VENTURA COUNTY
HEALTH CARE PLAN

UTILIZATION MANAGEMENT MEDICAL POLICY

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

REVIEW DATE: 10/02/2024

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 consolidation.
  - After failure of autologous hematopoietic stem cell transplantation or after failure of at least two prior multi-agent chemotherapy regimens in adults who are not autologous hematopoietic stem cell transplantation candidates.
  - In patients ≥ 2 years of age with previously untreated, high risk disease in combination with doxorubicin, vincristine, etoposide, prednisone, and cyclophosphamide.
- **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 3.2024 – August 26, 2024) 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, 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 3.2024 – March 18, 2024) 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 4.2024 – May 28, 2024) recommend Adcetris as a first-line or subsequent treatment option for a variety of CD30+ T-cell lymphomas, either as a single agent or in combination with cyclophosphamide, doxorubicin, and prednisone.[2,4] Primary cutaneous lymphomas guidelines (version 3.2024 – August 22, 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)** Adcetris is used for CD30+ T-cell lymphoma; AND

  Note: Examples include CD30+ systemic anaplastic large cell lymphoma, 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+ breast implant-associated anaplastic

large cell lymphoma, CD30+ adult T-cell leukemia/lymphoma, CD30+ hepatosplenic T-cell lymphoma, CD30+ extranodal NK/T-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.

Other Uses with Supportive Evidence

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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; June 2023.
2. The NCCN Drugs and Biologics Compendium. © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on Setpember 26, 2024. Search term: brentuximab.
3. The NCCN Hodgkin Lymphoma Clinical Practice Guidelines in Oncology (version 3.2024 – March 18, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on September 26, 2024.
4. The NCCN T-Cell Lymphomas Clinical Practice Guidelines in Oncology (version 4.2024 – May 28, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on September 26, 2024.
5. The NCCN Primary Cutaneous Lymphomas Clinical Practice Guidelines in Oncology (version 3.2024 – August 22, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on September 26, 2024.
6. The NCCN B-Cell Lymphomas Clinical Practice Guidelines in Oncology (version 3.2024 – August 26, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on September 26, 2024.
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 September 26, 2024.
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 September 26, 2024.
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	No criteria changes.	10/11/2023

Annual Revision	No criteria changes.	10/02/2024