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

MBP 5.0 Remicade (infliximab), Inflectra (infliximab-dyyb), Renflexis (infliximab-abda)- Updated policy

Remicade (infliximab), Inflectra (infliximab-dyyb) or Renflexis (infliximab-abda) will be considered medically necessary when all of the following criteria are met based on indication:

For Treatment of Rheumatoid Arthritis:

- Must be 18 years of age or greater **AND**
- Requesting provider must be a rheumatologist **AND**
- Diagnosis of moderate to severe rheumatoid arthritis according the American College of Rheumatology Criteria for the Classification and Diagnosis of Rheumatoid Arthritis

AND

- Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of Humira* AND Enbrel* **AND**
- Continuation of effective dose of methotrexate during infliximab therapy **AND**
- For new start Remicade or Renflexis requests, medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of Inflectra*

Recommended guidelines for use in the treatment of rheumatoid arthritis

- *3 mg/kg given as an intravenous infusion followed with additional similar doses at 2 and 6 weeks after the first infusion then every 8 weeks thereafter. Infliximab should be given in combination with methotrexate.*
- *For patients who have an incomplete response, consideration may be given to adjusting the dose up to 10 mg/kg or treating as often as every 4 weeks.*

For Treatment of Crohn's Disease, Pediatric Crohn's Disease, and/or Fistulizing Crohn's Disease:

- Must be 6 years of age or older; **AND**
- Prescription is written by a gastroenterologist **AND**
- Medical record documentation of a diagnosis of moderate to severe Crohn's disease **AND**
- One of the following:
  - Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Humira* **OR**
  - Physician documentation of Crohn's disease with actively draining fistulas.

  AND
- For new start Remicade or Renflexis requests, medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of Inflectra*

Recommended guidelines for use in the treatment of crohn's disease or fistulizing crohn's disease:

- *5 mg/kg given intravenously as an induction regimen at 0, 2, and 6 weeks followed by a maintenance regimen of 5 mg/kg every 8 weeks thereafter*
- *For adult members who respond and then lose response, consideration may be given to treatment with 10 mg/kg.*

For Treatment of Ulcerative Colitis:

- Must be at least 6 years of age; **AND**
- Must be prescribed by a gastroenterologist; **AND**
- Physician provided documentation of a diagnosis of moderate to severe ulcerative colitis;

  AND
- Physician provided documentation of failure on, intolerance to, or contraindication to adequate trials of conventional therapy that include corticosteroids, aminosalicylates and immunomodulators (eg, 6-mercaptopurine or azathioprine **AND**

- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to at least a 12 week trial of Humira* **OR** medical record documentation of age < 18 years **AND**
- For new start Remicade requests, medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of Inflectra* OR medical record documentation of age <18 years **OR**
- For new start Renflexis requests, medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3-month trial of Inflectra*

Recommended guidelines for the use in the treatment of ulcerative colitis

- *5 mg/kg as an intravenous infusion followed with additional similar doses at 2 and 6 weeks after the first infusion, then every 8 weeks thereafter.*

For Treatment of Ankylosing Spondylitis:

- Physician documentation of a diagnosis of ankylosing spondylitis **AND**
- Prescribing physician must be a rheumatologist **AND**
- Must be at least 18 years of age **AND**
- Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of Humira* **AND** Enbrel* **AND**
- For new start Remicade or Renflexis requests, medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of Inflectra*

Recommended guidelines for use in ankylosing spondylitis

- *5mg/kg at 0, 2 and 6 weeks, then every 6 weeks thereafter*

For the treatment of Plaque Psoriasis:

- Prescribed by a dermatologist **AND**
- Insured individual must be at least 18 years of age **AND**
- Physician provided 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 of an inadequate response to, contraindication to, or failure on at least 3 months of Humira* and Enbrel* **AND**
- For new start Remicade or Renflexis requests, medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of Inflectra*

Recommended guidelines for the use in the treatment of plaque psoriasis

- *5 mg/kg as an intravenous infusion followed with additional similar doses at 2 and 6 weeks after the first infusion, then every 8 weeks thereafter.*

For the treatment of Psoriatic Arthritis:

- Physician provided documentation of a diagnosis of moderately to severely active psoriatic arthritis which must include the following:
    - Documentation of either active psoriatic lesions or a documented history of psoriasis **AND**
- Must be prescribed by a rheumatologist or dermatologist **AND**
- Must be at least 18 years of age **AND**
- Medical record documentation of an inadequate response to, contraindication to, or failure on 12 weeks of **Enbrel*** **AND Humira*** **AND**
- For new start Remicade or Renflexis requests, medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of

Inflectra*

Recommended guidelines for the use in the treatment of psoriatic arthritis

- *5 mg/kg as an intravenous infusion followed with additional similar doses at 2 and 6 weeks after the first infusion, then every 8 weeks thereafter.*

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 infliximab 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 infliximab therapy.

