

## Adcetris® (brentuximab vedotin) (Intravenous)

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### I. Length of Authorization

Coverage will be provided for six months and may be renewed.

Treatment for cHL post-auto HSCT, primary cutaneous anaplastic large cell lymphoma (pcALCL), Mycosis Fungoides (MG)/Sezary Syndrome (SS) and Primary cutaneous CD30+ T-Cell Lymphoproliferative Disorders has a maximum of 16 cycles.

Treatment of previously untreated Stage III or IV classical Hodgkin Lymphoma (cHL) has a maximum of 12 doses.

Treatment of previously untreated Systemic Anaplastic Large Cell Lymphoma (sALCL) or other CD30-expressing Peripheral T-Cell Lymphomas (PTCL) has a maximum of 8 doses

Treatment of Breast-Implant Associated Anaplastic Large Cell Lymphoma (ALCL) has a maximum of 6 cycles as adjuvant therapy.

### II. Dosing Limits

#### A. Quantity Limit (max daily dose) [Pharmacy Benefit]:

- 50 mg vial: 4 vials per 21 days

#### B. Max Units (per dose and over time) [Medical Benefit]:

- 200 billable units per 21 days

### III. Initial Approval Criteria

Coverage is provided in the following conditions:

- Patient is 18 years or older; **AND**
- Patient is CD30-positive; **AND**

- Used as single agent therapy; **AND**
  - Patient is at high risk for relapse or progression as post-autologous hematopoietic stem cell transplant consolidation (auto-HSCT)†; **OR**
  - Patient with relapsed disease after failure of auto-HSCT or at least 2 prior multi-agent chemotherapy regimens who are not auto-HSCT candidates †; **OR**
  - Used as subsequent systemic therapy for relapsed or refractory disease‡; **OR**
  - Used as maintenance therapy following high-dose therapy and autologous stem cell rescue (HDT/ASCR) for relapsed or refractory disease with high risk for relapse‡; **OR**
- Used in combination with cytotoxic chemotherapy; **AND**
  - Used as subsequent systemic therapy for relapsed or refractory disease‡; **OR**
- Used in combination with doxorubicin, vinblastine, and dacarbazine; **AND**
  - Used as initial therapy for previously untreated Stage III or IV disease†

### Non-Hodgkin Lymphoma (NHL)

- Used as a single agent for relapsed or refractory disease as subsequent therapy for one of the following:
  - Systemic Anaplastic Large Cell Lymphoma (sALCL) †
  - Peripheral T-Cell Lymphoma (PTCL) ‡
  - Angioimmunoblastic T-cell Lymphoma (ATCL) ‡
- Used in combination with cyclophosphamide, doxorubicin, and prednisone as initial therapy for previous untreated:
  - Systemic Anaplastic Large Cell Lymphoma (sALCL) †
  - Peripheral T-Cell Lymphoma (PTCL) †
  - Angioimmunoblastic T-cell Lymphoma (ATCL) †
- Breast-Implant Associated Anaplastic Large Cell Lymphoma (ALCL) ‡; **AND**
  - Used as single agent for adjuvant therapy of localized disease to the capsule, implant or breast; **AND**
  - Patient had incomplete excision or partial capsulectomy with residual or extended disease
- Adult T-Cell Leukemia/Lymphoma ‡
  - Must be used as a single agent for acute disease or lymphoma; **AND**
    - Used second-line for non-responders to first-line therapy; **OR**
    - Subsequent therapy after high-dose therapy with autologous stem cell rescue (HDT/ASCR)
- Mycosis Fungoides (MF) †/Sezary Syndrome (SS) ‡
- Primary cutaneous CD30+ T-Cell Lymphoproliferative Disorders ‡
  - Used as a single agent; **AND**
    - Patient has primary cutaneous anaplastic large cell lymphoma (pcALCL) †; **OR**
    - Patient has cutaneous ALCL with regional nodes (excludes systemic ALCL); **OR**
    - Patient has lymphomatoid papulosis (LyP) relapsed or refractory to all treatment options

† FDA Approved Indication(s), ‡ Compendia Recommended Indication(s)

## IV. Renewal Criteria

Coverage can be renewed based on the following criteria:

- Patient continues to meet the criteria in section III; **AND**
- Disease response with treatment defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: progressive multifocal leukoencephalopathy, peripheral neuropathy, anaphylaxis and infusion reactions, hematologic toxicities (thrombocytopenia, neutropenia and anemia), serious infections, tumor lysis syndrome, increased toxicity in patients with severe renal (CrCl < 30 ml/min) and hepatic impairment (Child-Pugh B or C), hepatotoxicity, pulmonary toxicity, serious dermatologic reactions, gastrointestinal complications, etc.

