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Ascension

Brentuximab vedotin

(Adcetris®) J9042 (1mg)

Covered with prior authorization

Brentuximab vedotin (Adcetris®) may be authorized when the following criteria are met:

- Individual has a diagnosis of Hodgkin Lymphoma (HL); **AND**
- Individual is using for one of the following:
    - Previously untreated stage III or IV classical HL, in combination with AVD (doxorubicin, vinblastine and dacarbazine); **OR**
    - Previously untreated classical HL in older adults (≥60 years), as sequential therapy with AVD (doxorubicin, vinblastine, and dacarbazine), or in combination with dacarbazine (NCCN 2A); **OR**
    - Relapsed or refractory disease in a single line of therapy as a single agent or in combination with bendamustine (Label, NCCN 2A); **OR**
    - As consolidation therapy after an autologous stem cell transplantation for individuals at high risk of relapse or progression, that is, individuals with any of the following:
        - Primary refractory HL; **OR**
        - Relapsed HL with an initial remission duration of less than 12 months; **OR**
        - Extranodal involvement at the start of pre-transplantation salvage chemotherapy;

      OR
    - As maintenance therapy for 1 year following high-dose therapy and autologous stem cell rescue for relapsed or refractory disease in those who are brentuximab vedotin naïve and have a Deauville score of less than 5 (NCCN 2A);
    - NCCN recommends maintenance therapy for 1 year if brentuximab naïve and Deauville score less than 5.

OR

- Individual has a diagnosis of CD30+ Non-Hodgkin Lymphoma; **AND**
- Individual is using for one of the following:
    - Cutaneous anaplastic large cell lymphoma; **OR**
    - Cutaneous T-cell lymphoma, including mycosis fungoides/Sézary syndrome, for the following:
        - Relapsed or refractory disease; **OR**
        - As first-line therapy for advanced disease presentation (for example, folliculotropic, large-cell transformation or extracutaneous disease) (NCCN 2A);

      OR

- Relapsed or refractory lymphomatoid papulosis with extensive cutaneous lesions (NCCN 2A);

OR

- In combination with CAP (cyclophosphamide, doxorubicin, and prednisone, for previously untreated:
  - Peripheral T-cell lymphoma (including systemic anaplastic large cell lymphoma, angioimmunoblastic t-cell lymphoma, enteropathy-associated T-cell lymphoma, monomorphic epitheliotropic intestinal T-cell lymphoma, nodal peripheral T-cell lymphoma with TFH phenotype, follicular T-cell lymphoma) (Label, NCCN 2A);

OR

- Adult T-cell leukemia/lymphoma (NCCN 2A);

OR

- One of the following T-cell lymphomas, as treatment for relapsed or refractory disease:
  - Systemic anaplastic large cell lymphoma (Label);
  - Extranodal NK/T-Cell lymphomas (NCCN 2A);
  - Hepatosplenic T-Cell lymphoma (NCCN 2A);
  - Breast implant-associated anaplastic large cell lymphoma (NCCN 2A);
  - Peripheral T-cell lymphoma (NCCN 2A);
  - Angioimmunoblastic T-cell lymphoma (NCCN 2A);

OR

- As an adjuvant systemic therapy for breast implant-associated anaplastic large cell lymphoma for either of the following (NCCN 2A):
  - Residual, localized disease (confined to capsule/implant/breast) following partial excision or capsulectomy; **OR**
  - Extended disease (stage II-IV)

Requests for Adcetris® (brentuximab vedotin) may **not** be approved when the above criteria are not met and for all other indications.

Exclusion Criteria

- Doses, durations, or dosing intervals that exceed FDA maximum limits for any FDA-approved indication or are not supported by industry-accepted practice guidelines or peer-reviewed literature for the relevant off-label use.
- Individuals with significant known risk factors unless the record provides an assessment of clinical benefit that outweighs the risk.
- Concomitant use with bleomycin is contraindicated with Adcetris® (brentuximab vedotin).

Initial authorization is up to 12 months.

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Annual reauthorizations will require medical chart documentation that the patient has been seen within the past 12 months and that markers of disease are improved by therapy.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Note: Adcetris® (brentuximab vedotin) has a **black box warning** for John Cunningham (JC) virus infection resulting in progressive multifocal leukoencephalopathy (PML); death can occur in individuals receiving Adcetris.

U.S. Food and Drug Administration:
This section is to be used for informational purposes. FDA approval alone is not a basis for coverage. Adcetris® is a monoclonal antibody-drug conjugate (ADC) that consists of a chimeric IgG1 directed antibody against CD30 and a small molecule, monomethyl auristatin E (MMAE), a microtubule disrupting agent. The anticancer activity is due to the binding of the ADC to CD30-expressing cells causing disruption of the microtubule network leading to cell death. Adcetris® is FDA approved for certain patients with Hodgkin lymphoma (HL) and non-Hodgkin lymphoma. The National Comprehensive Cancer Network® (NCCN) provides additional recommendations with a category 2A level of evidence for the use of Adcetris®.

Key References Accessed 8/2022:
1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2022. URL: http://www.clinicalpharmacology.com. Updated periodically.
2. Cole PD, McCarten KM, Pei Q, et al. Brentuximab vedotin with gemcitabine for pediatric and young adult patients with relapsed or refractory Hodgkin's Lymphoma (AHOD1221): a Children's Oncology Group, multicentre single-arm, phase 1-2 trial. Lancet Oncol 2018; 19:1229-1238.
3. Cole PD, Mauz-Korholz C, Mascarin M, et al. Nivolumab and brentuximab vedotin (BV)-based, response-adapted treatment in children, adolescents, and young adults (CAYA) with standard-risk relapsed/refractory classical Hodgkin Lymphoma (R/R cHL): Primary analysis. J Clin Oncol 2020;38:8013 [Abstract].
4. Horwitz S, O'Connor OA, Pro B, et al. Brentuximab vedotin with chemotherapy for CD30-positive peripheral T-cell lymphoma (ECHELON-2): a global, double-blind, randomized, phase 3 trial. Lancet. 2019;393(10168):229-240.
5. Herrera AF, Moskowitz AJ, Bartlett NL, et al. Interim results of brentuximab vedotin in combination with nivolumab in patients with relapsed or refractory Hodgkin lymphoma. Blood 2018; 131: 1183-1194. [NCT02572167].
6. Jacobsen ED, Sharman JP, Oki Y, et al. Brentuximab vedotin demonstrates objective responses in a phase 2 study of relapsed/refractory DLBCL with variable CD30 expression. Blood 2015; 125:1394-1402.

7. NCCN Clinical Practice Guidelines in Oncology™. © 2022 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp.
a. B-Cell Lymphomas. V2.2022.
b. Hodgkin Lymphoma. V2.2022.
c. Pediatric Hodgkin Lymphoma. V3.2021.
d. Primary Cutaneous Lymphomas. V1.2022.
e. T-Cell Lymphomas. V2.2022.

Date	Summary of Changes
August 2022	Criteria for use summary developed by the Ascension Medical Specialty Prior Authorization Team.
September 2022	Criteria for use summary approved by the Ascension Ambulatory Care Expert Review Panel.
October 2022	Criteria for use summary approved by the Ascension Therapeutic Affinity Group.

If you have questions, call 833-980-2352 to speak to a member of the Ascension Rx prior authorization team, or email your questions to smarthealthspecialty@ascension.org.