LIMITATIONS: Inflectra and Renflexis are not approved for the use in pediatric ulcerative colitis due to orphan drug exclusivity for Remicade.

MBP 104.0 Emend IV (fosaprepitant)- Updated policy

Emend IV (fosaprepitant) will be considered medically necessary when all of the following criteria are met:

1. Medical record documentation that Emend is being used for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy; **OR**

2. Medical record documentation that Emend is being used for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy for insured individuals who have a treatment failure or contraindication to ondansetron (Zofran) or ~~and~~ granisetron (Kytril). Treatment failure is defined as allergy, intolerable side-effects, significant drug-drug interaction, or lack of efficacy.

ADDITIONAL INFORMATION:
The following antineoplastic agents are considered highly emetogenic (refer to NCCN for complete list ~~not a complete list~~):

- AC combination defined as any chemotherapy regimen that contains an anthracycline and cyclophosphamide ~~either doxorubicin or epirubicin with cyclophosphamide~~
- Carboplatin
- Carmustine ~~at doses >250mg/m^2~~
- Cisplatin
- Cyclophosphamide at doses >1500 mg/m^2
- Dacarbazine
- Dactinomycin
- Daunorubicin
- Doxorubicin ~~at doses ≥ 60mg/m^2~~
- Epirubicin ~~at doses >90mg/m^2~~
- Ifosfamide ~~at doses ≥2g/m^2~~
- Irinotecan
- Mechlorethamine
- Methotrexate at doses ≥ 250mg/m^2
- Oxaliplatin
- Streptozotocin
- Trabectedin

MBP 24.0 Aloxi (Palonosetron)- Updated policy

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

1. **PREVENTION OF ACUTE NAUSEA AND VOMITING**
   - Medical record documentation that Aloxi is being used for prevention of chemotherapy induced nausea or vomiting from low, or minimally, emetogenic cancer chemotherapy for members who have a treatment failure or contraindication to Granisetron (Kytril) or Ondansetron (Zofran). Treatment failure is defined as an allergy, intolerable side effects, significant drug-drug interactions, or lack of efficacy; **OR**
   - ~~Medical record documentation that Aloxi is being used for prevention of acute nausea or vomiting associated with initial and repeat courses of moderately or highly emetogenic cancer chemotherapy.~~
   - Medical record documentation that Aloxi is being used for prevention of acute and/or delayed nausea or vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy OR acute nausea or vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy.

   The following antineoplastic agents are considered MODERATELY emetogenic (refer to NCCN for complete list ~~not a complete list~~):
   - Aldesleukin >12-15 million IU/m^2
   - Amifostine >300 mg/m^2
   - Arsenic trioxide
   - Azacitidine
   - Bendamustine
   - Busulfan
   - ~~Carboplatin~~
   - ~~Carmustine ≤ 250 mg/m^2~~
   - Clofarabine
   - Cyclophosphamide ≤ 1500mg/m^2
   - Cytarabine >200mg/m^2
   - ~~Dactinomycin~~
   - ~~Daunorubicin~~
   - Dinutuximab
   - ~~Doxorubicin <60 mg/m^2~~
   - ~~Epirubicin ≤ 90 mg/m^2~~
   - Idarubicin
   - ~~Ifosfamide <2 g/m^2 per dose~~
   - Interferon alfa ≥ 10 million IU/m^2
   - ~~Irinotecan~~
   - Melphalan
   - ~~Methotrexate ≥250 mg/m^2~~
   - ~~Oxaliplatin~~
   - Temozolomide
   - ~~Trabectedin~~

