MEDICAL MUTUAL®

Drug Policy

Policy:	**201819**	**Initial Effective Date: 08/19/2018**
Code(s):	**HCPCS J9042**	**Annual Review Date: 12/20/2018**
SUBJECT:	**Adcetris ® (brentuximab vedotin)**	**Last Revised Date: 12/20/2018**

Prior approval is required for some or all procedure codes listed in this Corporate Drug Policy.

OVERVIEW

Adcetris is a CD30-directed antibody-drug conjugate indicated for the treatment of patients with Hodgkin lymphoma after failure of autologous stem cell transplant (ASCT) or after failure of at least two prior multi-agent chemotherapy regimens in patients who are not ASCT candidates and for the treatment of patients with systemic anaplastic large cell lymphoma after failure of at least one prior multi-agent chemotherapy regimen. These indications are based on response rate. There are no data available demonstrating improvement in patient reported outcomes or survival with Adcetris.

POLICY STATEMENT

This policy involves the use of Adcetris Prior authorization is recommended for medical benefit coverage of Adcetris Approval is recommended for those who meet the conditions of coverage in the **Criteria, Dosing, Initial/Extended Approval, Duration of Therapy**, and **Labs/Diagnostics** for the diagnosis provided. The requirement that the patient meet the Criteria for coverage of the requested medication applies to the initial authorization only. **Waste Management** applies for all covered conditions that are administered by a healthcare professional. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria and Waste Management section. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Adcetris as well as the monitoring required for AEs and long-term efficacy, initial approval requires Adcetris be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Adcetris is recommended in those who meet the following criteria:

1. Classical Hodgkin Lymphoma (cHL)

Criteria. *Patient must meet the following criteria (A, B, C, D, and E)*

A. Patient is 18 years or older; AND
B. Patient has CD30-positive disease; and
C. Adcetris is prescribed by an oncologist, hematologist, or provider who specializes in cHL treatment; AND
D. Patient must not be receiving concomitant bleomycin; AND
E. The patient must meet ONE of the following criteria (i or ii):
   i. Adcetris is used as a single agent and meets ONE of the following criteria (a, b, c, or d):
      a. Patient is at high risk for relapse or progression as post-autologous hematopoietic stem cell transplant consolidation (auto-HSCT); OR
      b. Patient with relapsed disease after failure of auto-HSCT or at least 2 prior multi-agent chemotherapy regimens who are not auto-HSCT candidates; OR
      c. Used as subsequent therapy for relapsed or refractory disease; OR
      d. Used as maintenance therapy following high-dose therapy and autologous stem cell rescue (HDT/ASCR) for relapsed or refractory disease with high risk for relapse;OR
   ii. Adcetris is used in combination with cytotoxic chemotherapy and meets ONE of the following criteria (a or b):
      a. Used as subsequent systemic therapy for relapsed or refractory disease: OR
      b. Used as initial therapy for previously untreated Stage III or IV disease

Dosing in cHL. *Dosing must meet ONE of the following (A, B, or C):*

A. **Hodgkin lymphoma, advanced, previously untreated:** IV: 1.2 mg/kg (maximum dose: 120 mg) every 2 weeks (in combination with doxorubicin, vinblastine, and dacarbazine [AVD]; begin brentuximab within ~1 hour after completion of AVD) until a maximum of 12 doses, disease progression, or unacceptable toxicity .
B. **Hodgkin lymphoma, relapsed or refractory:** IV: 1.8 mg/kg (maximum dose: 180 mg) every 3 weeks, continue until disease progression or unacceptable toxicities
C. **Hodgkin lymphoma, consolidation therapy after autologous hematopoietic stem cell transplantation (HSCT):** IV: 1.8 mg/kg (maximum dose: 180 mg) every 3 weeks, continue until a maximum of 16 cycles, disease progression, or unacceptable . Begin therapy within 4 to 6 weeks post HSCT or upon recovery from HSCT.

Initial Approval/ Extended Approval.
A) *Initial Approval:6 months*
B) *Extended Approval: 6 months and Patient has experienced beneficial response with stabilization of disease or decrease in size of tumor or tumor spread and has an absence of unacceptable toxicity from the drug.*

Duration of Therapy in cHL. Advanced and previously untreated cHL can be administered up to a maximum of 12 doses. cHL after HSCT can be administered up to a maximum of 16 cycles. OR patient experiences disease progression or unacceptable toxicity.

