Prior Authorization Review Panel

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CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: 08/01/2021**
Policy Number: PA.CP.PHAR.303	**Effective Date: 01/2018** **Revision Date: 07/2021**
Policy Name: Brentuximab Vedotin (Adcetris)	

Type of Submission – Check all that apply:

- ☐ **New Policy**
- ✓ **Revised Policy***
- ☐ **Annual Review - No Revisions**
- ☐ **Statewide PDL -** *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

3Q 2021 annual review: no significant changes; references reviewed and updated.

Name of Authorized Individual (Please type or print): **Venkateswara R. Davuluri, MD**	**Signature of Authorized Individual:**

Clinical Policy: Brentuximab Vedotin (Adcetris)

Reference Number: PA.CP.PHAR.303
Effective Date: 01/2018 Coding Implications
Last Review Date: 07/2021

Description
Brentuximab vedotin for injection (Adcetris®) is a CD30-directed antibody-drug conjugate.

FDA Approved Indication(s)
Adcetris is indicated for the treatment of adult patients with:

- Classical Hodgkin lymphoma:
  - Previously untreated Stage III or IV classical Hodgkin lymphoma (cHL), in combination with doxorubicin, vinblastine, and dacarbazine
  - cHL at high risk of relapse or progression as post-autologous hematopoietic stem cell transplantation (auto-HSCT) consolidation
  - cHL after failure of auto-HSCT or after failure of at least two prior multi-agent chemotherapy regimens in patients who are not auto-HSCT candidates
- T-cell lymphomas:
  - 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
  - sALCL after failure of at least one prior multiagent chemotherapy regimen
- Primary cutaneous lymphomas:
  - Primary cutaneous anaplastic large cell lymphoma (pcALCL) or CD30-expressing mycosis fungoides (MF) who have received prior systemic therapy

Policy/Criteria
It is the policy of Pennsylvania Health and Wellness ® that Adcetris is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Classical Hodgkin Lymphoma (must meet all)**:**

1. Diagnosis of classical Hodgkin lymphoma (cHL);
2. Prescribed by or in consultation with an oncologist or hematologist;
3. Age ≥ 18 years;
4. Request meets one of the following (a or b):
   a. Dose does not exceed (i, ii, or iii):
      i. Previously untreated Stage III or IV cHL: 1.2 mg/kg up to 120 mg every 2 weeks for a maximum of 12 doses;
      ii. cHL consolidation: 1.8 mg/kg up to 180 mg every 3 weeks for a maximum of 16 cycles;
      iii. Relapsed cHL: 1.8 mg/kg up to 180 mg every 3 weeks;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 6 months

B. T-Cell Lymphomas (must meet all)**:**
1. Diagnosis of one of the following (a, b, c, d, or e):
   a. PTCL - any of the following subtypes/histologies (i or ii):
      i. sALCL;
      ii. PTCL, including but not limited to the following (a, b, c, d, or e):
         a) Angioimmunoblastic T-cell lymphoma;
         b) Enteropathy-associated T-cell lymphoma;
         c) Monomorphic epitheliotropic intestinal T-cell lymphoma;
         d) Nodal peripheral T-cell lymphoma with TFH phenotype;
         e) Follicular T-cell lymphoma;
   b. Breast implant-associated ALCL (off-label);
   c. Adult T-cell leukemia/lymphoma (off-label);
   d. Extranodal NK/T-cell lymphoma, nasal type (off-label);
   e. Hepatosplenic Gamma-Delta T-cell lymphoma (off-label);
2. Prescribed by or in consultation with an oncologist or hematologist;
3. Age ≥ 18 years;
4. Disease is CD30-positive;
5. Request meets one of the following (a, b, or c):
   a. Previously untreated sALCL or other CD30-positive PTCL including angioimmunoblastic T-cell lymphoma: Dose does not exceed 1.8 mg/kg up to 180 mg every 3 weeks with each cycle of chemotherapy for 6 to 8 doses;
   b. Relapsed sALCL: Dose does not exceed 1.8 mg/kg up to 180 mg every 3 weeks;
   c. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 6 months