   The following antineoplastic agents are considered highly emetogenic (refer to NCCN for complete list ~~not a complete list~~):
   - AC combination defined as any chemotherapy regimen that contains an anthracycline and cyclophosphamide ~~either doxorubicin or epirubicin with cyclophosphamide~~
   - Carboplatin
   - Carmustine ~~at doses >250mg/m^2~~
   - Cisplatin
   - Cyclophosphamide at doses >1500 mg/m^2
   - Dacarbazine
   - Dactinomycin
   - Daunorubicin
   - Doxorubicin ~~at doses ≥ 60mg/m^2~~
   - Epirubicin ~~at doses >90mg/m^2~~
   - Ifosfamide ~~at doses ≥2g/m^2~~
   - Irinotecan
   - Mechlorethamine
   - Methotrexate at doses ≥ 250mg/m^2
   - Oxaliplatin
   - Streptozotocin
   - Trabectedin

MBP 113.0 Gazyva (obinutuzumab)- Updated policy

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

1. **Chronic Lymphocytic Leukemia**
   - Prescribed by a hematologist/oncologist; **AND**
   - Medical record documentation of previously untreated chronic lymphocytic leukemia; **AND**
   - Medical record documentation that Gazyva will be used in combination with chlorambucil
   - ~~Medical record documention that Gazyva will be used as a monotherapy or in combination with chlorambucil for disease without del(17p) or del(11q) in patients age ≥70 years or in younger patients with significant comorbidities; **OR**~~
   - ~~Medical record documention that Gazyva will be used in combination with chlorambucil for disease with del(11q) or del(17p)~~

   AUTHORIZATION DURATION for CLL: 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.

2. **Follicular Lymphoma**
   - Medical record documentation of a diagnosis of follicular lymphoma AND
     - For first line therapy:
       - Medical record documentation of previously untreated stage II bulky, III or IV follicular lymphoma AND
       - Medical record documentation that Gazyva will be used in combination with chemotherapy
       - OR
       - Medical record documentation that the patient has achieved at least a partial remission of stage II bulky, III, or IV follicular lymphoma if previously treated with at least 6 cycles of Gazyva in combination with chemotherapy AND
       - Medical record documentation that Gazyva will be used as monotherapy

     - For second line or subsequent therapy:
       - Medical record documentation that the patient has relapsed after, or is refractory to, a rituximab-containing regimen. AND
       - Medical record documentation that Gazyva is being used in combination with bendamustine
       - OR
       - Medical record documentation that the patient achieved a complete response, partial response, or has stable disease after at least 6 cycles of Gazyva in combination with bendamustine AND
       - Medical record documentation that Gazyva will be used as monotherapy.

     ***Note:** In clinical trials for the treatment of stage II bulky, III or IV follicular lymphoma chemotherapy was defined as: CHOP (cyclophosphamide, doxorubicin, vincristine and prednisone); CVP (cyclophosphamide, vincristine and prednisone); or bendamustine
   - ~~Medical record documentation of a diagnosis of follicular lymphoma **AND**~~
   - ~~Medical record documentation that Gazyva is being used in combination with bendamustine **OR** that the patient was previously treated with 6 cycles of Gazyva + bendamustine **AND**~~
   - ~~Medical record documentation that the patient has relapsed after, or is refractory to, a rituximab-containing regimen.~~

AUTHORIZATION DURATION for follicular lymphoma: Initial approval will be 6 months for this indication. The following criteria should apply to reauthorization requests for Gazyva:

- Medical record documentation that the patient achieved a complete response, partial response, or has stable disease after 6 cycles of Gazyva + bendamustine therapy OR after 6 cycles of Gazyva + chemotherapy **AND**
- Documentation that Gazyva will be used as monotherapy.

MBP 162.0 Yescarta (axicabtagene ciloleucel) - New policy

Yescarta (axicabtagene ciloleucel) is a CD19-directed genetically modified autologous T cell immunotherapy in which a patient's T cells are reprogrammed with a transgene encoding a chimeric antigen receptor (CAR) to identify and eliminate CD19-expressing malignant and normal cells. The CAR is comprised of a murine single-chain antibody fragment which recognizes CD19 and is fused to CD28 and CD3 zeta. CD3 zeta is a critical component for initiating T-cell activation and antitumor activity. After binding to CD19-expressing cells, the CD28 and CD3-zeta co-stimulatory domains activate downstream signaling cascades, which results in T cell activation, proliferation, acquisition of effector functions, and secretion of inflammatory cytokines and chemokines, leading to destruction of CD19-expressing cells. Axicabtagene ciloleucel is prepared from the patient's peripheral blood cells obtained via leukapheresis.

