

## Corporate Medical Policy

### Brentuximab Vedotin (Adcetris®)

<b>File Name:</b>	brentuximab_vedotin_adcetris
<b>Origination:</b>	9/1/2016
<b>Last CAP Review:</b>	4/2020
<b>Next CAP Review:</b>	4/2021
<b>Last Review:</b>	4/2020

#### Description of Procedure or Service

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Brentuximab Vedotin (Adcetris) is a CD30-directed antibody-drug conjugate indicated for the treatment of patients with Hodgkin lymphoma and systemic anaplastic large cell lymphoma.

**\*\*\*Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

#### Policy

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**BCBSNC will provide coverage for Brentuximab Vedotin (Adcetris) when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.**

#### Benefits Application

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This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

#### When Brentuximab Vedotin (Adcetris) is covered

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Brentuximab Vedotin (Adcetris) is considered medically necessary for the treatment of patients with classical Hodgkin lymphoma (cHL) who meet one of the following indications:

- After failure of autologous stem cell transplantation (ASCT); **OR**
- After failure of at least two prior multi-agent chemotherapy regimens in patients who are not ASCT candidates; **OR**
- As cytoreduction as 2<sup>nd</sup> line therapy, prior to either autologous or allogeneic stem cell transplantation for relapsed or refractory disease in selected patients to minimize use of more intensive chemotherapy; **OR**
- As consolidation or maintenance following autologous stem cell transplantation in patients who had primary refractory disease, extranodal disease, or initial remission duration less than 12 months following primary therapy in patients with no prior brentuximab treatment; **OR**
- In combination with chemotherapy (i.e. doxorubicin, vinblastine, and dacarbazine) for previously untreated Stage III or IV disease.

Brentuximab Vedotin (Adcetris) is considered medically necessary for the treatment of patients with systemic anaplastic large cell lymphoma after failure of at least one prior multi-agent chemotherapy regimen.

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Brentuximab Vedotin (Adcetris) is considered medically necessary in combination with cyclophosphamide, doxorubicin, and prednisone for the treatment of patients with previously untreated systemic anaplastic large cell lymphoma or other CD30+ peripheral T-cell lymphomas (PTCL), including angioimmunoblastic T-cell lymphoma and PTCL not otherwise specified.

Brentuximab Vedotin (Adcetris) is considered medically necessary for the treatment of patients with CD30+ cutaneous anaplastic large cell lymphoma (NCCN 2A).

Use of Brentuximab Vedotin (Adcetris) may be considered medically necessary for clinical indications not listed above when the drug is prescribed for the treatment of cancer either:

- In accordance with FDA label (when clinical benefit has been established, see Policy Guidelines); **OR**
- In accordance with specific strong endorsement or support by nationally recognized compendia, when such recommendation is based on strong/high levels of evidence, and/or uniform consensus of clinical appropriateness has been reached.

### **When Brentuximab Vedotin (Adcetris) is not covered**

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Brentuximab Vedotin (Adcetris) is considered not medically necessary and therefore not covered when above criteria are not met.

Brentuximab Vedotin (Adcetris) is considered investigational when used for:

1. Non-cancer indications; **OR**
2. When criteria are not met regarding FDA labeling **OR** strong endorsement/support by nationally recognized compendia, as stated under “When Brentuximab Vedotin (Adcetris) is covered.”

### **Policy Guidelines**

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The recommended dose as monotherapy is 1.8 mg/kg up to a maximum of 180 mg administered only as an intravenous infusion over 30 minutes every 3 weeks.

Continue treatment until a maximum of 16 cycles, disease progression or unacceptable toxicity.

The recommended dose in combination with chemotherapy for previously untreated Stage III or IV classical Hodgkin lymphoma is 1.2 mg/kg up to a maximum of 120 mg every 2 weeks for a maximum of 12 doses.

The recommended dose in combination with chemotherapy for previously untreated PTCL is 1.8 mg/kg up to a maximum of 180 mg administered only as an intravenous infusion over 30 minutes every three weeks for 6 to 8 doses.

Drugs prescribed for treatment of cancer in accordance with FDA label may be considered medically necessary when clinical benefit has been established, and should not be determined to be investigational as defined in Corporate Medical Policy (CMP), “Investigational (Experimental) Services.”

Please refer to CMP “Investigational (Experimental) Services” for a summary of evidence standards from nationally recognized compendia.