C. Primary Cutaneous CD30+ T-cell Lymphoproliferative Disorder (must meet all):
1. Diagnosis of one of the following (a, b, or c):
   a. pcALCL;
   b. Cutaneous ALCL and lymph node positive (off-label);
   c. Lymphomatoid papulosis - as subsequent therapy for relapsed/refractory disease (off-label);
2. Prescribed by or in consultation with an oncologist or hematologist;
3. Age ≥ 18 years;
4. Disease is CD30-positive;
5. Request meets one of the following (a or b):
   a. Relapsed pcALCL: Dose does not exceed 1.8 mg/kg up to 180 mg every 3 weeks for a maximum of 16 cycles;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use *(prescriber must submit supporting evidence).*

Approval duration: 6 months

D. Mycosis Fungoides/Sezary Syndrome (must meet all):
1. Diagnosis of MF or Sezary syndrome (off-label);
2. Prescribed by or in consultation with an oncologist or hematologist;
3. Age ≥ 18 years;

4. Disease is CD30-positive;
5. Request meets one of the following (a or b):
    a. Relapsed CD30-positive MF: Dose does not exceed 1.8 mg/kg up to 180 mg every 3 weeks for a maximum of 16 cycles;
    b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use *(prescriber must submit supporting evidence)*.

Approval duration: 6 months

E. B-Cell Lymphomas (off-label) (must meet all)**:**

1. Diagnosis of one of the following (a, b, c, or d):
    a. Diffuse large B-cell lymphoma, including but not limited to (i, ii, or iii):
        i. Follicular lymphoma that has undergone histologic transformation to diffuse large B-cell lymphoma;
        ii. Marginal zone lymphoma that has undergone histologic transformation to diffuse large B-cell lymphoma;
        iii. Primary mediastinal large B-cell lymphoma;
    b. High-grade B-cell lymphoma;
    c. AIDS-related B-cell lymphoma;
    d. Post-transplant lymphoproliferative disorder - monomorphic PTLD (T-cell type);
2. Prescribed by or in consultation with an oncologist or hematologist;
3. Age ≥ 18 years;
4. Disease is CD30-positive;
5. For subtypes other than monomorphic PTLD (T-cell type), Adcetris is prescribed as subsequent therapy;
6. Dose is within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 6 months

F. Other diagnoses/indications

1. Refer to the PA.CP.PMN.53 for Medicaid.

II. Continued Approval

A. All Indications (must meet all)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a or b):*
    a. New dose does not exceed (i, ii, iii, iv, v, vi, or vii):
        i. Previously untreated Stage III or IV cHL: 1.2 mg/kg up to 120 mg every 2 weeks for a maximum of 12 doses;
        ii. cHL consolidation: 1.8 mg/kg up to 180 mg every 3 weeks for a maximum of 16 cycles;
        iii. Relapsed cHL: 1.8 mg/kg up to 180 mg every 3 weeks;

iv. Previously untreated sALCL or other CD30-positive PTCL including angioimmunoblastic T-cell lymphoma: 1.8 mg/kg up to 180 mg every 3 weeks with each cycle of chemotherapy for 6 to 8 doses;
v. Relapsed sALCL: 1.8 mg/kg up to 180 mg every 3 weeks;
vi. Relapsed pcALCL: 1.8 mg/kg up to 180 mg every 3 weeks for a maximum of 16 cycles;
vii. Relapsed CD30-positive MF: 1.8 mg/kg up to 180 mg every 3 weeks for a maximum of 16 cycles;

b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies; or
2. Refer to PA.CP.PMN.53

III. Diagnoses/Indications for which coverage is NOT authorized

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

cHL: classical Hodgkin lymphoma
FDA: Food and Drug Administration
HSCT: hematopoietic stem cell transplantation
MF: mycosis fungoides
NCCN: National Comprehensive Cancer Network
pcALCL: primary cutaneous anaplastic large cell lymphoma
PTCL: peripheral T-cell lymphoma
sALCL: systemic analplastic large cell lymphoma
SS: Sezary syndrome

Appendix B: Therapeutic Alternatives

Not applicable

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): concomitant use with bleomycin due to pulmonary toxicity
- Boxed warning(s): progressive multifocal leukoencephalopathy