## V. Dosage/Administration

Indication	Dose
Previously Untreated Stage III or IV Classical Hodgkin Lymphoma	1.2 mg/kg (up to 120 mg) by intravenous infusion every 2 weeks until a maximum of 12 doses, disease progression, or unacceptable toxicity
cHL post-auto HSCT, MF/SS, Primary cutaneous CD30+ T-Cell Lymphoproliferative Disorders	1.8 mg/kg (up to 180 mg) by intravenous infusion every 3 weeks until a maximum of 16 cycles, disease progression, or unacceptable toxicity
Previously Untreated sALCL or Other CD30-expressing PTCL	1.8 mg/kg (up to 180 mg) by intravenous infusion every 3 weeks with each cycle of chemotherapy for a maximum of 6 to 8 doses
Breast-Implant Associated Anaplastic Large Cell Lymphoma (ALCL)	1.8 mg/kg (up to 180 mg) by intravenous infusion every 3 weeks until a maximum of 6 cycles, disease progression, or unacceptable toxicity
All other indications	1.8 mg/kg (up to 180 mg) by intravenous infusion every 3 weeks until disease progression or unacceptable toxicity

## VI. Billing Code/Availability Information

Jcode:

J9042 - Injection, brentuximab vedotin, 1 mg; 1 billable unit = 1 mg

NDC:

Adcetris single-use vial; 50 mg powder for injection: 51144-0050-xx

## VII. References

1. Adcetris [package insert]. Bothell, WA; Seattle Genetics, Inc; March 2018. Accessed November 2018.

2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for brentuximab vedotin. National Comprehensive Cancer Network, 2018. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed November 2018.
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) T-Cell Lymphomas. Version 5.2018. National Comprehensive Cancer Network, 2018. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed November 2018.
4. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Hodgkin Lymphoma. Version 3.2018. National Comprehensive Cancer Network, 2017. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed November 2018.
5. Duvoc M, Tetzlaff MT, Gangar P, et al. Results of a Phase II trial of brentuximab vedotin for CD20+ cutaneous T-cell lymphoma and lymphomatoid papulosis. J Clin Oncol 2015; 33:3759-65.
6. Horwitz SM, Advani RH, Bartlett NL, et al. Objective responses in relapsed T-cell lymphomas with single-agent brentuximab vedotin. Blood 2014;123:3095-3100.
7. Alderuccio, JP., Desai, A., Yepes, M.M., et al. Frontline brentuximab vedotin in breast implant-associated anaplastic large-cell lymphoma. Clin Case Rep 2018; 6(4): 634-637. doi:10.1002/ccr3.1382

## Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C81.10	Nodular sclerosis Hodgkin lymphoma, unspecified site
C81.11	Nodular sclerosis Hodgkin lymphoma, lymph nodes of head, face, and neck
C81.12	Nodular sclerosis Hodgkin lymphoma, intrathoracic lymph nodes
C81.13	Nodular sclerosis Hodgkin lymphoma, intra-abdominal lymph nodes
C81.14	Nodular sclerosis Hodgkin lymphoma, lymph nodes of axilla and upper limb
C81.15	Nodular sclerosis Hodgkin lymphoma, lymph nodes of inguinal region and lower limb
C81.16	Nodular sclerosis Hodgkin lymphoma, intrapelvic lymph nodes

