

Adcetris (Brentuximab)

Effective Date: 12/1/2022

Revision Date(s): n/a

Review Date: 10/19/2022

Policy type: Medical Necessity

Authorizations are for 6 months, after which time they must be reviewed for efficacy, safety, and tolerability.

Initial Approval Criteria

Coverage is provided for the following conditions:

Universal Criteria Applied to All Requests

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

Indication Specific Criteria

Hodgkin Lymphoma, Adult

- Member has stage I-II (unfavorable only) or stage III-IV disease; AND
 - Used in combination with dacarbazine; OR
 - Used in combination with doxorubicin, vinblastine, dacarbazine (AVD)¹; OR
- Member has relapsed or refractory disease; AND
 - Used as subsequent therapy; AND
 - Used as a single agent; OR
 - Used in combination with bendamustine; OR
 - Used in combination with nivolumab; OR
- Used as maintenance therapy following autologous stem cell transplant for relapsed or refractory disease; AND
 - Member has high-risk of relapse²

Hodgkin Lymphoma, Pediatric

- Used in combination with brentuximab, etoposide, prednisone, doxorubicin (AEPA); OR
- Used as re-induction therapy or subsequent therapy; AND
 - Member has relapsed or refractory disease; AND
 - Used in combination with bendamustine, nivolumab, or gemcitabine³; OR

¹ Regimen utilized as follows: brentuximab followed by AVD, conditionally followed by brentuximab in responding patients with a complete response or partial response.

² Patients with 2 or more of the following risk factors are considered high risk: remission duration less than 1 year, extranodal involvement, PET positive response at time of transplant, B symptoms, and/or >1 salvage/subsequent therapy regimen.

³ As a consideration in patients heavily pretreated (with platinum or anthracycline-based chemotherapy) or if a decrease in cardiac function observed. If used in combination with ISRT (involved-site radiation therapy), member should have highly favorable disease including those who

- Used as maintenance therapy following autologous stem cell transplant; AND
 - Member has relapsed or refractory disease; AND
 - Used for select high-risk patients⁴; OR
- Used for high-risk disease as a component of cyclophosphamide, brentuximab vedotin, prednisone, dacarbazine (CAPDAC) regimen following primary treatment with AEPA regimen

T-Cell Lymphomas

- Member has anaplastic large cell lymphoma (ALCL); AND
 - Used in combination with cyclophosphamide, doxorubicin, prednisone (CHP); AND
 - Used as first-line therapy; OR
- Member has T-cell Leukemia/Lymphoma; AND
 - Used as subsequent therapy; AND
 - Member has acute or lymphoma subtypes and is CD30+; AND
 - Used in combination with CHP for CD30+ cases in specific situations⁵; OR
 - As a single agent; OR
- Member has one of the following relapsed/refractory diseases:
 - Used as a single agent; AND
 - Used as subsequent therapy; AND
 - Member has CD30+ peripheral T-cell Lymphoma; OR
 - Member has CD30+ angioimmunoblastic T-cell Lymphoma (AITL); OR
 - Member has anaplastic large cell lymphoma; OR
- Member has one of the following diseases:
 - Used in combination with CHP; AND
 - Used as first-line therapy; AND
 - Member has CD30+ stage I-IV peripheral T-cell lymphoma not otherwise specified; OR
 - Member has AITL; OR
 - Member has enteropathy-associated T-cell lymphoma (EATL); OR
 - Member has monomorphic epitheliotropic intestinal T-cell lymphoma (MEITL); OR
 - Member has nodal peripheral T-cell lymphoma with TFH phenotype; OR
 - Member has follicular T-cell lymphoma; OR
- Member has hepatosplenic T-cell Lymphoma; AND
 - Used as a single agent; AND
 - Member has CD30+ refractory disease; AND
 - Used in third-line setting and beyond; OR
- Member has breast-implant associated ALCL; AND
 - Member has relapsed/refractory disease; AND

may avoid transplant and have initial stage other than IIIB or IVB, no prior exposure to RT, duration of CR1 >1 year, absence of extranodal disease or B symptoms at relapse.

⁴ High-risk defined as any patient with progressive disease, refractory disease, or relapse within 1 year of original diagnosis.

⁵ Specific situations: chemotherapy in non-responders to first-line therapy for chronic/smoldering subtype OR first-line therapy for acute subtype OR continued treatment in responders to first-line therapy for acute subtype OR first-line therapy for lymphoma subtype OR continued treatment in responders to first-line therapy for lymphoma subtype.

- Used as subsequent therapy; AND
 - Used as a single agent; OR
- Member has localized disease; AND
 - Used as adjuvant therapy; AND
 - Used as a single agent; OR
 - Used in combination with CHP; OR
- Member has Extranodal NK/T-cell Lymphoma; AND
 - Used as a single agent; AND
 - Member has CD30+ relapsed/refractory disease; AND
 - Used as subsequent therapy

Primary Cutaneous Lymphomas

- Member has lymphomatoid papulosis; AND
 - Used as a single agent; AND
 - Used as subsequent therapy; OR
- Member has cutaneous ALCL; AND
 - Used in combination with CHP; OR
 - Used as a single agent; OR
- Member has Mycosis Fungoides/Sezary Syndrome

B-Cell Lymphomas

- Member has post-transplant lymphoproliferative disorder; AND
 - Member has CD30+ monomorphic T-cell type disease; AND
 - Used in combination with CHP; OR
 - Used as a single agent as subsequent-line therapy; AND
 - Member is not a candidate for transplant
- Member has a high-grade, CD30+ B-cell Lymphoma; AND
 - Used as subsequent therapy; AND
 - Member is not a candidate for transplant; OR
- Member has one of the following CD30+ diseases:
 - AIDS-related diffuse large B-cell Lymphoma (DLBCL); OR
 - Primary effusion lymphoma; OR
 - DLBCL; OR
 - HHV8-positive DLBCL; AND
 - Used as subsequent therapy; AND
 - Member is not a candidate for transplant

Billing

Drug Name	HCPSC Code	Description
Adcetris	J9042	Inj., brentuximab, 1 mg

References

1. Adcetris. NCCN Drugs & Biologics Compendium. Available at: https://www.nccn.org/professionals/drug_compendium/content/. Accessed 8/29/2022
2. Adcetris [package insert]. Seagen, Inc., Bothell, WA. Available at: https://seagendocs.com/Adcetris_Full_Ltr_Master.pdf
3. B-Cell Lymphomas: NCCN Clinical Practice Guidelines in Oncology. Available at: https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf. Accessed 8/29/22
4. Hodgkin Lymphoma: NCCN Clinical Practice Guidelines in Oncology. Available at: https://www.nccn.org/professionals/physician_gls/pdf/hodgkins.pdf. Accessed 8/29/22
5. Pediatric Hodgkin Lymphoma: NCCN Clinical Practice Guidelines in Oncology. Available at: https://www.nccn.org/professionals/physician_gls/pdf/ped_hodgkin.pdf. Accessed 8/29/22
6. Primary Cutaneous Lymphoma. NCCN Clinical Practice Guidelines in Oncology. Available at: https://www.nccn.org/professionals/physician_gls/pdf/primary_cutaneous.pdf. Accessed 8/29/22
7. T-Cell Lymphomas. NCCN Clinical Practice Guidelines in Oncology. Available at: https://www.nccn.org/professionals/physician_gls/pdf/t-cell.pdf. Accessed 8/29/22

Disclaimer

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. OncoHealth reserves the right to request medical documentation as needed to validate medical necessity determinations.

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