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Clinical Policy: Brentuximab Vedotin (Adcetris)

Reference Number: LA.PHAR.303 Effective Date: 07.23.22 Last Review Date: 05.13.24 06.02.23 Line of Business: Medicaid

Coding Implications Revision Log

See <u>Important Reminder</u> at the end of this policy for important regulatory and legal information.

Description

Brentuximab vedotin for injection (Adcetris®) is a CD30-directed antibody-drug conjugate.

Please note: This policy is for medical benefit

FDA Approved Indication(s)

Adcetris is indicated for the treatment of adult patients with:

- <u>Classical Hodgkin lymphoma:</u>
 - Previously untreated Stage III or IV classical Hodgkin lymphoma (cHL), in combination with doxorubicin, vinblastine, and dacarbazine
 - cHL at high risk of relapse or progression as post-autologous hematopoietic stem cell transplantation (auto-HSCT) consolidation
 - cHL after failure of auto-HSCT or after failure of at least two prior multi-agent chemotherapy regimens in patients who are not auto-HSCT candidates
- T-cell lymphomas:
 - Previously untreated systemic anaplastic large cell lymphoma (sALCL) or other CD30expressing peripheral T-cell lymphomas (PTCL), including angioimmunoblastic T-cell lymphoma and PTCL not otherwise specified, in combination with cyclophosphamide, doxorubicin, and prednisone
- o sALCL after failure of at least one prior multiagent chemotherapy regimen
- Primary cutaneous lymphomas:
 - Primary cutaneous anaplastic large cell lymphoma (pcALCL) or CD30-expressing mycosis fungoides (MF) who have received prior systemic therapy

Adcetris is indicated for the treatment of pediatric patients 2 years old and older with:

- <u>Classical Hodgkin lymphoma:</u>
 - Previously untreated high risk classical Hodgkin lymphoma<u>cHL</u>, in combination with doxorubicin, vincristine, etoposide, prednisone, and cyclophosphamide

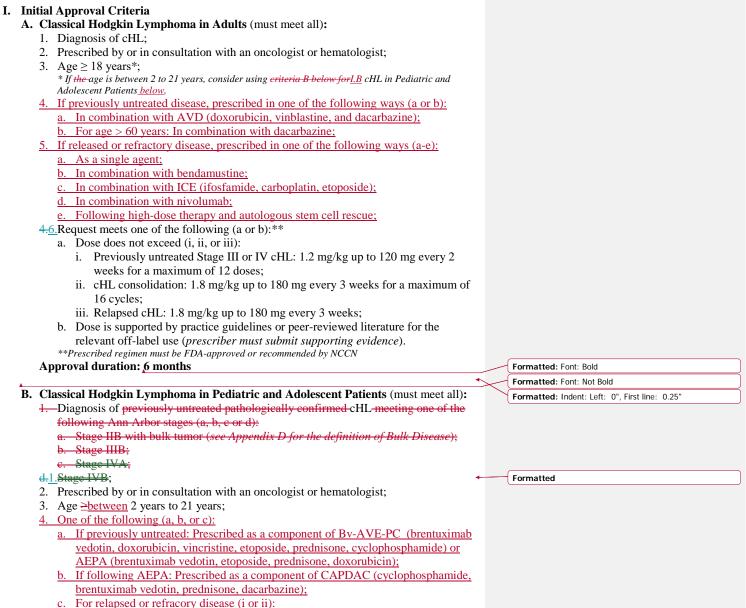
Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of Louisiana HealthCare Connections[®] that Adcetris is **medically necessary** when the following criteria are met:

