

POLICY Document for Adcetris

The overall objective of this policy is to support the appropriate and cost-effective use of the medication, specific to use of preferred medication options, and overall, clinically appropriate use. This document provides specific information to both sections of the overall policy.

Section 1: Clinical Criteria

- Policy information specific to the clinical appropriateness for the medication

Section 2: Oncology Clinical Policy

- Policy information specific to regimen review per NCCN Guidelines.

Section 1: Clinical Criteria

• Specialty Guideline Management Adcetris

• Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Adcetris	brentuximab vedotin

• 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 Indications¹

- Classical Hodgkin Lymphoma (cHL)
 - Treatment of adult patients with cHL after failure of autologous hematopoietic stem cell transplantation (auto-HSCT) or after failure of at least two prior multi-agent chemotherapy regimens in patients who are not auto-HSCT candidates

- Treatment of adult patients with cHL at high risk of relapse or progression as post-auto-HSCT consolidation
- Treatment of adult patients with previously untreated Stage III or IV classical Hodgkin lymphoma (cHL), in combination with doxorubicin, vinblastine, and dacarbazine
- Treatment of pediatric patients 2 years and older with previously untreated high risk classical Hodgkin lymphoma (cHL) in combination with doxorubicin, vincristine, etoposide, prednisone and cyclophosphamide
- Systemic anaplastic large cell lymphoma (sALCL)
 - Treatment of adult patients with systemic anaplastic large cell lymphoma (sALCL) after failure of at least one prior multi-agent chemotherapy regimen
 - Treatment of adult patients with previously untreated systemic anaplastic large cell lymphoma (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 primary cutaneous anaplastic large cell lymphoma (pcALCL) or CD30-expressing mycosis fungoides (MF) in patients who have received prior systemic therapy

• Compendial Uses²

- cHL stage I-II unfavorable
- CD30+ B-Cell Lymphomas
 - Monomorphic post-transplant lymphoproliferative disorders (B-cell type)
 - Diffuse large B-cell lymphoma
 - HIV-Related B-cell lymphomas (CD30+ HIV-related diffuse large B-cell lymphoma, primary effusion lymphoma, and human herpesvirus-8 (HHV8)-positive diffuse large B-cell lymphoma)
 - High-grade B-Cell lymphomas
 - Pediatric primary mediastinal large B-cell lymphoma
- 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
 - Adult T-cell leukemia/lymphoma
 - Breast implant-associated anaplastic large cell lymphoma (ALCL)
 - Peripheral T-cell lymphoma (PTCL)
 - Extranodal NK/T-cell Lymphoma
 - Angioimmunoblastic T-cell lymphoma

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:

Testing or analysis confirming CD30 expression on the surface of the cell (initial requests).

• Coverage Criteria

• Classic Hodgkin lymphoma (cHL)¹⁻²

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

- The requested drug will be used as a single agent, or
- The requested drug will be used in combination with doxorubicin, vinblastine, and dacarbazine, or
- The requested drug will be used in combination with bendamustine for subsequent therapy, or
- The requested drug will be used in combination with dacarbazine, or
- The requested drug will be used in combination with nivolumab for subsequent therapy, or
- The requested drug will be used in combination with gemcitabine for subsequent therapy, or
- The requested drug will be used in combination with ifosfamide, carboplatin and etoposide for subsequent therapy, or
- The requested drug will be used in combination with etoposide, prednisone and doxorubicin, or
- The requested drug will be used in combination with cyclophosphamide, prednisone, and dacarbazine for subsequent therapy, or
- The requested drug will be used in combination with doxorubicin, vincristine, etoposide, prednisone and cyclophosphamide, or
- The requested drug will be used in combination with etoposide, cyclophosphamide, doxorubicin, dacarbazine and dexamethasone.

• B-Cell Lymphomas^{1,2}

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

- Monomorphic post-transplant lymphoproliferative disorders (B-cell type) when both of the following are met:
 - The requested drug will be used for subsequent therapy, and
 - The member is not a candidate for transplant.
- Diffuse large B-cell lymphoma when all of the following are met:
 - The requested drug will be used as subsequent therapy, and
 - The member is not a candidate for transplant.

