (tildrakizumab-asnm) - New policy**

**DESCRIPTION:**
Ilumya (tildrakizumab-asnm) is human IgG1/k monoclonal antibody which selectively binds to the p19 subunit of interleukin (IL)-23, thereby inhibiting its interaction with the IL-23 receptor, resulting in inhibition of the proinflammatory cytokines and chemokines associated with the binding of naturally occurring 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

Ilumya (tildrakizumab-asnm) will be considered medically necessary when ALL of the following criteria are met:

- Prescribed by a dermatologist **AND**
- Medical record documentation that the patient is 18 years of age or older **AND**
- Medical record documentation of a diagnosis of moderate to severe plaque psoriasis characterized by greater than or equal to 5% body surface area involved or disease affecting crucial body areas such as the hands, feet, face, or genitals **AND**
- Medical record documentation that Ilumya is not being used concurrently with a TNF blocker or other biologic agent **AND**
- Medical record documentation of an inadequate response to, contraindication to, or failure on at least 3 months of Humira AND Cosentyx

**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 the treated indication at six (6) months of Ilumya 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 the treated indication while on Ilumya therapy.

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

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

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

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

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

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

**MBP 85.0 Cinryze (C1 esterase inhibitor, human)- Updated policy**

**DESCRIPTION:**
Cinryze (C1 esterase inhibitor, human) is indicated for routine prophylaxis against angioedema attacks in adult and adolescent patients with Hereditary Angioedema.

**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.

Cinryze (C1 esterase inhibitor, human) will be considered medically necessary for prophylaxis against attacks of hereditary angioedema in adults and adolescents when the following criteria are met:
- Member is 13 years of age or older; and
- Prescription is written by an allergist, immunologist, hematologist or dermatologist; and
- Medication is being used as prophylactic therapy for HAE attacks; and
- Diagnosis of hereditary angioedema has been established and supported by physician provided documentation of:
  - Recurrent, self-limiting non-inflammatory subcutaneous angioedema without urticaria, lasting more than 12 hours; or
  - Laryngeal edema; or
  - Recurrent, self-remitting abdominal pain lasting more than 6 hours, without clear organic etiology

  **And**

- the presence of specific abnormalities in complement proteins, in the setting of a suggestive clinical history of episodic angioedema without urticaria; supported by
  - Medical record documentation of 2 or more sets of complement studies, separated by one month or more, showing consistent results of
    - Low C4 levels and
    - Less than 50% of the lower limit of normal C1-INH antigenic protein levels OR
    - Less than 50% of the lower limit of normal C1-INH function levels

  **AND**

- Physician provided documentation of failure on, intolerance to, or contraindication to danazol; and

- Physician provided documentation of history of more than one (1) severe event per month OR a history of laryngeal attacks
MBP 119.0 Keytruda (pembrolizumab)- Updated policy

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

1. **Unresectable or Metastatic 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 that Keytruda is not being used in combination with any other agents for the treatment of unresectable or metastatic melanoma.

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 that Keytruda is being given as monotherapy 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 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:
     - Medical record documentation of progression following prior treatment(s) AND
     - Medical record documentation of no satisfactory alternative treatment options
   - For colorectal cancer:
     - 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:
     - Disease progression during or following platinum-containing chemotherapy OR
     - Disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy OR
     - Patient is not eligible cisplatin-containing chemotherapy* AND
     - Tumors express PD-L1 (combined positive score [CPS] greater than or equal to 10) as determined by an FDA-approved test OR
     - 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 AND
• 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 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

MBP 144.0 Tecentriq (atezolizumab) - Updated policy

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:
  o Disease progression during or following platinum-containing chemotherapy OR
  o Patient is not eligible for cisplatin-containing therapy AND
  o Tumors express PD-L1 (greater than or equal to 5%) as determined by an FDA-approved test OR
  o 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 AND
• Medical record documentation that the patient has had either:
  o Disease progression during or following platinum-containing chemotherapy OR
  o 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.).
  o Medical record documentation of disease progression during or following platinum-containing chemotherapy OR
o 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

o Medical record documentation of a non-squamous histologic subtype AND

o Medical record documentation that Tecentriq will be given as first-line treatment AND

o Medical record documentation that Tecentriq will be given in combination with bevacizumab, paclitaxel, AND carboplatin AND

o Medical record documentation that the patient does not have an EGFR or ALK genomic tumor aberration.

