POLICY: Oncology (Injectable) – Adcetris Utilization Management Medical Policy
- Adcetris® (brentuximab intravenous infusion – Seattle Genetics)

EFFECTIVE DATE: 1/1/2021
LAST REVISION DATE: 03/05/2025

COVERAGE CRITERIA FOR: All Aspirus Medicare Plans

OVERVIEW

Adcetris, a CD30-directed antibody conjugate, is indicated for the following uses:[1]

- **Classical Hodgkin lymphoma**:
  - In adults with previously untreated Stage III or IV disease, in combination with doxorubicin, vinblastine, and dacarbazine.
  - In adults at high risk of relapse or progression as post-autologous hematopoietic stem cell transplantation (HSCT) consolidation.
  - After failure of autologous HSCT or after failure of at least two prior multi-agent chemotherapy regimens in adults who are not autologous HSCT candidates.
  - In patients ≥ 2 years of age with previously untreated, high risk disease in combination with doxorubicin, vincristine, etoposide, prednisone, and cyclophosphamide.
- **Large B-Cell Lymphoma**, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, DLBCL arising from indolent lymphoma, or high-grade B-cell lymphoma, in adults with relapsed or refractory disease, after two more lines of systemic therapy who are not eligible for autologous HSCT or chimeric antigen receptor (CAR) T-cell therapy, in combination with lenalidomide and a rituximab product.
- **Primary cutaneous anaplastic large cell lymphoma** or **CD30-expressing mycosis fungoides**, in adults who have received prior systemic therapy.
- **Systemic anaplastic large cell lymphoma** or other **CD30-expressing peripheral T-cell lymphomas**, including angioimmunoblastic T-cell lymphoma and peripheral T-cell lymphomas not otherwise specified, in previously untreated adults in combination with cyclophosphamide, doxorubicin, and prednisone.
- **Systemic anaplastic large cell lymphoma**, in adults who have failed at least one prior multi-agent chemotherapy regimen.

Dosing Information

A Phase II study assessed the efficacy of Adcetris in patients with relapsed/refractory B-cell CD30+ non-Hodgkin lymphoma.[7] Patients received Adcetris 1.8 mg/kg intravenously every 3 weeks until disease progression, unacceptable adverse events, or study closure. The overall

response rate in patients with diffuse large B-cell lymphoma was 44% (n = 21/48) and 26% (n = 5/19) in patients with other B-cell lymphomas.

Guidelines

Adcetris is addressed in National Comprehensive Cancer Network (NCCN) guidelines:

- **B-Cell Lymphomas:** Guidelines for adults (version 2.2025 – February 10, 2025) recommend Adcetris for second-line or subsequent treatment of CD30+ diffuse large B-cell lymphoma (DLBCL), CD30+ high-grade B-cell lymphoma, CD30+ human immunodeficiency virus (HIV)-related B-cell lymphoma, CD30+ primary effusion lymphoma, CD30+ human herpes virus 8-positive DLBCL, CD30+ plasmablastic lymphoma, and CD30+ post-transplant lymphoproliferative disorders.[2,6] Pediatric guidelines (version 2.2024 – September 3, 2024) recommend Adcetris for consolidation/additional therapy if partial response is achieved after therapy for relapsed or refractory disease.[2,9] While these guidelines recommend Adcetris for the treatment of primary mediastinal B-cell lymphoma, the study cited by NCCN to support this indication only included patients > 18 years of age.[10] The median age in this study was 35.5 years (range: 19 to 83 years).
- **Hodgkin Lymphoma:** Guidelines for adults (version 2.2025 – January 30, 2025) recommend Adcetris for the treatment of classical Hodgkin lymphoma in combination with chemotherapy, as primary treatment, as second-line or subsequent therapy for relapsed or refractory disease, as maintenance therapy following high-dose therapy and autologous stem cell rescue for relapsed or refractory disease, or as palliative therapy.[2,3] Pediatric guidelines (version 1.2024 – May 14, 2024) recommend Adcetris for primary and additional treatment of high risk disease; re-induction or subsequent therapy for relapsed or refractory disease in heavily pretreated patients or patients with reduced cardiac function in combination with bendamustine, Opdivo® (nivolumab intravenous infusion), and gemcitabine; and as maintenance therapy following high-dose therapy and autologous stem cell rescue.[2,8]
- **T-Cell Lymphomas:** Guidelines (version 1.2025 – November 11, 2024) recommend Adcetris as a first-line or subsequent treatment option for a variety of T-cell lymphomas, either as a single agent or in combination with cyclophosphamide, doxorubicin, and prednisone.[2,4] Primary cutaneous lymphomas guidelines (version 1.2025 – November 11, 2024) recommend Adcetris for the systemic therapy of CD30+: mycosis fungoides/Sezary syndrome, primary cutaneous anaplastic large cell lymphoma, and lymphomatoid papulosis.[2,5]

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Adcetris. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indications. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-

by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Adcetris as well as the monitoring required for adverse events and long-term efficacy, approval requires Adcetris to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Adcetris is recommended in those who meet one of the following criteria:

FDA-Approved Indications

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1. Hodgkin Lymphoma. Approve for 1 year if the patient meets BOTH of the following (A and B):

A) Patient has classical Hodgkin lymphoma; AND

B) The medication is prescribed by or in consultation with an oncologist.