Labs/Diagnostics. CBC with differential prior to each dose (more frequently if clinically indicated); liver and renal function tests. Pregnancy test (in women of reproductive potential) prior to treatment initiation.

2. Non Hodgkin Lymphoma (NHL)

Criteria. *Patient must meet the following criteria (A, B, C, and D)*

A. Patient is 18 years or older; AND

B. Adcetris is prescribed by an oncologist, hematologist, or provider who specializes in NHL treatment; AND
C. Patient must not be receiving concomitant bleomycin; AND
D. Patient must meet ONE of the following (i, ii, iii, iv, v, or vi)

i. Patient has Follicular Lymphoma with transformation to CD30-positive diffuse large B-cell lymphoma (DLBCL) and has received multiple lines of chemoimmunotherapy for indolent or transformed disease OR
ii. Patient has Marginal Zone Lymphoma with transformation to CD30+ DLBCL after multiple lines of chemoimmunotherapy for indolent or transformed disease; OR
iii. Patient has DLBCL and Adcetris is being used as Second-line or subsequent therapy for CD30+ relapsed or refractory disease in noncandidates for high-dose therapy; OR
iv. Patient has DLBCL and Adcetris is being used as Second-line or subsequent therapy for CD30+ relapsed or refractory primary cutaneous diffuse large B-cell lymphoma, leg type in noncandidates for high-dose therapy; OR
v. Patient has AIDS related B-Cell Lymphoma and Adcetris is being used as Second-line or subsequent therapy for relapse of CD30+ AIDS-related diffuse large B-cell lymphoma, primary effusion lymphoma, and HHV8-positive diffuse large B-cell lymphoma, not otherwise specified (NOS) in noncandidates for high-dose therapy; OR
vi. Patient has Post-Transplant Lymphoproliferative Disorder and Adcetris is being used as Second-line and subsequent therapy for patients with partial response, persistent or progressive disease after receiving chemoimmunotherapy as first-line treatment for CD30+ monomorphic PTLD (B-cell type)

Dosing in NHL. *Dosing must meet the following:*
1.8 mg/kg (up to 180 mg) by intravenous infusion every 3 weeks
NOTE: Alternate dosing regimens may be accepted based on compendia and/or evidence-based practice guidelines

Initial Approval/ Extended Approval.
A) *Initial Approval:6 months*
B) *Extended Approval:6 months and Patient has experienced beneficial response with stabilization of disease or decrease in size of tumor or tumor spread and has an absence of unacceptable toxicity from the drug.*

Duration of Therapy in NHL. Patient receives maximum number of doses/cycles, experiences disease progression or unacceptable toxicity.

Labs/Diagnostics. CBC with differential prior to each dose (more frequently if clinically indicated); liver and renal function tests. Pregnancy test (in women of reproductive potential) prior to treatment initiation.

3. T-Cell Lymphoma

Criteria. *Patient must meet the following criteria (A, B, C, and D)*

A. Patient is 18 years or older; AND

B. Adcetris is prescribed by an oncologist, hematologist, or provider who specializes in T-Cell Lymphoma treatment; AND

C. Patient must not be receiving concomitant bleomycin; AND

D. Patient must meet ONE of the following (i, ii, iii, iv, v, vi, or vii)

i. Adcetris is being used as a single agent for second-line and subsequent therapy for relapsed/refractory anaplastic large cell lymphoma, CD30+ peripheral T-cell lymphoma, or CD30+ angioimmunoblastic T-cell lymphoma; OR

ii. Patient has Breast implant- Associated ALCL and Adetris is being used as single agent, adjuvant systemic therapy for localized disease to capsule/implant/breast following incomplete excision or partial capsulectomy with residual disease, or for extended disease (stage II - IV); OR

iii. Adcetris is being used as systemic therapy for Mycosis Fungoides/Sézary Syndrome; OR