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

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 163.0 Mylotarg (gemtuzumab ozogamicin)- New policy

Mylotarg (gemtuzumab ozogamicin) is a humanized CD-33 directed monoclonal antibody-drug conjugate, which is composed of the IgG4 kappa antibody gemtuzumab linked to a cytotoxic calicheamicin derivative. CD33 is expressed on leukemic cells in over 80% of patients with AML (Castaigne 2012). Gemtuzumab ozogamicin binds to the CD33 antigen, resulting in internalization of the antibody-antigen complex. Following internalization, the calicheamicin derivative is released inside the myeloid cell. The calicheamicin derivative binds to DNA resulting in double strand breaks, inducing cell cycle arrest and apoptosis.

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

Mylotarg (gemtuzumab ozogamicin) will be considered medically necessary when ALL of the following

criteria are met:

Newly-diagnosed CD33-positive Acute Myeloid Leukemia

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation of a diagnosis of newly diagnosed CD33-positive Acute Myeloid Leukemia **AND**
- Medical record documentation of the member being ≥ 18 years

Relapsed or refractory CD33-positive Acute Myeloid Leukemia

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation of relapsed or refractory CD33-positive Acute Myeloid Leukemia **AND**
- Medical record documentation of the member being ≥ 2 years

AUTHORIZATION DURATION: If approved, authorization should be for a maximum of 9 cycles for an authorization duration of 12 months.

For requests exceeding the above limits, medical record documentation of the following is required: Peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing beyond the FDA-approved treatment duration.

MBP 164.0 Vyxeos (daunorubicin/cytarabine liposomal) - New policy

Vyxeos (daunorubicin/cytarabine liposomal) is a combination product with a fixed 1:5 (daunorubicin:cytarabine) molar ratio; this ratio has been shown to have synergistic effects in killing leukemia cells in vitro and in animal models. Daunorubicin (conventional) inhibits DNA and RNA synthesis by intercalation between DNA base pairs and by steric obstruction. Daunomycin intercalates at points of local uncoiling of the double helix. Although the exact mechanism is unclear, it appears that direct binding to DNA (intercalation) and inhibition of DNA repair (topoisomerase II inhibition) result in blockade of DNA and RNA synthesis and fragmentation of DNA. Cytarabine (conventional) is a pyrimidine analog and is incorporated into DNA; however, the primary action is inhibition of DNA polymerase resulting in decreased DNA synthesis and repair. The degree of cytotoxicity correlates linearly with incorporation into DNA; therefore, incorporation into the DNA is responsible for drug activity and toxicity. Cytarabine is specific for the S phase of the cell cycle (blocks progression from the G1 to the S phase).

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

Vyxeos (daunorubicin/cytarabine liposomal) will be considered medically necessary when ALL of the following criteria are met:

Acute Myeloid Leukemia (AML)

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation of age of ≥18 years **AND**
- Medical record documentation of one of the following diagnoses:
    - Newly-diagnosed therapy-related acute myeloid leukemia (t-AML) OR
    - AML with myelodysplasia-related changes (AML-MRC)

  AND
- Medical record documentation of rationale why 7+3 (cytarabine + daunorubicin) is not a medically appropriate treatment for the member (i.e. Unable to tolerate 7+3 regimen due to performance status or age, unable to administer full dose 7+3 regimen without exceeded maximum lifetime cumulative anthracycline dose, etc.)

QUANTITY LIMIT: Vyxeos should not exceed four (4) cycles or the patient's maximum lifetime cumulative anthracycline dosage, whichever comes first.

AUTHORIZATION DURATION: If approved, initial approval should be for a period of six (6) months. Subsequent approvals will be for an additional six (6) months and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if the member experiences unacceptable toxicity or worsening of disease.

Authorization of Vyxeos should not exceed four (4) cycles or the patient's maximum lifetime cumulative anthracycline dosage, whichever comes first. For requests exceeding the above limits, 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 and/or maximum cumulative anthracycline dose.