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose

Previously untreated Stage III or IV cHL	1.2 mg/kg IV up to a maximum of 120 mg in combination with chemotherapy. Administer every 2 weeks until a maximum of 12 doses, disease progression, or unacceptable toxicity.	120 mg every 2 weeks up to 12 doses
cHL consolidation	1.8 mg/kg IV up to a maximum of 180 mg. Initiate Adcetris treatment within 4-6 weeks post-autoHSCT or upon recovery from auto-HSCT. Administer every 3 weeks until a maximum of 16 cycles, disease progression, or unacceptable toxicity.	180 mg every 3 weeks up to 16 cycles
Relapsed cHL	1.8 mg/kg IV up to a maximum of 180 mg. Administer every 3 weeks until disease progression or unacceptable toxicity.	180 mg every 3 weeks
Previously untreated sALCL or other CD30-expressing PTCLs	1.8 mg/kg IV up to a maximum of 180 mg in combination with cyclophosphamide, doxorubicin, and prednisone. Administer every 3 weeks with each cycle of chemotherapy for 6 to 8 doses.	180 mg every 3 weeks up to 6 to 8 doses
Relapsed sALCL	1.8 mg/kg IV up to a maximum of 180 mg. Administer every 3 weeks until disease progression or unacceptable toxicity.	180 mg every 3 weeks
Relapsed pcALCL or CD30-expressing MF	1.8 mg/kg IV up to a maximum of 180 mg. Administer every 3 weeks until a maximum of 16 cycles, disease progression, or unacceptable toxicity.	180 mg every 3 weeks up to 16 cycles

VI. Product Availability

Single-use vial: 50 mg for reconstitution

VII. References

1. Adcetris Prescribing Information. Bothell, WA: Seattle Genetics, Inc.; October 2019. Available at: http://adcetrisupdate.com/. Accessed March 16, 2021.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at www.nccn.org. Accessed March 16, 2021.
3. National Comprehensive Cancer Network. Hodgkin Lymphoma Version 3.2021. Available at www.nccn.org. Accessed March 16, 2021.
4. National Comprehensive Cancer Network. Primary Cutaneous Lymphomas Version 2.2021. Available at www.nccn.org. Accessed March 16, 2021.
5. National Comprehensive Cancer Network. T-Cell Lymphomas Version 1.2021. Available at www.nccn.org. Accessed March 16, 2021.
6. National Comprehensive Cancer Network. B-Cell Lymphomas Version 3.2021. Available at www.nccn.org. Accessed March 16, 2021.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J9042	Injection, brentuximab vedotin, 1 mg

Reviews, Revisions, and Approvals	Date	Approval Date
Added new FDA approved status for pcALCL and MF indications (previously off-label coverage) and previously untreated cHL in combination with chemotherapy; added examples of prerequisite drugs for HL, sALCL, adult T-cell leukemia/ lymphoma, and LyP; references reviewed and updated.	04.18	
3Q 2019 annual review: No changes per Statewide PDL implementation 01-01-2020	07/17/19	
Q3 2020 annual review: updated Non-Hodgkin T-Cell Lymphomas criteria set to allow use as first-line therapy for PTCL to align with updated FDA-approved indication; NCCN and FDA-approved uses summarized for clarity; PI directed dosing details (i.e., weight-based dosing, and maximum dose and duration) are added to all criteria sets in Sections I.A. and II, and the dosing table in Section V; parentheticals are added to each criteria set indicating off-label NCCN recommended uses which would require supportive dosing literature. Reference to CD30+ disease is expanded to all indications under the Primary Cutaneous CD30+ T-cell Lymphoproliferative Disorders criteria set for clarity; NCCN recommended uses added - B-cell lymphomas, additional T-cell lymphomas; per NCCN, breast-implant associated ALCL stage restriction removed, primary mediastinal large B-cell lymphoma added, post-transplant lymphoproliferative disorder limited to monomorphic PTLD (T-cell type) inclusive of primary therapy; references reviewed and updated.	08/2020	
3Q 2021 annual review: no significant changes; references reviewed and updated.	07/2021	