

Market Applicability														
Market	DC	FL & FHK	FL MMA	FL LTC	GA	KS	KY	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	X

*FHK- Florida Healthy Kids

Adcetris (brentuximab vedotin)

CG-DRUG-106

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
Adcetris (brentuximab vedotin)

APPROVAL CRITERIA

Adcetris (brentuximab vedotin) requests may be approved if the following criteria are met:

- I. Diagnosis of Hodgkin lymphoma with any of the following indications:
 - A. Previously untreated stage III or IV classical Hodgkin lymphoma, in combination with doxorubicin, vinblastine and dacarbazine; **OR**
 - B. For relapsed or refractory disease in a single line of therapy as a single agent or in combination with bendamustine; **OR**
 - C. As consolidation therapy after an autologous stem cell transplantation for individuals at high risk of relapse or progression, that is, individuals with any of the following:
 1. Primary refractory Hodgkin lymphoma; **OR**
 2. Relapsed Hodgkin lymphoma with an initial remission duration of less than 12 months; **OR**
 3. Extranodal involvement at the start of pre-transplantation salvage chemotherapy;

OR

 - D. As maintenance therapy for 1 year following high-dose therapy and autologous stem cell rescue for relapsed or refractory disease in those who are brentuximab vedotin naïve and have a Deauville score of less than 5;
- OR**
- II. Diagnosis of CD30+ non-Hodgkin Lymphoma with any of the following indications:
 - A. Cutaneous anaplastic large cell lymphoma; **OR**
 - B. Cutaneous T-cell lymphoma, including mycosis fungoides/Sézary syndrome which is relapsed, refractory or as first-line therapy for advanced disease presentation (for example, folliculotropic, large-cell transformation or extracutaneous disease); **OR**
 - C. Previously untreated peripheral T-cell lymphoma in combination with cyclophosphamide, doxorubicin, and prednisone; **OR**

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

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- D. Relapsed or refractory disease after at least one prior multi-agent chemotherapy regimen for treatment of any of the following:
1. Systemic anaplastic large cell lymphoma; **OR**
 2. T-cell lymphoma (excluding cutaneous T-cell lymphoma); **OR**
 3. Lymphomatoid papulosis that is symptomatic or characterized by extensive cutaneous lesions;
- OR**
- E. As a single-agent for adult T-cell leukemia/lymphoma after high dose therapy and autologous stem cell rescue; **OR**
- F. As an adjuvant systemic therapy for breast implant-associated anaplastic large cell lymphoma for either of the following:
1. Residual, localized disease (confined to capsule/implant/breast) following partial excision or capsulectomy; **OR**
 2. Extended disease (stage II–IV).

Adcetris (brentuximab vedotin) may **not** be approved when the above criteria are not met and for all other indications.

Note: Adcetris (brentuximab vedotin) has a black box warning for progressive multifocal leukoencephalopathy (PML). PML and death may occur, as a result of John Cunningham (JC) virus infection, in individuals receiving Adcetris.

State Specific Mandates		
State	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

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Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	X

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Key References:

1. Brentuximab Vedotin Monograph. Lexicomp® Online, American Hospital Formulary Service® (AHFS®) Online, Hudson, Ohio, Lexi-Comp., Inc. Last revised March 9, 2015. Accessed on December 18, 2018.
2. Brentuximab vedotin [Product Information]. Seattle Genetics, Inc., Bothell, WA; November 16, 2018. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/125388s099lbl.pdf. Accessed on December 18, 2018.
3. Brentuximab vedotin. In: DrugPoints® System (electronic version). Truven Health Analytics. Greenwood Village, CO. Updated November 26, 2018. Available at: <http://www.micromedexsolutions.com>. Accessed on December 18, 2018.
4. National Comprehensive Cancer Network®. NCCN Drugs & Biologic Compendium® (electronic version). For additional information visit the NCCN website: <http://www.nccn.org>. Accessed on December 18, 2018.
5. NCCN Clinical Practice Guidelines in Oncology®. © 2018 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website at: <http://www.nccn.org/index.asp>. Accessed on December 18, 2018.
 - B-Cell Lymphomas. V.1.2019. Updated November 30, 2018.
 - Hodgkin Lymphoma. V.3.2018. Updated April 16, 2018.
 - Primary Cutaneous Lymphomas. V.2.2019. Updated December 17, 2018.
 - T-Cell Lymphomas. V.2.2019. Updated December 17, 2018.

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