MBP 165.0 Rituxan Hycela (rituximab/hyaluronidase) - New policy

Rituxan Hycela is a combination product containing rituximab and hyaluronidase. Rituximab is a monoclonal antibody directed against the CD20 antigen on the surface of pre-B and mature B-lymphocytes. CD20 regulates cell cycle initiation; and, possibly, functions as a calcium channel. Rituximab binds to the antigen on the cell surface, activating complement-dependent B-cell cytotoxicity; and to human Fc receptors, mediating cell killing through an antibody-dependent cellular toxicity. Hyaluronidase increases the absorption rate of rituximab-containing products by increasing permeability of subcutaneous tissue through temporary depolymerization of hyaluronan

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

Rituxan Hycela (rituximab/hyaluronidase) will be considered medically necessary when ALL of the following criteria are met:

Chronic Lymphocytic Leukemia (CLL)

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation of a diagnosis of Chronic Lymphocytic Leukemia (CLL) **AND**
- Medical record documentation that Rituxan Hycela is being given in combination with fludarabine and cyclophosphamide **AND**
- Medical record documentation that member has received and tolerated a minimum of one (1) cycle of intravenous rituximab (Rituxan)

Note: The FDA-approved dosage for CLL is 1,600mg/26,800units of Rituxan Hycela per dose.

Diffuse Large B-Cell Lymphoma (DLBCL)

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation of a diagnosis of Diffuse Large B-Cell Lymphoma (DLBCL) **AND**
- Medical record documentation that member has NOT received prior treatment for DLBCL **AND**
- Medical record documentation that Rituxan Hycela is being given in combination with cyclophosphamide, doxorubicin, vincristine, and prednisone (CHOP) or other anthracycline-based chemotherapy regimen **AND**
- Medical record documentation that member has received and tolerated a minimum of one (1) cycle of intravenous rituximab (Rituxan)

Note: The FDA-approved dosage for DLBCL is 1,400mg/23,400units of Rituxan Hycela per dose.

Follicular Lymphoma (FL)

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation of a diagnosis of Follicular Lymphoma (FL) **AND**
- Medical record documentation that member has received and tolerated a minimum of one (1) full dose of intravenous rituximab (Rituxan)

Note: The FDA-approved dosage for FL is 1,400mg/23,400units of Rituxan Hycela per dose. The schedule of Rituxan Hycela is specific to diagnosis.

Note: Rituxan Hycela has not been studied in and is not FDA-approved for non-malignant conditions. For this reason, Rituxan Hycela is considered off-label and investigational for use in non-malignant conditions and is not covered.

QUANTITY LIMIT: Authorizations should be entered by **GPID** with the following quantity limits (authorized strength will be dependent on diagnosis):

- Rituxan Hycela 1,400mg/23,400units: **4 vials (46.8mL) per 28 days**
- Rituxan Hycela 1,600mg/26,800units: **1 vial (13.4mL) per 28 days**

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.

Requests exceeding the maximum FDA-approved treatment duration (listed below) will require the following:

- Medical record documentation of peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing beyond the FDA-approved treatment duration.

MBP 166.0 Adcetris (brentuximab vedotin) - New policy

Adcetris (brentuximab vedotin) is an antibody drug conjugate (ADC) directed at CD30 consisting of 3 components: 1) a CD30-specific chimeric IgG1 antibody cAC10; 2) a microtubule-disrupting agent, monomethylauristatin E (MMAE); and 3) a protease cleavable dipeptide linker (which covalently conjugates MMAE to cAC10). The conjugate binds to cells which express CD30, 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

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

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

AND

- Medical record documentation of a diagnosis of classical Hodgkin Lymphoma (cHL) AND
- Medical record documentation of failure of autologous hematopoietic stem cell transplant (auto-HSCT) OR
- Medical record documentation of failure of at least 2 multi-agent chemotherapy regimens in patients who are not candidates for auto-HSCT OR

- Medical record documentation of use as consolidation treatment following auto-HSCT in patients with high risk of relapse or progression post-auto-HSCT (high risk patients include: refractory to first line therapy, relapse within 12 months of first line therapy, presence of extranodal disease)

OR

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

OR

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

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

The following policies were reviewed with no changes:

- MBP 88.0 Halaven (eribulin mesylate)
- MBP 91.0 Yervoy (Ipilimumab)
- MBP 97.0 Kyprolis (carfilzomib)
- MBP 141.0 Nucala (mepolizumab)
- MBP 142.0 Portrazza (necitumumab)
- MBP 143.0 Praxbind (idarucizumab)
- MBP 151.0 Spinraza (nusinersen)