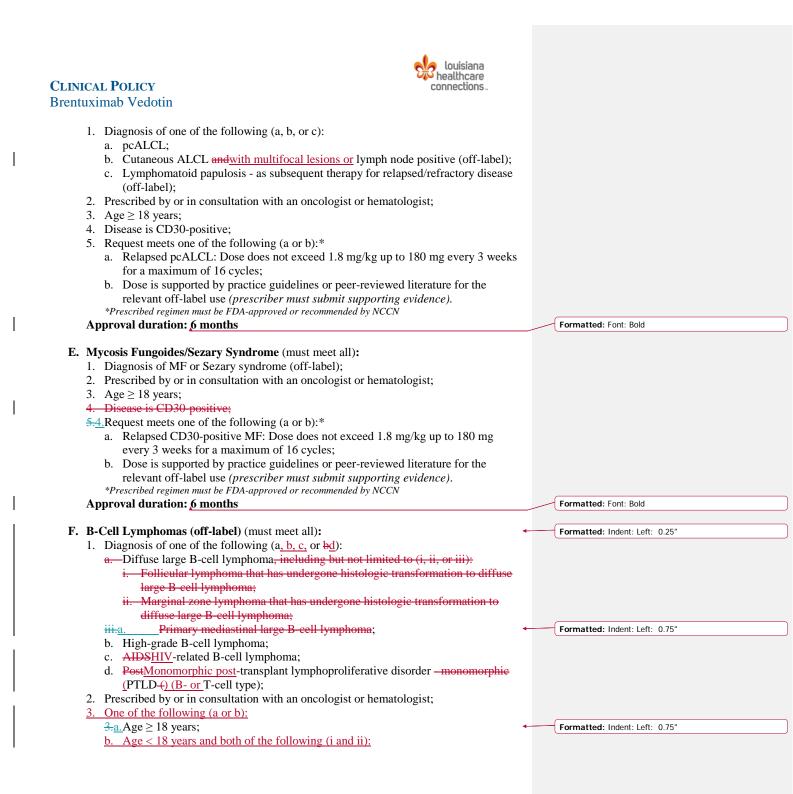
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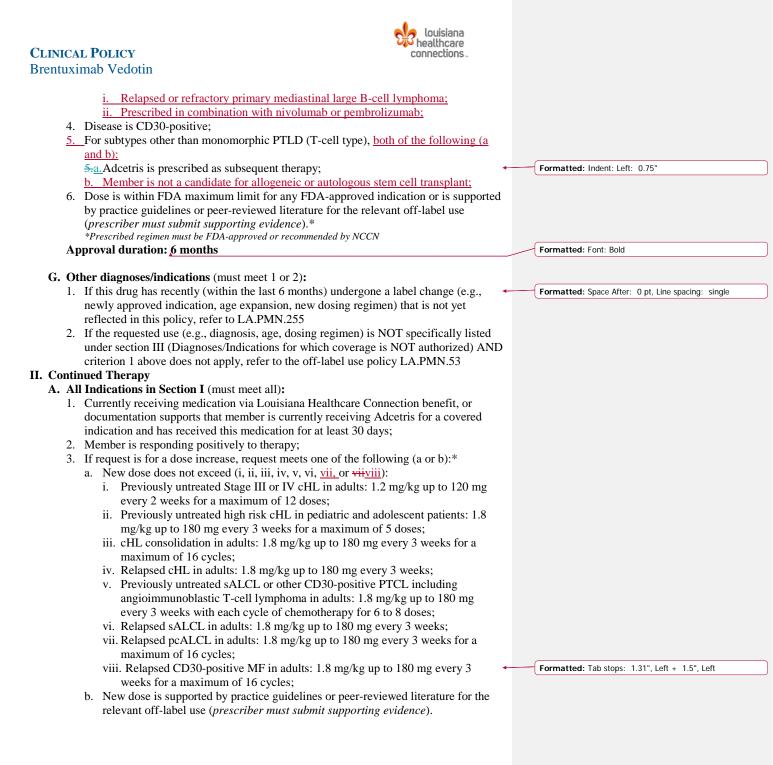


