

Lumoxiti™ (moxetumomab pasudotox-tdfk) (Intravenous)

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I. Length of Authorization

Coverage is provided for six months (6 cycles) and may not be renewed.

II. Dosing Limits

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

- Lumoxiti 1 mg SDV: 15 vials per 28 day cycle

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

- 5 mg on days 1, 3 and 5 of a 28-day cycle

III. Initial Approval Criteria

Coverage is provided in the following conditions:

- Patient is at least 18 years or older; **AND**
- Patient is pseudomonas-immunotoxin naïve (e.g., moxetumomab pasudotox, etc.); **AND**
- Patient does not have severe renal impairment defined as $\text{CrCl} \leq 29$ mL/min; **AND**

Hairy Cell Leukemia (HCL) †

- Patient has a confirmed diagnosis of Hairy Cell Leukemia or a HCL variant; **AND**
- Patient must have relapsed or refractory disease; **AND**
- Patient has previously failed at least TWO prior systemic therapies as one of the following:
 - Failure to two courses of purine analog therapy (e.g., cladribine, pentostatin, etc.); **OR**
 - Failure to at least one purine analog therapy **AND** one course of rituximab or a BRAF-inhibitor (e.g., vemurafenib, etc.)

† FDA Approved Indication(s); ‡ Compendia recommended indication(s)

IV. Renewal Criteria

V. Dosage/Administration

Indication	Dose
Hairy Cell Leukemia (HCL)	Infuse 0.04 mg/kg intravenously on days 1, 3, and 5 of a 28-day cycle. Continue Lumoxiti for a maximum of 6 cycles or until disease progression or unacceptable toxicity.

VI. Billing Code/Availability Information

Jcode:

- J9999: Not otherwise classified, antineoplastic drugs.

NDC:

- Lumoxiti 1 mg single-dose vial: 00310-4700-xx
 - IV solution stabilizer for use during administration: 00310-4715-xx

VII. References

1. Lumoxiti [package insert]. Wilmington, DE; Astra Zeneca Pharmaceuticals; September 2018. Accessed September 2018.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for moxetumomab pasudotox. 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 September 2018.
3. Kreitman RJ, Dearden C, Zingani PL, et al. Moxetumomab pasudotox in relapsed/refractory hairy cell leukemia. *Leukemia*. 2018; 32(8): 1768–1777.
4. Robbins BA, Ellison DJ, Spinosa JC, et al. Diagnostic application of two-color flow cytometry in 161 cases of hairy cell leukemia. *Blood* 1993;82:1277-1287.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C91.40	Hairy cell leukemia not having achieved remission
C91.42	Hairy cell leukemia, in relapse

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 Government Benefit Administrators, 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