BlueCross BlueShield Federal Employee Program

ADECTRIS
(brentuximab)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Adcetris (brentuximab vedotin) is a CD30-directed antibody-drug conjugate consisting of three components: a chimeric IgG1 antibody specific for human CD30, the microtubule-disrupting agent MMAE, and a protease-cleavable linker that covalently attaches MMAE to the antibody. Binding of MMAE to tubulin disrupts the microtubule network within the cell, subsequently inducing cell cycle arrest and apoptotic death of the cells (1).

Regulatory Status

FDA-approved indications: Adcetris is a CD30-directed antibody-drug conjugate indicated for the treatment of: (1)

1. Adult patients with previously untreated Stage III or IV classical Hodgkin's lymphoma (cHL), in combination with doxorubicin, vinblastine, and dacarbazine
2. Pediatric patients 2 years and older with previous untreated high risk classical Hodgkin lymphoma (cHL), in combination with doxorubicin, vincristine, etoposide, prednisone, and cyclophosphamide
3. Adult patients with classical Hodgkin lymphoma (cHL) at high risk of relapse or progression as post-autologous hematopoietic stem cell transplantation (auto-HSCT) consolidation
4. Adult patients with classical Hodgkin's lymphoma (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
5. 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 (NOS), in combination with cyclophosphamide, doxorubicin, and prednisone
6. Adult patients with systemic anaplastic large cell lymphoma (sALCL) after failure of at least 1 prior multi-agent chemotherapy regimen
7. Adult patients with primary cutaneous anaplastic large cell lymphoma (pcALCL) or CD30-expressing mycosis fungoides (MF) who have received prior systemic therapy
8. Adult patients with relapsed or refractory large B-cell lymphoma (LBCL), including diffuse large B-cell lymphoma (DLBCL) NOS, DLBCL arising from indolent

lymphoma, of 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

Adcetris has a boxed warning for progressive multifocal leukoencephalopathy. JC virus infection resulting in progressive multifocal leukoencephalopathy (PML) and death can occur in patients receiving Adcetris (1).

The use of Adcetris is associated with development of peripheral neuropathy and neutropenia, in which case a dose modification may be required. Monitor patients for symptoms of neuropathy, such as hypoesthesia, hyperesthesia, paresthesia, discomfort, a burning sensation, neuropathic pain or weakness. Complete blood counts should be monitored prior to each dose of Adcetris and more frequently for patients with Grade 3 or 4 neutropenia. Patients with rapidly proliferating tumor and high tumor burden may be at increased risk of tumor lysis syndrome (1).

Based on mechanism of action and findings in animals, Adcetris can cause fetal harm when administered to pregnant women. Female patients of reproductive potential should be advised of the potential risk to a fetus and to avoid pregnancy (1).

The safety and effectiveness of Adcetris have been established in pediatric patients age 2 and older with previously untreated high risk cHL in combination with doxorubicin, vincristine, etoposide, prednisone, and cyclophosphamide. The safety and effectiveness of Adcetris in pediatric patients have not been established for all other indications (1).

Summary

Adcetris (brentuximab vedotin) is indicated for the treatment of patients with classical Hodgkin lymphoma (cHL), systemic anaplastic large cell lymphoma (sALCL) or other CD30-expressing peripheral T-cell lymphomas (PTCL), primary cutaneous anaplastic large cell lymphoma (pcALCL) or CD30-expressing mycosis fungoides (MF), and relapsed or refractory large B-cell lymphoma (LBCL). The use of Adcetris is associated with development of peripheral neuropathy, neutropenia, tumor lysis syndrome, and progressive multifocal leukoencephalopathy (PML) (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Adcetris while maintaining optimal therapeutic outcomes.

References

1. Adcetris [package insert]. Bothell, WA: Seattle Genetics, Inc.; February 2025.
2. NCCN Drugs & Biologics Compendium® Brentuximab vedotin 2025. National Comprehensive Cancer Network, Inc. Accessed on February 12, 2025.