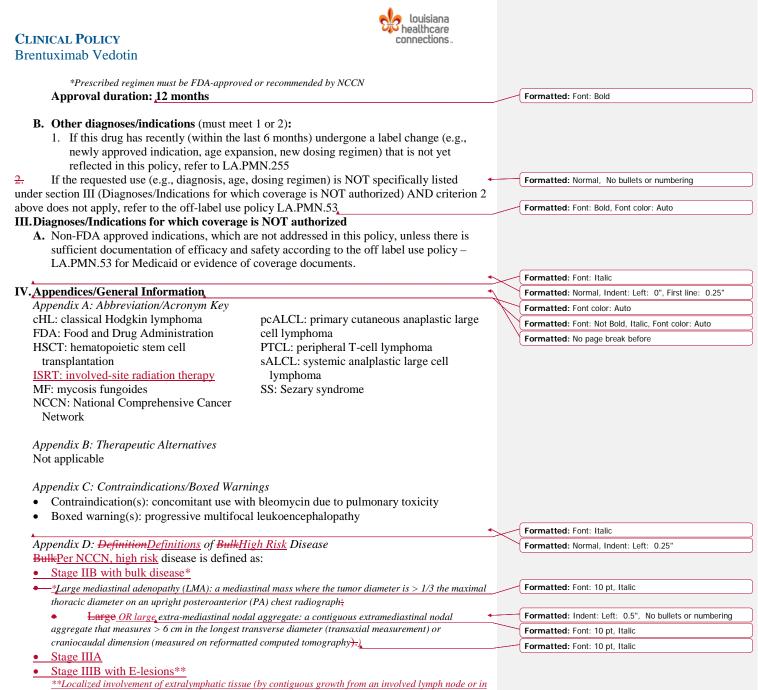
CLINICAL POLICY CONNECT	iana care
Brentuximab Vedotin	duns
Brentuxiniab vedotni	
i. Prescribed in combination with involved-site radiation therapy (ISI	RT) or
bendamustine/nivolumab/gemcitabine;	
ii. Prescribed following high-dose therapy and autologous stem cell re	escue;
5. For all requests except when prescribed in combination with ISRT or	
bendamustine/nivolumab/gemcitabine: Disease is classified as high risk (s	<u>ee</u>
<u>Appendix D);</u>	
4.6. Request meets one of the following (a or b):*a. Dose does not exceed: 1.8 mg/kg up to 180 mg every 3 weeks for a ma	winum of
5 doses;	
b. Dose is supported by practice guidelines or peer-reviewed literature fo	r the
relevant off-label use (<i>prescriber must submit supporting evidence</i>).	
*Prescribed regimen must be FDA-approved or recommended by NCCN	
Approval duration: <u>6 months</u>	Formatted: Font: Bold
C. T-Cell Lymphomas (must meet all):	
 Diagnosis of one of the following (a, b, c, d, or e): a. PTCL - any of the following subtypes/histologies (i or ii): 	
i. sALCL:	
 SALCE; PTCL, including but not limited to the following (a, b, c, d<u>1, 2, 3, 4</u>) 	1 or =5):
a) Angioimmunoblastic T-cell lymphoma;	+, OI e_).
b)2) Enteropathy-associated T-cell lymphoma;	Formatted. Builds and Multipernig
(a) Monomorphic epitheliotropic intestinal T-cell lymphon	19.
$\frac{d}{d}$ Nodal PTCL with TFH phenotype;	14,
e)5) Follicular T-cell lymphoma;	
b. Breast implant-associated ALCL (off-label);	
c. Adult T-cell leukemia/lymphoma (off-label);	
d. Relapsed or refractory Extranodalextranodal NK/T-cell lymphoma (of	f-label);
e. Hepatosplenic T-cell lymphoma after failure of two first-line therapy r	regimens
(off-label);	
2. Prescribed by or in consultation with an oncologist or hematologist;	
3. Age ≥ 18 years;	
4. For all requests except ALCL: Disease is CD30-positive;	
5. Prescribed as a single agent or in combination with CHP (cyclophosphami	ide,
doxorubicin, prednisone);	Environte de Duillete and Numberion
 5-6.Request meets one of the following (a, b, or c):* a. Previously untreated sALCL or other CD30-positive PTCL including 	Formatted: Bullets and Numbering
angioimmunoblastic T-cell lymphoma: Dose does not exceed 1.8 mg/k	ra up to 180
mg every 3 weeks with each cycle of chemotherapy for 6 to 8 doses;	tg up to 100
b. Relapsed sALCL: Dose does not exceed 1.8 mg/kg up to 180 mg every	v 3 weeks
c. Dose is supported by practice guidelines or peer-reviewed literature fo	
relevant off-label use (<i>prescriber must submit supporting evidence</i>).	
*Prescribed regimen must be FDA-approved or recommended by NCCN	
Approval duration: 6 months	

D. Primary Cutaneous CD30+ T-Cell Lymphoproliferative Disorders (must meet all):



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close anatomic relation) that is treatable by irradiation



• Stage IV

Per the Adcetris pediatric cHL pivotal study, high risk was defined as the following Ann Arbor stages:

- Stage IIB with bulk disease (see definition of bulk disease above)
- Stage IIIB
- <u>Stage IVA</u>
- <u>Stage IVB</u>

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V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Previously	1.2 mg/kg IV up to a maximum of 120 mg in	120 mg every
untreated Stage III	combination with chemotherapy. Administer every 2	2 weeks up to
or IV cHL in	weeks until a maximum of 12 doses, disease	12 doses
adults	progression, or unacceptable toxicity.	
Previously	1.8 mg/kg IV up to a maximum of 180 mg in	180 mg every
untreated high risk	combination with chemotherapy. Administer every 3	3 weeks up to
cHL in pediatric	weeks with each cycle of chemotherapy for a	5 doses
and adolescent	maximum of 5 doses, disease progression, or	
patients	unacceptable toxicity.	
cHL consolidation	1.8 mg/kg IV up to a maximum of 180 mg. Initiate	180 mg every
<u>in adults</u>	Adcetris treatment within 4-6 weeks post-autoHSCT	3 weeks up to
	or upon recovery from auto-HSCT. Administer every	16 cycles
	3 weeks until a maximum of 16 cycles, disease	
	progression, or unacceptable toxicity.	
Relapsed cHL in	1.8 mg/kg IV up to a maximum of 180 mg.	180 mg every
adults	Administer every 3 weeks until disease progression or unacceptable toxicity.	3 weeks
Previously	1.8 mg/kg IV up to a maximum of 180 mg in	180 mg every
untreated sALCL	combination with cyclophosphamide, doxorubicin,	3 weeks up to
or other CD30-	and prednisone. Administer every 3 weeks with each	6 to 8 doses
expressing PTCLs	cycle of chemotherapy for 6 to 8 doses.	
<u>in adults</u>		
Relapsed sALCL	1.8 mg/kg IV up to a maximum of 180 mg.	180 mg every
in adults	Administer every 3 weeks until disease progression or unacceptable toxicity.	3 weeks
Relapsed pcALCL	1.8 mg/kg IV up to a maximum of 180 mg.	180 mg every
or CD30-	Administer every 3 weeks until a maximum of 16	3 weeks up to
expressing MF in adults	cycles, disease progression, or unacceptable toxicity.	16 cycles

VI. Product Availability

Single-use vial: 50 mg for reconstitution

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VII. References

- Adcetris Prescribing Information. Bothell, WA: Seagen, Inc.; November 2022. Available at: http://adcetrisupdate.com/. Accessed <u>November 30, 2022May 17, 2023</u>.
- 2. Castellino, SM, et al. Brentuximab vedotin with chemotherapy in pediatric high-risk Hodgkin's lymphoma. New Engl J Med 2022; 387(18):1649-1660.
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- National Comprehensive Cancer Network. Hodgkin Lymphoma Version 2.20222023. Available at https://www.nccn.org/professionals/physician_gls/pdf/hodgkins.pdf. Accessed May 2, 202217, 2023.
- National Comprehensive Cancer Network.Pediatric Hodgkin Lymphoma Version <u>1.20222.2023</u>. Available at: https://www.nccn.org/professionals/physician_gls/pdf/ped_hodgkin.pdf. Accessed May 2, <u>202217</u>, 2023.
- National Comprehensive Cancer Network. Primary Cutaneous Lymphomas Version 1.20222023. Available at
- https://www.nccn.org/professionals/physician_gls/pdf/primary_cutaneous.pdf. Accessed May 2, 202217, 2023.
- National Comprehensive Cancer Network. T-Cell Lymphomas Version <u>2.20221.2023</u>. Available at https://www.nccn.org/professionals/physician_gls/pdf/t-cell.pdf. Accessed May <u>2,202217, 2023</u>.
- 8. National Comprehensive Cancer Network. B-Cell Lymphomas Version 3.20222023. Available at https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf. Accessed May 2,202217,2023.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for

reimbursement of covered services.				
HCPCS	Description			
Codes				
J9042	Injection, brentuximab vedotin, 1 mg			

Reviews, Revisions, and Approvals	Date	LDH Approval Date
Converted corporate to local policy	04.22	07.23.22
Per NCCN Compendium clarified extranodal NK/T-cell lymphoma should be in the relapsed or refractory setting and removed requirement for nasal type; clarified hepatosplenic T-cell lymphoma should be after two first-line therapy regimens; references reviewed and updated.	06.02.23	<u>10.05.23</u>

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Reviews, Revisions, and Approvals Date LDH Approval Date New indication of previously untreated high risk cHL in pediatric and adolescent patients added to policy. Template changes applied to other diagnoses/indications and continued therapy section. Annual review: for adult cHL, added specific regimens for use per 05.13.24 both FDA and NCCN; for pediatric cHL, moved specific staging requirements for high risk disease to Appendix D to also allow for NCCN high risk definition and updated criteria per NCCN, including requirements for use in combination with chemotherapy as well as allowance for use as subsequent therapy; for T-cell lymphomas, clarified that CD30-positive disease requirement does not apply to ALCL and added requirement for use as a single agent or in combination with CHP per NCCN: for cutaneous ALCL, added pathway for disease multifocal lesions per NCCN; for MF/SS, removed requirement for CD30-positive disease per NCCN: for Bcell lymphomas, removed specific subtypes of DLBCL to simplify criteria, revised "AIDS-related" to "HIV-related", added B-cell type monomorphic PTLD, added pathway for pediatric primary mediastinal large B-cell lymphoma, and added that member is not a transplant candidate for all requests except T-cell type monomorphic PTLD per NCCN; references reviewed and updated.

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. LHCC makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable LHCC administrative policies and procedures.



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