ICD-10	ICD-10 Description
C81.17	Nodular sclerosis Hodgkin lymphoma, spleen
C81.18	Nodular sclerosis Hodgkin lymphoma, lymph nodes of multiple sites
C81.19	Nodular sclerosis Hodgkin lymphoma, extranodal and solid organ sites
C81.20	Mixed cellularity Hodgkin lymphoma, unspecified site
C81.21	Mixed cellularity Hodgkin lymphoma, lymph nodes of head, face, and neck
C81.22	Mixed cellularity Hodgkin lymphoma, intrathoracic lymph nodes
C81.23	Mixed cellularity Hodgkin lymphoma, intra-abdominal lymph nodes
C81.24	Mixed cellularity Hodgkin lymphoma, lymph nodes of axilla and upper limb
C81.25	Mixed cellularity Hodgkin lymphoma, lymph nodes of inguinal region and lower limb
C81.26	Mixed cellularity Hodgkin lymphoma, intrapelvic lymph nodes
C81.27	Mixed cellularity Hodgkin lymphoma, spleen
C81.28	Mixed cellularity Hodgkin lymphoma, lymph nodes of multiple sites
C81.29	Mixed cellularity Hodgkin lymphoma, extranodal and solid organ sites
C81.30	Lymphocyte depleted Hodgkin lymphoma, unspecified site
C81.31	Lymphocyte depleted Hodgkin lymphoma, lymph nodes of head, face, and neck
C81.32	Lymphocyte depleted Hodgkin lymphoma, intrathoracic lymph nodes
C81.33	Lymphocyte depleted Hodgkin lymphoma, intra-abdominal lymph nodes
C81.34	Lymphocyte depleted Hodgkin lymphoma, lymph nodes of axilla and upper limb
C81.35	Lymphocyte depleted Hodgkin lymphoma, lymph nodes of inguinal region and lower limb
C81.36	Lymphocyte depleted Hodgkin lymphoma, intrapelvic lymph nodes
C81.37	Lymphocyte depleted Hodgkin lymphoma, spleen
C81.38	Lymphocyte depleted Hodgkin lymphoma, lymph nodes of multiple sites
C81.39	Lymphocyte depleted Hodgkin lymphoma, extranodal and solid organ sites
C81.40	Lymphocyte-rich Hodgkin lymphoma, unspecified site
C81.41	Lymphocyte-rich Hodgkin lymphoma, lymph nodes of head, face, and neck
C81.42	Lymphocyte-rich Hodgkin lymphoma, intrathoracic lymph nodes
C81.43	Lymphocyte-rich Hodgkin lymphoma, intra-abdominal lymph nodes
C81.44	Lymphocyte-rich Hodgkin lymphoma, lymph nodes of axilla and upper limb
C81.45	Lymphocyte-rich Hodgkin lymphoma, lymph nodes of inguinal region and lower limb
C81.46	Lymphocyte-rich Hodgkin lymphoma, intrapelvic lymph nodes
C81.47	Lymphocyte-rich Hodgkin lymphoma, spleen
C81.48	Lymphocyte-rich Hodgkin lymphoma, lymph nodes of multiple sites
C81.49	Lymphocyte-rich Hodgkin lymphoma, extranodal and solid organ sites
C81.70	Other Hodgkin lymphoma unspecified site
C81.71	Other Hodgkin lymphoma lymph nodes of head, face, and neck

ICD-10	ICD-10 Description
C81.72	Other Hodgkin lymphoma intrathoracic lymph nodes
C81.73	Other Hodgkin lymphoma intra-abdominal lymph nodes
C81.74	Other Hodgkin lymphoma lymph nodes of axilla and upper limb
C81.75	Other Hodgkin lymphoma lymph nodes of inguinal region and lower limb
C81.76	Other Hodgkin lymphoma intrapelvic lymph nodes
C81.77	Other Hodgkin lymphoma spleen
C81.78	Other Hodgkin lymphoma lymph nodes of multiple sites
C81.79	Other Hodgkin lymphoma extranodal and solid organ sites
C81.90	Hodgkin lymphoma, unspecified, unspecified site
C81.91	Hodgkin lymphoma, unspecified, lymph nodes of head, face and neck
C81.92	Hodgkin lymphoma, unspecified, intrathoracic lymph nodes
C81.93	Hodgkin lymphoma, unspecified, intra-abdominal lymph nodes
C81.94	Hodgkin lymphoma, unspecified, lymph nodes of axilla and upper limb
C81.95	Hodgkin lymphoma, unspecified, lymph nodes of inguinal region and lower limb
C81.96	Hodgkin lymphoma, unspecified, intrapelvic lymph nodes
C81.97	Hodgkin lymphoma, unspecified, spleen
C81.98	Hodgkin lymphoma, unspecified, lymph nodes of multiple sites
C81.99	Hodgkin lymphoma, unspecified, extranodal and solid organ sites
C84.00	Mycosis fungoides, unspecified site
C84.01	Mycosis fungoides, lymph nodes of head, face and neck
C84.02	Mycosis fungoides, intrathoracic lymph nodes
C84.03	Mycosis fungoides, intra-abdominal lymph nodes
C84.04	Mycosis fungoides, lymph nodes of axilla and upper limb
C84.05	Mycosis fungoides, lymph nodes of inguinal region and lower limb
C84.06	Mycosis fungoides, intrapelvic lymph nodes
C84.07	Mycosis fungoides, spleen
C84.08	Mycosis fungoides, lymph nodes of multiple sites
C84.09	Mycosis fungoides, extranodal and solid organ sites
C84.10	Sézary disease, unspecified site
C84.11	Sézary disease, lymph nodes of head, face, and neck
C84.12	Sézary disease, intrathoracic lymph nodes
C84.13	Sézary disease, intra-abdominal lymph nodes
C84.14	Sézary disease, lymph nodes of axilla and upper limb
C84.15	Sézary disease, lymph nodes of inguinal region and lower limb