- HIV-Related B-cell lymphomas (HIV-related diffuse large B-cell lymphoma, primary effusion lymphoma, and human herpesvirus-8 (HHV8)-positive diffuse large B-cell lymphoma) when both of the following are met:
 - The requested drug will be used for subsequent therapy, and
 - The member is not a candidate for transplant.
- Pediatric primary mediastinal large B-cell lymphoma when both of the following are met:
 - The requested drug will be used for relapsed or refractory disease, and
 - The requested drug will be used in combination with nivolumab or pembrolizumab
- High-grade B-cell lymphomas when both of the following are met:
 - The requested drug will be used for subsequent therapy, and
 - The member is not a candidate for transplant.

- **Primary Cutaneous Lymphomas^{1,2}**

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 are met:
 - The requested drug will be used as a single agent, and
 - The disease is relapsed or refractory.
- Cutaneous anaplastic large cell lymphoma when either of the following are met:
 - The requested drug will be used as a single agent, or
 - The requested drug will be used in combination with cyclophosphamide, doxorubicin, and prednisone (CHP)

- **T-Cell Lymphomas^{1,2}**

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

- Hepatosplenic T-cell lymphoma when the requested drug will be used as a single agent after two or more primary treatment regimens
- Adult T-cell leukemia/lymphoma when either of the following are met:
 - The requested drug will be used as a single agent for subsequent therapy, or
 - The requested drug will be used in combination with cyclophosphamide, doxorubicin, and prednisone.
- Breast implant associated anaplastic large cell lymphoma (ALCL) when either of the following are met:
 - The requested drug will be used as a single agent, or
 - The requested drug will be used in combination with cyclophosphamide, doxorubicin, and prednisone.
- Peripheral T-cell lymphoma (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 either of the following are met:

- The requested drug will be used a single agent for subsequent or palliative therapy, or
- The requested drug will be used in combination with cyclophosphamide, doxorubicin, and prednisone.
- Extranodal NK/T-cell lymphoma when all of the following are met:
 - The requested drug will be used as a single agent, and
 - The member has relapsed or refractory disease, and
 - The member has had an inadequate response or contraindication to asparaginase-based therapy (e.g., pegaspargase).
- Systemic anaplastic large cell lymphoma when either of the following are met:
 - The requested drug will be used as a single agent, or
 - The requested drug will be used in combination with cyclophosphamide, doxorubicin, and prednisone (CHP).

• 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.

Section 2: Oncology Clinical Policy

PURPOSE

The purpose of this policy is to define the Novologix NCCN® Regimen Prior Authorization Program.

SCOPE

This policy applies to clients who have implemented the Novologix NCCN® Program as a part of their medical and/or pharmacy prior authorization solution.

PROGRAM DESCRIPTION

The National Comprehensive Care Network® (NCCN®) is an alliance of leading cancer centers devoted to patient care, research and education dedicated to improving the quality, effectiveness, and efficiency of cancer care so patients can live better lives.¹ It is comprised of oncology experts who convene regularly to establish the best treatments for patients. NCCN develops various resources for use by stakeholders in the health care delivery system. These

resources include, but are not limited to, the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines[®]), the NCCN Drugs & Biologics Compendium (NCCN Compendium[®]) and the NCCN Chemotherapy Order Templates (NCCN Templates[®]).

NCCN Templates[®] are based on NCCN Guidelines[®] and NCCN Compendium[®]. The NCCN Compendium lists the appropriate drugs and biologics as treatment options for specific cancers using U.S. Food and Drug Administration (FDA)-approved disease indications and specific NCCN panel recommendations. Each recommendation is supported by a level of evidence category.

NCCN Categories of Evidence and Consensus²

- Category 1: Based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
- Category 2A: Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
- Category 2B: Based upon lower-level evidence, there is NCCN consensus that the intervention is appropriate.
- Category 3: Based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate.

POLICY

Policy for Regimen Prior Authorization

A regimen prior authorization allows submission of a single prior authorization request for all oncology drugs or biologics within an NCCN template that require prior authorization.

PROCEDURE

This policy provides coverage of a regimen review when all of the following criteria are met:

1. Regimen prior authorization reviews, based on NCCN templates, are initiated through the provider portal.
 - If the prior authorization request is submitted via phone or fax, each drug or biologic will need to be submitted and reviewed as a separate prior authorization request for review with drug-specific criteria.
2. The prior authorization review is requested for an oncology drug or biologic.
3. The member is eligible for regimen review.
4. The indication is for a cancer that is eligible for regimen review. Currently, the cancer types in scope for regimen review include the following:
 - o Ampullary Adenocarcinoma
 - o Anal Carcinoma

