Adcetris (brentuximab vedotin)

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
Adcetris (brentuximab vedotin)

APPROVAL CRITERIA

Requests for Adcetris (brentuximab vedotin) may be approved if the following criteria are met:

I. Individual has a diagnosis of Hodgkin Lymphoma (HL); **AND**
II. Individual is using for one of the following:
   A. Previously untreated stage III or IV classical HL, in combination with doxorubicin, vinblastine and dacarbazine; **OR**
   B. Previously untreated classical HL in older adults (≥60 years), as sequential therapy with doxorubicin, vinblastine, and dacarbazine, or in combination with dacarbazine (NCCN 2A); **OR**
   C. Relapsed or refractory disease in a single line of therapy as a single agent or in combination with bendamustine (Label, NCCN 2A); **OR**
   D. 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:
      1. Primary refractory HL; **OR**
      2. Relapsed HL with an initial remission duration of less than 12 months; **OR**
      3. Extranodal involvement at the start of pre-transplantation salvage chemotherapy;

   OR
   E. 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);

OR

III. Individual has a diagnosis of CD30+ Non-Hodgkin Lymphoma; **AND**
IV. Individual is using for one of the following:
   A. Cutaneous anaplastic large cell lymphoma; **OR**
   B. Cutaneous T-cell lymphoma, including mycosis fungoides/Sézary syndrome, for the following:
      1. Relapsed or refractory disease; **OR**
      2. As first-line therapy for advanced disease presentation (for example, large cell transformation, extensive skin involvement, higher skin disease burden, primarily plaque disease, blood involvement, inadequate response to skin-directed therapy, or stage IIB or higher) (NCCN 2A);

   OR
   C. Relapsed or refractory lymphomatoid papulosis with extensive cutaneous lesions (NCCN 2A);

OR

D. In combination with 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

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

OR

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

OR

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

Note:
Adcetris (brentuximab vedotin) has a black box warning for John Cunningham (JC) virus infection resulting in progressive multifocal leukoencephalopathy (PML).
Fatal cases of JC virus infection resulting in PML have been reported in individuals receiving Adcetris.

Key References:

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 paediatric 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. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: March 2022.

5. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
6. 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, randomised, phase 3 trial. Lancet. 2019;393(10168):229-240.
7. 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].
8. 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.
9. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
10. 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. Accessed March 2022.
    a. B-Cell Lymphomas. V2.2022. Revised March 21, 2022.
    b. Hodgkin Lymphoma. V2.2022. Revised February 23, 2022.
    c. Pediatric Hodgkin lymphoma. V3.2021. Revised March 18, 2021.
    d. Primary Cutaneous Lymphomas. V1.2022. Revised January 26, 2022.
    e. T-Cell Lymphomas. V2.2022. Revised March 7, 2022.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.