MBP 159.0 Kymriah (tisagenlecleucel)- Updated policy

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

Acute Lymphoblastic Leukemia (ALL)

• Prescription written by a hematologist/oncologist AND

• Medical record documentation that patient is less than 26 years of age AND

• Medical record documentation of a diagnosis of B-cell precursor acute lymphoblastic leukemia (ALL) that is refractory or in second (or later) relapse AND

• Medical record documentation that the member has not received prior treatment with CAR-T cell therapy or other genetically modified T cell therapy

Note: The indication of Kymriah for Acute Lymphoblastic Leukemia (ALL) is intended to treat patients up to the age of 25 years 364 days. Upon reaching 26 years of age the patient is no longer a candidate for Kymriah treatment. Per Novartis, Kymiah will not be manufactured for any patient who does not meet the specific FDA approved indication, including these age restrictions. (This does not apply to Large B-Cell Lymphoma)

Large B-Cell Lymphoma

• Prescription written by a hematologist/oncologist AND

• Medical record documentation that patient is 18 years of age or greater AND

• Medical record documentation of one of the following diagnoses:
  • High grade B-cell lymphoma OR
  • Diffuse Large B-Cell Lymphoma (DLBCL) arising from follicular lymphoma OR
  • Diffuse Large B-cell Lymphoma (DLBCL) not otherwise specified

AND

• Medical record documentation of relapsed or refractory disease after at least two lines of systemic therapy AND

• Medical record documentation that the member has not received prior treatment with CAR-T cell therapy or other genetically modified T cell therapy

Limitation of use: Kymriah is not indicated for treatment of patients with primary central nervous system lymphoma.

AUTHORIZATION DURATION: (For all indications) Approved requests will be for a One-time authorization for one administration of Kymriah.
MBP 162.0 Yescarta (axicabtagene ciloleucel)- Updated policy

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

Yescarta (axicabtagene ciloleucel) will be considered medically necessary when ALL of the following criteria are met:

Large B-Cell Lymphoma
- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that patient is 18 years of age or older **AND**
- Medical record documentation of one of the following diagnoses:
  - Relapsed or refractory diffuse large B-cell lymphoma (DLBCL) **OR**
  - Relapsed or refractory primary mediastinal large B-cell lymphoma **OR**
  - Relapsed or refractory high-grade B-cell lymphoma **AND**
- Medical record documentation of a therapeutic failure on two or more previous lines of therapy **AND**
- Medical record documentation that the member has not received prior treatment with CAR-T cell therapy or other genetically modified T cell therapy

Note: Yescarta is not indicated for the treatment of patients with primary central nervous system lymphoma.

**AUTHORIZATION DURATION:** Yescarta will be approved for a one-time authorization for one administration of Yescarta.

MBP 166.0 Adcetris (brentuximab vedotin)- 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

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

**Classical Hodgkin Lymphoma (cHL)**
- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that patient is at least 18 years of age **AND**
- Medical record documentation of a diagnosis of classical Hodgkin Lymphoma meeting one of the following situations:
  - Medical record documentation of failure of autologous hematopoietic stem cell transplant (auto-HSCT)
  **OR**
  - Medical record documentation of failure of at least 2 multi-agent chemotherapy regimens in patients who are not candidates for auto-HSCT
  **OR**
  - Medical record documentation of use as consolidation treatment following auto-HSCT in patients with high risk of relapse or progression post-auto-HSCT (high risk patients
include: refractory to first line therapy, relapse within 12 months of first line therapy, presence of extranodal disease)

OR

- Medical record documentation of previously untreated Stage III or IV cHL AND
  - Medical record documentation that Adcetris will be used in combination with doxorubicin, vinblastine, and dacarbazine.

