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

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Adcetris (brentuximab vedotin)

DRUG.00047

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 chemotherapy; **OR**
   B. As a single-agent for relapsed or refractory disease in a single line of therapy; **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

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

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presentation (for example, folliculotropic, large-cell transformation or extracutaneous disease); **OR**

C. 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

D. As a single-agent for adult T-cell leukemia/lymphoma after high dose therapy and autologous stem cell rescue; **OR**

E. 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.

****Examples of drugs used for treatment of Systemic Anaplastic Large Cell lymphoma may include the following:**

CHOEP (cyclophosphamide, doxorubicin, vincristine, etoposide, prednisone)
CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone)
CHOP followed by ICE (cyclophosphamide, doxorubicin, vincristine, prednisone followed by ifosfamide, carboplatin, etoposide)
CHOP followed by IVE (cyclophosphamide, doxorubicin, vincristine, prednisone followed by ifosfamide, etoposide, and epirubicin) alternating with intermediate dose methotrexate [this is also called the New Castle Regimen]
DHAP (dexamethasone, cisplatin, cytarabine)
ESHAP (etoposide, methylprednisolone, high-dose cytarabine and cisplatin)
GDP (gemcitabine, dexamethasone, cisplatin)
GemOx (gemcitabine, oxaliplatin)
Hyper CVAD (cyclophosphamide, vincristine, doxorubicin, and dexamethasone alternating with high-dose methotrexate and cytarabine)
ICE (ifosfamide, carboplatin, etoposide)
MINE (etoposide, ifosfamide, mesna, mitoxantrone)

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

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

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 March 27, 2018.
2. Brentuximab vedotin [Product Information]. Seattle Genetics, Inc., Bothell, WA; March 20, 2018. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/125388s097lbl.pdf. f. Accessed on March 27, 2018.
3. Brentuximab vedotin. In: DrugPoints® System (electronic version). Truven Health Analytics. Greenwood Village, CO. Updated March 01, 2018. Available at: http://www.micromedexsolutions.com. Accessed on March 27, 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 March 27, 2018.
5. NCCN Clinical Practice Guidelines in Oncology®. © 2017 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website at: http://www.nccn.org/index.asp. Accessed on April 03, 2018.
    - Hodgkin Lymphoma. V.1.2018. Updated December 20, 2017.
    - T-Cell Lymphomas V.3.2018. Updated February 22, 2018.