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. Previously untreated high risk classical HL, in combination with doxorubicin, vincristine, etoposide, prednisone, and cyclophosphamide; **OR**
   D. Relapsed or refractory disease in a single line of therapy as a single agent or in combination with bendamustine nivolumab or pembrolizumab (Label, NCCN 2A); **OR**
   E. Relapsed or refractory disease as second or subsequent line of therapy in combination with ifosfamide, carboplatin, etoposide; **OR**
   F. 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
   G. 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 or persistent 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:
    1. 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);

OR

H. Individual has relapsed or refractory Primary Mediastinal Large B-Cell Lymphoma; **AND**
    1. Individual is using in combination with nivolumab (NCCN 2A);

OR

I. One of the following B-Cell Lymphomas (NCCN 2A):
    1. Relapsed or refractory Diffuse Large B-Cell Lymphomas (DLBCL) (NCCN 2A); **OR**
    2. Post-Transplant lymphoproliferative disorders; **OR**
    3. High-grade B-Cell Lymphomas;

OR

J. Individual has a diagnosis of pediatric Hodgkin Lymphoma; **AND**

K. Individual is using for one of the following:

1. Primary or subsequent treatment for high-risk disease (high risk defined as progressive disease, refractory disease, or relapse within 1 year of original diagnosis) (NCCN 1, 2A); **OR**
2. Treatment therapy for heavily pretreated disease or decrease in cardiac function (NCCN 2A) in combination with bendamustine or nivolumab or gemcitabine.

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. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: April 5, 2023.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
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4. 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.
5. 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].
6. Harker-Murray P, Mauz-Körholz C, Leblanc TM, et al. Nivolumab, Brentuximab Vedotin, +/- Bendamustine For R/R Hodgkin Lymphoma in Children, Adolescents, and Young Adults [published online ahead of print, 2022 Dec 23]. Blood. 2022;blood.2022017118. doi:10.1182/blood.2022017118. Available at: https://ashpublications.org/blood/article/doi/10.1182/blood.2022017118/493879/Nivolumab-Brentuximab-Vedotin-Bendamustine-For-R-R. Accessed March 30, 2023.
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10. Lynch RC, Cassaday RD, Smith SD, et al. Dose-dense brentuximab vedotin plus ifosfamide, carboplatin, and etoposide for second-line treatment of relapsed or refractory classical Hodgkin lymphoma: a single centre, phase 1/2 study. Lancet Haematol. 2021;8(8):e562-e571. doi:10.1016/S2352-3026(21)00170-8. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8457616/. Accessed April 3, 2023.
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12. 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 2023.
13. B-Cell Lymphomas. V2.2023. Revised February 8, 2023.
14. Hodgkin Lymphoma. V2.2023. Revised November 8, 2022.
15. Pediatric Aggressive Mature B-Cell Lymphomas. V1.2023. Revised April 4, 2023.

16. Pediatric Hodgkin lymphoma. V2.2023. Revised March 9, 2023.
17. Primary Cutaneous Lymphomas. V1.2023. Revised January 5, 2023.
18. T-Cell Lymphomas. V1.2023. Revised January 5, 2023.

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.