iv. Patient has primary cutaneous anaplastic large cell lymphoma (ALCL) with multifocal lesions, or cutaneous ALCL with regional nodes (excludes systemic ALCL), and Adcetris is being used as a single agent for primary treatment or relapsed/refractory disease; OR

v. Patient has lymphomatoid papulosis (LyP) with extensive lesions and Adcetris is being used as a single agent for relapsed/refractory disease following clinical trial, observation, retreatment with primary treatment, or treatment with alternative regimen not used for primary treatment; OR

vi. Patient has Adult T-Cell Leukemia/Lymphoma and Adcetris is being used as second-line therapy (with intention to proceed to high-dose therapy/allogeneic stem cell rescue [HDT/ASCR]) or subsequent therapy to HDT/ASCR as a single agent for nonresponders to first-line therapy for acute or lymphoma subtypes (for CD30 expressing cases); OR

vii. Adult patients with previously untreated systemic anaplastic large cell lymphoma (sALCL) or other CD30-expressing peripheral T-cell lymphomas (PTCL), including angioimmunoblastic T-cell lymphoma and PTCL not otherwise specified, in combination with cyclophosphamide, doxorubicin, and prednisone,

Dosing in T-Cell Lymphoma. *Dosing must meet the following:*
Systemic anaplastic large cell lymphoma, relapsed:
1.8 mg/kg (up to 180 mg) by intravenous infusion every 3 weeks

Systemic anaplastic large cell lymphoma (sALCL), previously untreated: IV: 1.8 mg/kg (maximum dose: 180 mg) every 3 weeks for 6 to 8 doses (in combination with cyclophosphamide, doxorubicin, and prednisone)

NOTE: Alternate dosing regimens may be accepted based on compendia and/or evidence-based practice guidelines

Initial Approval/ Extended Approval.
A) *Initial Approval:6 months*
B) *Extended Approval: 6 months and Patient has experienced beneficial response with stabilization of disease or decrease in size of tumor or tumor spread and has an absence of unacceptable toxicity from the drug.*

Duration of Therapy in T-Cell Lymphoma. Patient receives maximum number of doses/cycles, experiences disease progression or unacceptable toxicity.

Labs/Diagnostics. CBC with differential prior to each dose (more frequently if clinically indicated); liver and renal function tests. Pregnancy test (in women of reproductive potential) prior to treatment initiation.

Other Uses With Supportive Evidence

4. Patient has been Started on Adcetris. Approve if the patient meets the conditions for coverage required for **Dosing**, **Extended Approval**, **Duration of Therapy**, and **Labs/Diagnostics** for an approved use in this *Adcetris Utilization Review* policy.

5. **Other Cancer-Related Indications.** Forward to the Medical Director for review on a case-by-case basis. An example of other indications supported in *NCCN Compendium* are given a category 1, 2A, and 2B recommendation.

Waste Management for All Indications.
Adcetris single-use vial; 50 mg powder for injection

CONDITIONS NOT RECOMMENDED FOR APPROVAL
Adcetris has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the services performed were not medically necessary,

investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

- Adcetris [package insert]. Bothell, WA; Seattle Genetics, Inc; March 2018.
- The NCCN T-Cell Lymphomas Clinical Practice Guidelines in Oncology (Version 2.2019). © 2018 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed December 18, 2018.
- The NCCN B-Cell Lymphomas Clinical Practice Guidelines in Oncology (Version 1.2019). © 2018 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed December 18, 2018.
- The NCCN Primary Cutaneous Lymphomas Clinical Practice Guidelines in Oncology (Version 2.2019). © 2018 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed December 18, 2018.
- The NCCN Hodgkin Lymphoma Clinical Practice Guidelines in Oncology (Version 3.2018). © 2018 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed December 18, 2018.
- The NCCN Drugs & Biologics Compendium. © 2018 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on July 13, 2018. Search term: Acetris.
- Adcetris Monograph. Lexicomp® Online, Hudson, Ohio, Lexi-Comp., Inc. Last revised 12/5/2018. Accessed on December 18, 2018.

FOR MEDICAL BENEFIT COVERAGE REQUESTS:

Prior approval is required for HCPCS Codes J9042

HCPCS Code(s):	
J9042	Injection, brentuximab vedotin, 1 mg