

Coverage of any drug intervention discussed in the plans prior authorization guideline is subject to the limitations and exclusions outlined in the member's benefit certificate or policy and to applicable state and/or federal laws.

Lumoxiti™ (moxetumomab pasudotox-tdfk) (Intravenous)

Document Number: IC-0393

Last Review Date: 07/20/2022

Date of Origin: 10/02/2018

Dates Reviewed: 10/2018, 11/2019, 11/2020, 11/2021, 07/2022

Effective Date: 01/01/2023

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) [NDC Unit]:

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

B. Max Units (per dose and over time) [HCPCS Unit]:

- 500 billable units on days 1, 3 and 5 of a 28-day cycle

III. Initial Approval Criteria ^{1,3}

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**
- Patient does not have severe renal impairment defined as $CrCl \leq 29$ mL/min; **AND**
- Patient does not have prior history of severe thrombotic microangiopathy (TMA) or hemolytic uremic syndrome (HUS); **AND**
- Must be used as a single agent; **AND**

Hairy Cell Leukemia (HCL) † Φ ¹⁻⁴

- 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, including at least one purine analog (e.g., cladribine, pentostatin, etc.)

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

IV. Renewal Criteria

Coverage cannot be renewed.

V. Dosage/Administration

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

VI. Billing Code/Availability Information

HCPCS Code:

- J9313 – Injection, moxetumomab pasudotox-tdfk, 0.01 mg; 1 billable unit = 0.01 mg

NDC:

- Lumoxiti 1 mg single-dose vial: 00310-4700-xx
 - IV solution stabilizer for use during administration: 73380-4715-xx

VII. References

1. Lumoxiti [package insert]. Rockville, MD; Innate Pharma; April 2020. Accessed September 2021.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for moxetumomab pasudotox. National Comprehensive Cancer Network, 2021. 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 2021.
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.
5. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Hairy Cell Leukemia. Version 1.2022. National Comprehensive Cancer Network, 2021. 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 2021.

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), Local Coverage Articles (LCAs), and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: <https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCA/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