Brentuximab Vedotin (Adcetris®)

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

POLICY

INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

- Classical Hodgkin Lymphoma (cHL)
- Treatment of adult patients with previously untreated Stage III or IV cHL, in combination with doxorubicin, vinblastine, and dacarbazine.
- Treatment of pediatric patients 2 years and older with previously untreated high risk cHL in combination with doxorubicin, vincristine, etoposide, prednisone and cyclophosphamide.
- Treatment of adult patients with cHL at high risk of relapse or progression as post-autologous hematopoietic stem cell transplantation (auto-HSCT) consolidation.
- Treatment of adult patients with 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.
- Systemic anaplastic large cell lymphoma (sALCL)
- Treatment of adult patients with previously untreated 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.
- Treatment of adult patients with sALCL after failure of at least one prior multi-agent chemotherapy regimen.
- Treatment of adult patients with primary cutaneous anaplastic large cell lymphoma (pcALCL) or CD30-expressing mycosis fungoides (MF) who have received prior systemic therapy
- Treatment of adult patients with relapsed or refractory large B-cell lymphoma (LBCL), including diffuse large B-cell lymphoma (DLBCL) NOS, DLBCL arising from indolent lymphoma, or high-grade B-cell lymphoma (HGBL), after two or more lines of systemic therapy who are not eligible for auto-HSCT or CAR T-cell therapy, in combination with lenalidomide and a rituximab product

Compendial Uses

- CD30+cHL stage I-II unfavorable disease
- CD30+ B-Cell Lymphomas
  - Diffuse large B-cell lymphoma (DLBCL)
  - High-grade B-cell lymphomas (HGBL)
  - Histologic transformation of indolent lymphoma to DLBCL
  - HIV-related B-cell lymphomas
  - Pediatric primary mediastinal large B-cell lymphoma
  - Post-transplant lymphoproliferative disorders (B-cell type)
- CD30+ Primary Cutaneous Lymphomas

  - Mycosis Fungoides (MF)/Sezary Syndrome (SS)
  - Lymphomatoid papulosis (LyP)
  - Cutaneous anaplastic large cell lymphoma
- CD30+ T-Cell Lymphomas
  - Hepatosplenic T-cell lymphoma (HSTCL)
  - Adult T-cell leukemia/lymphoma (ATLL)
  - Breast implant-associated anaplastic large cell lymphoma (BIA-ALCL)
  - Peripheral T-cell lymphomas (PTCL)
  - Extranodal NK/T-cell Lymphoma s
- Relapsed and refractory DLBCL, HGBL, and histologic transformation of indolent lymphoma to DLBCL

All other indications are considered experimental/investigational and not medically necessary.

DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:
Documentation of laboratory report confirming CD30 expression on the surface of the cell (initial requests), where applicable.

COVERAGE CRITERIA

Classic Hodgkin lymphoma (cHL)

Authorization of 12 months may be granted for treatment of CD30+ cHL when any of the following criteria are met:

- The requested medication will be used as a single agent.
- The requested medication will be used in combination with doxorubicin, vinblastine, and dacarbazine (BV - AVD).
- The requested medication will be used in combination with bendamustine for re-induction or subsequent therapy.
- The requested medication will be used in combination with dacarbazine.
- The requested medication will be used in combination with nivolumab.
- The requested medication will be used in combination with gemcitabine for re-induction or subsequent therapy.
- The requested medication will be used in combination with ifosfamide, carboplatin and etoposide (ICE) as subsequent therapy.
- The requested medication will be used in combination with etoposide, prednisone and doxorubicin (AEPA).
- The requested medication will be used in combination with cyclophosphamide, prednisone, and dacarbazine (CAPDAC) for subsequent therapy.
- The requested medication will be used in combination with doxorubicin, vincristine, etoposide, prednisone, and cyclophosphamide (Bv-AVE-PC).
- The requested medication will be used in combination with cyclophosphamide, doxorubicin, and prednisone (BV-CHP).
- The requested medication will be used in combination with etoposide, cyclophosphamide, doxorubicin, dacarbazine, and dexamethasone (BrECADD).

B-Cell Lymphomas

Authorization of 12 months may be granted for treatment of CD30+ B-cell lymphomas with any of the following subtypes:

- Diffuse large B-cell lymphoma (DLBCL) as subsequent therapy.

- High-grade B-cell lymphomas (HGBL) as subsequent therapy.
- Histologic transformation of indolent lymphoma to DLBCL as subsequent therapy.
- HIV-related B-cell lymphomas (HIV-related diffuse large B-cell lymphoma, primary effusion lymphoma, human herpesvirus-8 (HHV8)-positive diffuse large B-cell lymphoma, or plasmablastic lymphoma) as subsequent therapy.
- Pediatric primary mediastinal large B-cell lymphoma when both of the following criteria are met:
  - The requested medication will be used for relapsed or refractory disease.
  - The requested medication will be used in combination with nivolumab or pembrolizumab.
- Post-transplant lymphoproliferative disorders (B-cell type) as subsequent therapy.

Authorization of 12 months may be granted for treatment of relapsed or refractory DLBCL, HGBL, and histologic transformation of indolent lymphoma to DLBCL when either of the following criteria are met:

- The requested medication will be used as a single agent.
- The requested medication will be used in combination with lenalidomide and a rituximab product.

