Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

Adcetris (brentuximab vedotin)

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
Adcetris (brentuximab vedotin)

APPROVAL CRITERIA

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

I. Individual has a diagnosis of Hodgkin Lymphoma (HL); **AND**
II. Individual is using for one of the following:
   A. Previously untreated stage III or IV classical HL, in combination with doxorubicin, vinblastine and dacarbazine; **OR**
   B. Previously untreated classical HL in older adults (≥60 years), as sequential therapy with doxorubicin, vinblastine, and dacarbazine, or in combination with dacarbazine (NCCN 2A); **OR**
   C. Relapsed or refractory disease in a single line of therapy as a single agent or in combination with bendamustine (Label, NCCN 2A); **OR**
   D. 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 HL; **OR**
      2. Relapsed HL with an initial remission duration of less than 12 months; **OR**
      3. Extranodal involvement at the start of pre-transplantation salvage chemotherapy;

   OR
   E. 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 (NCCN 2A);

OR

III. Individual has a diagnosis of CD30+ Non-Hodgkin Lymphoma; **AND**
IV. Individual is using for one of the following:
   A. Cutaneous anaplastic large cell lymphoma; **OR**
   B. Cutaneous T-cell lymphoma, including mycosis fungoides/Sézary syndrome, for the following:
      1. Relapsed or refractory disease; **OR**
      2. As first-line therapy for advanced disease presentation (for example,

Market Applicability							
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Applicable	X	X	X	X	X	X	X

folliculotropic, large-cell transformation or extracutaneous disease) (NCCN 2A);

OR

C. In combination with cyclophosphamide, doxorubicin, and prednisone, for previously untreated:
   1. Previously T-cell lymphoma (including systemic anaplastic large cell lymphoma); **OR**
   2. Adult T-cell leukemia/lymphoma (NCCN 2A); **OR**
   3. Hepatosplenic Gamma-Delta T-Cell Lymphoma (NCCN 2A);

OR

D. As a single agent for adult T-cell leukemia/lymphoma that has not responded to first-line therapy (NCCN 2A); **OR**

E. 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) (NCCN 2A); **OR**
   3. Lymphomatoid papulosis that is symptomatic or characterized by extensive cutaneous lesions (NCCN 2A);

OR

F. As an adjuvant systemic therapy for breast implant-associated naplastic large cell lymphoma for either of the following (NCCN 2A):
   1. Residual, localized disease (confined to capsule/implant/breast) following partial excision or capsulectomy; **OR**
   2. Extended disease (stage II–IV).

Requests for 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 John Cunningham (JC) virus infection resulting in progressive multifocal leukoencephalopathy (PML); death can occur in individuals receiving Adcetris.

Key References:

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2020. URL: http://www.clinicalpharmacology.com. Updated periodically.
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3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Horwitz S, O'Connor OA, Pro B, et al. Brentuximab vedotin with chemotherapy for CD30-positive peripheral T-cell lymphoma (ECHELON-2): a global, double-blind, randomised, phase 3 trial. Lancet. 2019;393(10168):229-240.
5. Herrera AF, Moskowitz AJ, Bartlett NL, et al. Interim results of brentuximab vedotin in combination with nivolumab in patients with relapsed or refractory Hodgkin lymphoma. Blood 2018; 131: 1183-1194. [NCT02572167]
6. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2020; Updated periodically.
7. NCCN Clinical Practice Guidelines in Oncology™. © 2019 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed April 2020.
    - B-Cell Lymphomas. V1.2020. Revised January 22, 2020.
    - Hodgkin Lymphoma. V2.2020. Revised April 17, 2020.
    - Primary Cutaneous Lymphomas. V2.2020. Revised April 10, 2020.
    - T-Cell Lymphomas. V1.2020. Revised January 6, 2020.