Dosing. Approve up to 1.8 mg/kg or a maximum of 180 mg administered by intravenous infusion no more frequently than once weekly.

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2. T-Cell Lymphoma. Approve for 1 year if the patient meets ALL of the following (A, B, and C):

A) Patient is ≥ 18 years of age; AND

B) Patient meets ONE of the following (i, ii, or iii):

- **i.** Patient has CD30+ T-cell lymphoma; OR
  Note: Examples include CD30+ angioimmunoblastic T-cell lymphoma, CD30+ peripheral T-cell lymphoma not otherwise specified, CD30+ mycosis fungoides/Sezary syndrome, CD30+ primary cutaneous anaplastic large cell lymphoma, CD30+ lymphomatoid papulosis, CD30+ adult T-cell leukemia/lymphoma, CD30+ hepatosplenic T-cell lymphoma, CD30+ extranodal NK/T-cell lymphoma.
- **ii.** Patient has anaplastic large cell lymphoma; OR
- **iii.** Patient has breast implant-associated anaplastic large cell lymphoma; AND

C) The medication is prescribed by or in consultation with an oncologist.

Dosing. Approve up to 1.8 mg/kg or a maximum of 180 mg administered by intravenous infusion no more frequently than once every 3 weeks.

Other Uses with Supportive Evidence

3. B-Cell Lymphoma. Approve for 1 year if the patient meets ALL of the following (A, B, and C):

A) Patient is ≥ 18 years of age; AND

B) Adcetris is used as second-line or subsequent therapy for CD30+ B-cell lymphoma; AND
Note: Examples include CD30+ diffuse large B-cell lymphoma, CD30+ post-transplant lymphoproliferative disorders, CD30+ HIV-related B-cell lymphoma, CD30+ high-grade B-cell lymphoma, CD30+ primary mediastinal large B-cell lymphoma.

C) The medication is prescribed by or in consultation with an oncologist.

Dosing. Approve up to 1.8 mg/kg or a maximum of 180 mg administered by intravenous infusion no more frequently than once every 3 weeks.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Adcetris is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Adcetris® intravenous infusion [prescribing information]. Bothell, WA: Seattle Genetics; February 2025.
2. The NCCN Drugs and Biologics Compendium. © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on February 25, 2025. Search term: brentuximab.
3. The NCCN Hodgkin Lymphoma Clinical Practice Guidelines in Oncology (version 2.2025 – January 30, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on February 26, 2025.
4. The NCCN T-Cell Lymphomas Clinical Practice Guidelines in Oncology (version 1.2025 – November 11, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on February 25, 2025.
5. The NCCN Primary Cutaneous Lymphomas Clinical Practice Guidelines in Oncology (version 1.2025 – November 11, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on February 26, 2025.
6. The NCCN B-Cell Lymphomas Clinical Practice Guidelines in Oncology (version 2.2025 – February 10, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on February 26, 2025.
7. 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.
8. The NCCN Pediatric Hodgkin Lymphoma Clinical Practice Guidelines in Oncology (version 1.2024 – May 14, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on February 26, 2025.
9. The NCCN Pediatric Aggressive Mature B-Cell Lymphoma Clinical Practice Guidelines in Oncology (version 2.2024 – September 3, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on February 25, 2025.
10. Zinzani PL, Santoro A, Gritti G, et al. Nivolumab combined with brentuximab vedotin for relapsed/refractory primary mediastinal large B-cell lymphoma: Efficacy and safety from the Phase II CheckMate 436 study. *J Clin Oncol*. 2019;37:3081-3089.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	**Hodgkin Lymphoma:** Revised dose from no more frequently than once every 2 weeks, to no more frequently than once weekly. **T-cell Lymphoma:** Added CD30+ hepatosplenic T-cell lymphoma and CD30+ extranodal NK/T-cell lymphoma to Note with examples of T-cell lymphomas. **B-cell lymphoma:** Added CD30+ primary mediastinal large B-cell lymphoma to Note with examples of B-cell lymphomas.	10/19/2022
Annual Revision	No criteria changes.	10/11/2023
Aspirus P&T Review	Policy reviewed and approved by Aspirus P&T committee. Annual review process	09/16/2024
Early Annual Revision	**T-Cell Lymphoma:** Removed CD30+ systemic anaplastic large cell lymphoma and CD30+ breast implant-associated anaplastic large cell lymphoma from the Note. Added patient has anaplastic large cell lymphoma and patient has breast implant-associated anaplastic large cell lymphoma as options for approval.	03/05/2025