Primary Cutaneous Lymphomas

Authorization of 12 months may be granted for treatment of CD30+ primary cutaneous lymphomas with any of the following subtypes:

- Mycosis fungoides (MF)/Sezary syndrome (SS).
- Lymphomatoid papulosis (LyP) when both of the following criteria are met:
  - The requested medication will be used as a single agent.
  - The disease is relapsed or refractory.
- Cutaneous anaplastic large cell lymphoma (ALCL) when either of the following criteria are met:
  - The requested medication will be used as a single agent.
  - The requested medication will be used in combination with cyclophosphamide, doxorubicin, and prednisone (CHP).

T-Cell Lymphomas

Authorization of 12 months may be granted for treatment of CD30+ T-cell lymphomas with any of the following subtypes:

- Hepatosplenic T-cell lymphoma (HSTCL) when the requested medication will be used as a single agent after two or more primary treatment regimens
- Adult T-cell leukemia/lymphoma (ATLL) when either of the following criteria are met:
  - The requested medication will be used as a single agent for subsequent therapy.
  - The requested medication will be used in combination with cyclophosphamide, doxorubicin, and prednisone (CHP).
- Breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) when either of the following criteria are met:
  - The requested medication will be used as a single agent.
  - The requested medication will be used in combination with cyclophosphamide, doxorubicin, and prednisone (CHP).
- Peripheral T-cell lymphomas (PTCL) [including the following subtypes: anaplastic large cell lymphoma, peripheral T-cell lymphoma not otherwise specified, angioimmunoblastic T-cell lymphoma, enteropathy associated T-cell lymphoma, monomorphic epitheliotropic intestinal T-cell lymphoma, nodal peripheral T-cell lymphoma with TFH phenotype, or follicular T-cell lymphoma] when any of the following criteria are met:
  - The requested medication will be used as a single agent as subsequent or palliative therapy.

  - The requested medication will be used in combination with cyclophosphamide, doxorubicin, and prednisone (CHP).
  - The requested medication will be used in combination with cyclophosphamide, doxorubicin, etoposide, and prednisone (CHEP).
- Extranodal NK/T-cell lymphomas (ENKL) when all of the following criteria are met:
  - The requested medication will be used as a single agent.
  - The disease is relapsed or refractory.
  - The member has had an inadequate response or contraindication to asparaginase-based therapy (e.g., pegaspargase).

CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria section when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

MEDICATION QUANTITY LIMITS

Drug Name	Diagnosis	Maximum Dosing Regimen
Adcetris (Brentuximab vedotin)	B-Cell Lymphomas: Diffuse Large B-Cell Lymphoma, High-Grade B-Cell Lymphomas, HIV-Related B-Cell Lymphomas (HIV-related Diffuse Large B- cell Lymphoma, Primary Effusion Lymphoma, and HHV8-positive Diffuse Large B-cell Lymphoma, Plasmablastic Lymphoma), Monomorphic Post-Transplant Lymphoproliferative Disorders (B-cell type), or Primary Mediastinal Large B-cell Lymphoma	Route of Administration: Intravenous 1.8mg/kg (up to a maximum of 180 mg) every 3 weeks
Adcetris (Brentuximab vedotin)	CD30+ Primary Cutaneous Lymphomas: Cutaneous Anaplastic Large Cell Lymphoma, Lymphomatoid Papulosis (LyP)	Route of Administration: Intravenous 1.8mg/kg (up to a maximum of 180 mg) every 3 weeks
Adcetris (Brentuximab vedotin)	CD30+ Primary Cutaneous Lymphomas: Mycosis Fungoides (MF)/Sezary Syndrome (SS)	Route of Administration: Intravenous 1.8mg/kg (up to a maximum of 180 mg) every 3 weeks
Adcetris (Brentuximab vedotin)	Classical Hodgkin Lymphoma	Route of Administration: Intravenous ≥18 Years 1.2mg/kg (up to a maximum of 120 mg) every 2 weeks

		1.5mg/kg (up to a maximum of 150 mg) on day 1 and 8 of a 21 day cycle for 2 cycles 1.8mg/kg (up to a maximum of 180 mg) every 3 weeks <u>≥2 to <18 year(s)</u> 1.8mg/kg (up to a maximum of 180 mg) every 3 weeks for a maximum of 5 doses 1.2mg/kg (up to a maximum of 120 mg) on days 1, 8, and 15 of a 28-day cycle for 2 cycles, followed by 1.2 mg/kg (up to a maximum of 120 mg) on days 1 and 8 of a 21-day cycle for 4 cycles
Adcetris (Brentuximab vedotin)	T-Cell Lymphomas: Hepatosplenic T-cell Lymphoma, Adult T-cell Leukemia/Lymphoma, Breast Implant- Associated Anaplastic Large Cell Lymphoma (ALCL), Peripheral T-cell Lymphoma (PTCL), Systemic Anaplastic Large cell Lymphoma (sALCL), Extranodal NK/T-cell Lymphoma, Angioimmunoblastic T-cell Lymphoma	Route of Administration: Intravenous 1.8mg/kg (up to a maximum of 180 mg) every 3 weeks

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

REFERENCES

1. Adcetris [package insert]. Bothell, WA: Seagen, Inc.; February 2025.
2. The NCCN Drugs & Biologics Compendium® © 2026 National Comprehensive Cancer Network, Inc. Available at: https://www.nccn.org. Accessed April 6, 2026.

This document has been classified as public information

3. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines: B-Cell Lymphomas. Version 4.2026. Available at: https://www.nccn.org. Accessed August 10, 2026.

EFFECTIVE DATE 1/30/2027

ID_CHS_17002025_1126

This document has been classified as public information