ICD-10	ICD-10 Description
C84.16	Sézary disease, intrapelvic lymph nodes
C84.17	Sézary disease, spleen
C84.18	Sézary disease, lymph nodes of multiple sites
C84.19	Sézary disease, extranodal and solid organ sites
C84.40	Peripheral T-cell lymphoma, not classified, unspecified site
C84.41	Peripheral T-cell lymphoma, not classified, lymph nodes of head, face and neck
C84.42	Peripheral T-cell lymphoma, not classified, intrathoracic lymph nodes
C84.43	Peripheral T-cell lymphoma, not classified, intra-abdominal lymph nodes
C84.44	Peripheral T-cell lymphoma, not classified, lymph nodes of axilla and upper limb
C84.45	Peripheral T-cell lymphoma, not classified, lymph nodes of inguinal region of lower limb
C84.46	Peripheral T-cell lymphoma, not classified, intrapelvic lymph nodes
C84.47	Peripheral T-cell lymphoma, not classified, spleen
C84.48	Peripheral T-cell lymphoma, not classified, lymph nodes of multiple sites
C84.49	Peripheral T-cell lymphoma, not classified, extranodal and solid organ sites
C84.60	Anaplastic large cell lymphoma, ALK-positive, unspecified site
C84.61	Anaplastic large cell lymphoma, ALK-positive, lymph nodes of head, face and neck
C84.62	Anaplastic large cell lymphoma, ALK-positive, intrathoracic lymph nodes
C84.63	Anaplastic large cell lymphoma, ALK-positive, intra-abdominal lymph nodes
C84.64	Anaplastic large cell lymphoma, ALK-positive, lymph nodes of axilla and upper limb
C84.65	Anaplastic large cell lymphoma, ALK-positive, lymph nodes of inguinal region and lower limb
C84.66	Anaplastic large cell lymphoma, ALK-positive, intrapelvic lymph nodes
C84.67	Anaplastic large cell lymphoma, ALK-positive, spleen
C84.68	Anaplastic large cell lymphoma, ALK-positive, lymph nodes of multiple sites
C84.69	Anaplastic large cell lymphoma, ALK-positive, extranodal and solid organ sites
C84.70	Anaplastic large cell lymphoma, ALK-negative, unspecified site
C84.71	Anaplastic large cell lymphoma, ALK-negative, lymph nodes of head, face and neck
C84.72	Anaplastic large cell lymphoma, ALK-negative, intrathoracic lymph nodes
C84.73	Anaplastic large cell lymphoma, ALK-negative, intra-abdominal lymph nodes
C84.73	Anaplastic large cell lymphoma, ALK-negative, lymph nodes of axilla and upper limb
C84.75	Anaplastic large cell lymphoma, ALK-negative, lymph nodes of inguinal region and lower limb
C84.76	Anaplastic large cell lymphoma, ALK-negative, intrapelvic lymph nodes
C84.77	Anaplastic large cell lymphoma, ALK-negative, spleen
C84.78	Anaplastic large cell lymphoma, ALK-negative, lymph nodes of multiple sites
C84.79	Anaplastic large cell lymphoma, ALK-negative, extranodal and solid organ sites

ICD-10	ICD-10 Description
C86.5	Angioimmunoblastic T-cell lymphoma
C86.6	Primary cutaneous CD30-positive T-cell proliferations
C91.50	Adult T-cell lymphoma/leukemia (HTLV-1-associated) not having achieved remission
C91.52	Adult T-cell lymphoma/leukemia (HTLV-1-associated) in relapse
Z85.71	Personal history of Hodgkin lymphoma
Z85.72	Personal history of non-Hodgkin lymphomas

## Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: <http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC