Brentuximab Vedotin (Adcetris®)

Prior Authorization Drug Coverage Policy

Effective Date: 9/1/2020
Revision Date: n/a
Review Date: 9/17/2021
Lines of Business: Commercial
Policy type: Prior Authorization

Brentuximab vedotin (Adcetris®) authorizations are for 6 months, after which they must be reviewed for efficacy, safety, and tolerability. Brentuximab vedotin (Adcetris®) requires prior authorization and is considered medically necessary for the following oncology indications if criteria are met.

FDA Approved Indications

Classical Hodgkin Lymphoma (cHL) – Previously Untreated

- The member has a diagnosis of cHL **AND**
- The member has stage 3 or 4 disease **AND**
- The member has not been previously treated with systemic chemotherapy or radiotherapy **AND**
- The member will be treated with brentuximab vedotin in combination with doxorubicin, vinblastine, and dacarbazine

Classical Hodgkin Lymphoma (cHL) - Consolidation

- The member has a diagnosis of cHL **AND**
- The member has undergone high-dose therapy and autologous stem cell transplantation **AND**
- The member has at least one of the following risk factors for progression after autologous stem cell transplantation:
    - Primary refractory disease (failure to achieve complete remission) **OR**
    - Relapsed disease with an initial remission duration of less than 12 months **OR**
    - Extranodal involvement at the start of pre-transplantation salvage chemotherapy with complete remission, partial remission, or stable disease after pre-transplantation salvage chemotherapy **AND**
- The member will be treated with single-agent brentuximab vedotin as post-autologous hematopoietic stem cell transplantation consolidation

Classical Hodgkin Lymphoma (cHL) – Relapsed or Refractory

- The member has a diagnosis of cHL **AND**

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- The member has relapsed or refractory disease after high-dose therapy and autologous hematopoietic stem cell transplantation **OR**
- The member has not received allogeneic hematopoietic stem cell transplantation AND
- The member will be treated with brentuximab vedotin as monotherapy

Recommended dosage: 1.8 mg/kg (maximum dose: 180 mg) IV every 3 weeks

Systemic Anaplastic Large Cell Lymphoma (sALCL) – Previously Untreated

- The member has a diagnosis of sALCL **AND**
- The member has confirmed CD30-positive disease **AND**
- The member has previously untreated disease **AND**
- The member will be treated with brentuximab vedotin in combination with cyclophosphamide, doxorubicin, and prednisone

Systemic Anaplastic Large Cell Lymphoma (sALCL) – Relapsed or Refractory

- The member has a diagnosis of sALCL **AND**
- The member has confirmed CD30-positive disease **AND**
- The member has relapsed or refractory disease **AND**
- The member has failed at least one prior multiagent chemotherapy regimen with curative intent (such as the combination of cyclophosphamide, doxorubicin, vincristine, and prednisone) **AND**
- The member has not received allogeneic hematopoietic stem cell transplantation **AND**
- The member will be treated with brentuximab vedotin as monotherapy

Peripheral T-Cell Lymphoma (PTCL)

- The member has a diagnosis of PTCL **AND**
- The member has confirmed CD30-positive disease **AND**
- The member has previously untreated disease **AND**
- The member will be treated with brentuximab vedotin in combination with cyclophosphamide, doxorubicin, and prednisone

Cutaneous T-Cell Lymphoma (CTCL)

- The member has a diagnosis of one of the following:
  - Primary cutaneous anaplastic large cell lymphoma **OR**
  - Mycosis fungoides **AND**
- The member has CD30-positive disease **AND**
- The member has received at least one prior systemic therapy **AND**
- The member has not progressed on previous therapies with methotrexate and bexarotene **AND**
- The member will be treated with brentuximab vedotin as monotherapy

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Coverage Limitations

Dose and frequency should be consistent with FDA labeling or indication specific peer-reviewed literature.

Billing

- Description: inj., brentuximab vedotin, 1 mg
  - HCPCS: J9042

References

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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, randomized, phase 3 trial. Lancet. 2019 Jan 19;393:229–240. DOI: 10.1016/S0140-6736(18)32984-2.
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9. Pro B, Advani R, Brice P, et al. Brentuximab Vedotin (SGN-35) in Patients With Relapsed or Refractory Systemic Anaplastic Large-Cell Lymphoma: Results of a Phase II Study. J Clin Oncol. 2012 Jun 20;30(18):2190-2196. DOI: 10.1200/JCO.2011.38.0402.
10. Younes A, Gopal AK, Smith SE, et al. Results of a Pivotal Phase II Study of Brentuximab Vedotin for Patients With Relapsed or Refractory Hodgkin's Lymphoma. J Clin Oncol. 2012 Jun 20;30(18):2183-2189. DOI: 10.1200/JCO.2011.38.0410.

Disclaimer

This Drug Coverage Policy provides parameters for the coverage of brentuximab vedotin. Consideration of medically necessary indications are based upon U.S. Food and Drug Administration (FDA) indications, recommended uses within the Centers of Medicare & Medicaid Services (CMS) five recognized compendia, including the National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium (Category 1 or 2A recommendations), and peer-reviewed scientific literature eligible for coverage according to the CMS, Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 titled, "Off-Label Use of Anti-Cancer Drugs and Biologics." This policy evaluates whether the drug therapy is proven to be effective based on published evidence-based medicine.

Drug Coverage Policies are developed as needed, regularly reviewed, updated at least annually, and are subject to change. Other policies and coverage determination guidelines may apply. Federal and state regulatory

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