- o B-Cell Lymphomas
- o Basal Cell Skin Cancer
- o Biliary Tract Cancers
- o Bone Cancer
- o Breast Cancer
- o Bladder Cancer
- o Central Nervous System Cancers
- o Cervical Cancer
- o Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma
- o Chronic Myeloid leukemia
- o Colon Cancer
- o Dermatofibrosarcoma Protuberans
- o Esophageal Cancer
- o Gastric Cancer
- o Gastrointestinal Stromal Tumors
- o Gestational Trophoblastic Neoplasms
- o Hairy Cell Leukemia
- o Head and Neck Cancers
- o Histiocytic Neoplasms
- o Hodgkin Lymphoma
- o Hepatocellular Carcinoma
- o Kaposi Sarcoma
- o Kidney Cancer
- o Melanoma: Cutaneous
- o Melanoma: Uveal
- o Merkel Cell Carcinoma
- o Mesothelioma: Peritoneal
- o Mesothelioma: Pleural
- o Multiple Myeloma
- o Myelodysplastic Syndromes
- o Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Gene Fusions
- o Myeloproliferative Neoplasms
- o Neuroendocrine and Adrenal Tumors
- o Non-Small Cell Lung Cancer
- o Occult Primary
- o Ovarian Cancer
- o Pancreatic Cancer
- o Penile Cancer
- o Primary Cutaneous Lymphomas

- o Prostate Cancer
- o Rectal Cancer
- o Small Bowel Adenocarcinoma
- o Small Cell Lung Cancer
- o Soft Tissue Sarcoma
- o Squamous Cell Skin Cancer
- o Systemic Mastocytosis
- o Systemic Light Chain Amyloidosis
- o T-Cell Lymphomas
- o Testicular Cancer
- o Thymomas and Thymic Carcinomas
- o Thyroid Carcinoma
- o Uterine Neoplasms
- o Vaginal Cancer
- o Vulvar Cancer
- o Waldenström Macroglobulinemia / Lymphoplasmacytic Lymphoma
- o Wilms Tumor (Nephroblastoma)

In addition, the following criteria must be met for approval:

1. The requested regimen for the drug(s) or biologic(s) and indication is consistent with an NCCN recommendation with a level of evidence category of 1 or 2A.
2. The NCCN template must be accepted by the provider without modification.

Further review may be indicated when the above criteria are not met.

Authorizations may be granted for 12 months or as medically required, based on the member's condition and provider's assessment.

Supportive Care: Myeloid Growth Factor Therapy

Granulocyte colony stimulating factors are recommended for primary prophylaxis based on the febrile neutropenia risk of the chemotherapy regimen. Febrile neutropenia risk levels vary by NCCN Chemotherapy Order template and are listed at the top of the template. Regimens associated with a high or intermediate risk of febrile neutropenia may include a granulocyte colony stimulating factor as part of the prior authorization.

Continuation of Therapy

To submit a request for continuation of therapy, a new regimen prior authorization review must be requested. Upon template selection, the template must be modified to include the appropriate therapies being used for maintenance treatment. The regimen request will be submitted for further review.

Dosage and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and evidence-based practice guidelines.

REFERENCES:

SECTION 1

1. Adcetris [package insert]. Bothell, WA: Seagen Inc; June 2023.
2. The NCCN Drugs & Biologics Compendium® © 2024 National Comprehensive Cancer Network, Inc. Available at: <https://www.nccn.org>. Accessed April 5, 2024.

SECTION 2

1. National Comprehensive Cancer Network. About NCCN website. <https://www.nccn.org/home/about>, accessed September 9, 2024.
2. National Comprehensive Cancer Network. NCCN Categories of Evidence and Consensus website, <https://www.nccn.org/guidelines/guidelines-process/development-and-update-of-guidelines>, accessed September 9, 2024.
3. National Comprehensive Cancer Network. NCCN Guidelines website. https://www.nccn.org/guidelines/category_1, accessed September 9, 2024. (Note: An account may be required.)
4. National Comprehensive Cancer Network. NCCN Drugs and Biologics Compendium website <https://www.nccn.org/compendia-templates/compendia/drugs-and-biologics-compendia>, accessed September 9, 2024. (Note: A subscription may be required.)
5. National Comprehensive Cancer Network. NCCN Chemotherapy Order Templates (NCCN Templates) website. <https://www.nccn.org/compendia-templates/nccn-templates-main/browse-by-cancer-type>, accessed September 9, 2024. (Note: A subscription may be required.)