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## Billing/Coding/Physician Documentation Information

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This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at [www.bcbsnc.com](http://www.bcbsnc.com). They are listed in the Category Search on the Medical Policy search page.

*Applicable service codes: J9042, S0353, S0354*

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

## Scientific Background and Reference Sources

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U.S. Food and Drug Administration (FDA). Available at:  
[http://www.accessdata.fda.gov/drugsatfda\\_docs/label/2011/125388s000,125399s000lbl.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/label/2011/125388s000,125399s000lbl.pdf)

Moskowitz CH et al. *Lancet* 2015; 385:1853-1862.

Duvic et al. *J Clin Oncol* 2015; 33:3759-65 and Kim YH, Tavallae M, Sundram U, et al. *J Clin Oncol* 2015.

Medical Director review 9/2016

Specialty Matched Consultant Advisory Panel review 4/2017

Seattle Genetics, Inc. Adcetris (brentuximab vedotin) for injection, for intravenous use. Prescribing Information. Bothell, WA:Seattle Genetics; Revised 3/2018. Available at:  
<https://adcetrispro.com/sites/default/files/2016-06/AD CETRIS%20%28brentuximab%20vedotin%29%20Prescribing%20Information.pdf>. Accessed April 2018.

Specialty Matched Consultant Advisory Panel review 4/2018

Seattle Genetics, Inc. Adcetris (brentuximab vedotin) injection for intravenous use. Highlights of prescribing information. November 2018. Available at:  
<https://www.adcetrispro.com/presinfo/pi.pdf>. Accessed April 2019.

Specialty Matched Consultant Advisory Panel review 4/2019

Specialty Matched Consultant Advisory Panel review 4/2020

## Policy Implementation/Update Information

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12/30/16 New policy developed. Brentuximab Vedotin (Adcetris) is considered medically necessary for the treatment of patients with classical Hodgkin lymphoma. Medical Director review 9/2016. Reference added. Added HCPCS codes S0353, S0354 to Billing/Coding section. Notification given 12/30/16 for effective date 4/1/17. (lpr)

5/26/17 Added the following statement to “When Covered” section: “Use of Brentuximab Vedotin (Adcetris) may be considered medically necessary for clinical indications not listed above when the drug is prescribed for the treatment of cancer either: In accordance with FDA label (when clinical benefit has been established, see Policy Guidelines); OR In accordance with

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specific strong endorsement or support by nationally recognized compendia, when such recommendation is based on strong/high levels of evidence, and/or uniform consensus of clinical appropriateness has been reached”. Under “When Not Covered” section, added the statement “Brentuximab Vedotin (Adcetris) is considered investigational when used for: 1)Non-cancer indications; **OR** 2) When criteria are not met regarding FDA labeling **OR** strong endorsement/ support by nationally recognized compendia, as stated under “When Brentuximab Vedotin (Adcetris) is covered.” Added the following statements under “Policy Guidelines” section: 1)Drugs prescribed for treatment of cancer in accordance with FDA label may be considered medically necessary when clinical benefit has been established, and should not be determined to be investigational as defined in Corporate Medical Policy, Investigational (Experimental) Services.” 2) Please refer to CMP “Investigational (Experimental) Services” for a summary of evidence standards from nationally recognized compendia. Medical director review 3/2017. Specialty Matched Consultant Advisory Panel review 4/26/2017. No change to policy statement. (lpr)

- 5/11/18 Added the following statement to “When Covered” section for classical Hodgkin lymphoma: “In combination with chemotherapy for previously untreated Stage III or IV disease” and updated “Policy Guidelines” section to include dosing for this indication. References added. Specialty Matched Consultant Advisory Panel review 4/25/2018. (krc)
- 4/30/19 Added the following indication to “When Covered” section: “in combination with cyclophosphamide, doxorubicin, and prednisone for the treatment of patients with previously untreated systemic anaplastic large cell lymphoma or other CD30+ peripheral T-cell lymphomas (PTCL), including angioimmunoblastic T-cell lymphoma and PTCL not otherwise specified,” and added the following statement for clarity “(i.e. doxorubicin, vinblastine, and dacarbazine)” for previously untreated stage III/IV cHL. Updated dosing in Policy Guidelines to reflect additional indication. References added. Specialty Matched Consultant Advisory Panel review 4/17/2019. (krc)
- 6/9/20 Specialty Matched Consultant Advisory Panel review 4/15/2020. No change to policy statements. (krc)

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Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.