Geisinger Health Plan

POLICIES AND PROCEDURE MANUAL

Policy: MBP 166.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Adcetris (brentuximab vedotin)

I. Policy:
Adcetris (brentuximab vedotin)

II. Purpose/Objective:
To provide a policy of coverage regarding Adcetris (brentuximab vedotin)

III. Responsibility:
A. Medical Directors
B. Medical Management
C. Pharmacy Department

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than
3. the department requiring/authoring the policy.
4. Devised – the date the policy was implemented.
5. Revised – the date of every revision to the policy, including typographical and grammatical changes.
6. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Medicaid Business Segment
Medical Necessity shall mean a service or benefit that is compensable under the Medical Assistance Program and if it meets any one of the following standards:

(i) the service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.

(ii) the service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or development effects of an illness, condition, injury or disability.

(iii) the service or benefit will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for members of the same age

DESCRIPTION:
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

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:

Indication	Initial Authorization	Subsequent Authorizations
Previously Untreated 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.
cHL Consolidation	Initial approval will be limited to 6 months or less if the reviewing provider feels it is medically appropriate.	Subsequent approval will be for one additional 6-month authorization to allow for a total of 16 cycles of treatment. Subsequent approval for treatment past 16 cycles will require documentation of well-controlled, peer-reviewed literature with evidence to support this request.
Previously Untreated sALCL or Other CD30-expressing PTCLs	Initial approval will be limited to 8 doses (6 months) or less if the reviewing provider feels it is medically appropriate.	Subsequent approval for treatment past the initial 8 doses will require documentation of well-controlled, peer-reviewed literature with evidence to support this request.
Relapsed cHL **Relapsed sALCL** **Relapsed pcALCL or CD30-expressing MF**	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.

LINE OF BUSINESS:
Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

This policy will be revised as necessary and reviewed no less than annually**.**

Devised: 2/1/18

Revised: 5/15/18 (cHL), 1/15/19 (PTCL, updated criteria for all indications, and auth durations)

Reviewed: 11/1/19, 9/30/20, 9/22/21