**Systemic Anaplastic Large Cell Lymphoma (sALCL)**

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that patient is at least 18 years of age **AND**
- Medical record documentation of a diagnosis of systemic anaplastic large cell lymphoma (sALCL) meeting one of the following situations:
  - Medical record documentation of failure of at least 1 prior multi-agent chemotherapy regimen

OR

- Medical record documentation of previously untreated sALCL AND
- Medical record documentation that Adcetris will be used in combination with cyclophosphamide, doxorubicin, and prednisone

**Primary Cutaneous Anaplastic Large Cell Lymphoma (pcALCL)**

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that patient is at least 18 years of age **AND**
- Medical record documentation of a diagnosis of primary cutaneous anaplastic large cell lymphoma (pcALCL) OR CD30-expressing mycosis fungoides (MF) **AND**
- Medical record documentation of failure of prior radiation or systemic therapy

**Peripheral T-cell Lymphomas (PTCL)**

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that patient is at least 18 years of age **AND**
- Medical record documentation of a diagnosis of a CD30-expressing peripheral T-cell lymphoma (PTCL), including angioimmunoblastic T-cell lymphoma and PTCL not otherwise specified **AND**
- Medical record documentation that Adcetris will be used in combination with cyclophosphamide, doxorubicin, and prednisone

**AUTHORIZATION DURATION:**

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

*For all other indications: Initial approval will be for 6 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. Adcetris will no longer be covered if the member experiences unacceptable toxicity or worsening of disease.*

**AUTHORIZATION DURATION:**

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<tr>
<th>Indication</th>
<th>Initial Authorization</th>
<th>Subsequent Authorizations</th>
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<tr>
<td>Previously Untreated Stage III or IV cHL</td>
<td>Initial approval will be limited to 12 doses (6 months) or less if the reviewing provider feels it is medically appropriate.</td>
<td>Subsequent approval for treatment past the initial 12 doses will require documentation of well-controlled, peer-reviewed literature with evidence to support this request.</td>
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<tr>
<td>Condition</td>
<td>Initial Approval</td>
<td>Subsequent Approval</td>
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<td>cHL Consolidation</td>
<td>Initial approval will be limited to 6 months or less if the reviewing provider feels it is medically appropriate.</td>
<td>Subsequent approval will be for one additional 6-month authorization to allow for a total of 16 cycles of treatment.</td>
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<td>Previously Untreated sALCL or Other CD30-expressing PTCLs</td>
<td>Initial approval will be limited to 8 doses (6 months) or less if the reviewing provider feels it is medically appropriate.</td>
<td>Subsequent approval for treatment past the initial 8 doses will require documentation of well-controlled, peer-reviewed literature with evidence to support this request.</td>
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<tr>
<td>Relapsed cHL</td>
<td>Initial approval will be for 6 months or less if the reviewing provider feels it is medically appropriate.</td>
<td>Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. Adcetris will no longer be covered if the member experiences unacceptable toxicity or worsening of disease.</td>
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<td>Relapsed sALCL</td>
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<td>Relapsed pcALCL or CD30-expressing MF</td>
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**MBP 167.0 Vabomere (meropenem/vaborbactam) - Updated policy**

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

Vabomere (meropenem/vaborbactam) will be considered medically necessary when ALL of the following criteria are met:

- Prescribed by or in consultation with an infectious disease specialist **AND**
- Age of 18 years or greater **AND**
- Medical record documentation of a diagnosis of complicated urinary tract infections (cUTI) including pyelonephritis caused by the following susceptible microorganisms: *Enterobacter cloacae species complex, Escherichia coli, or Klebsiella pneumoniae 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 **OR**
- **If initiated during an inpatient stay:** Medical record documentation of a 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

**AUTHORIZATION DURATION:** Approvals will be made for a one-time authorization of 14 days.

**QUANTITY LIMIT:** 6 vials per day
The following policies were reviewed with no changes:

- MBP 60.0 Cerezyme (imiglucerase)
- MBP 64.0 Arranon (nelarabine)
- MBP 65.0 Torisel (temsirolimus)
- MBP 90.0 Benlysta (belimumab)
- MBP 93.0 Nulojix (belatacept)
- MBP 96.0 Voraxaze (glucarpidase)
- MBP 105.0 VPRIV (velaglucerase alfa)
- MBP 108.0 Kadcyla (ado-trastuzumab emtansine)
- MBP 111.0 Marqibo (vincristine sulfate liposome injection)
- MBP 117.0 Beleodaq (belinostat)
- MBP 118.0 Entyvio (vedolizumab)
- MBP 131.0 Cosentyx (secukinumab)
- MBP 168.0 Parsabiv (etelcalcetide)
- MBP 169.0 Baxdela IV (delaflouxacin)
- MBP 170.0 Lutathera (lutetium Lu 177 dotatate)
- MBP 172.0 Trisenox (arsenic trioxide)