Lumoxiti™ (moxetumomab pasudotox-tdfk)
(Intravenous)

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I. Length of Authorization [1]

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

II. Dosing Limits

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

- 1500 billable units every 28 days

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 ≤ 29 mL/min; **AND**
- Patient does not have prior history of severe thrombotic microangiopathy (TMA) or hemolytic uremic syndrome (HUS); **AND**
- Used as a single agent; **AND**

Hairy Cell Leukemia (HCL) † Φ [1-5]

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

Preferred therapies and recommendations are determined by review of clinical evidence. NCCN category of recommendation is taken into account as a component of this review. Regimens deemed equally efficacious (i.e., those having the same NCCN categorization) are considered to be therapeutically equivalent.

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

IV. Renewal Criteria [1]

Duration of authorization has not been exceeded *(refer to Section I)*.

V. Dosage/Administration [1]

Indication	Dose
Hairy Cell Leukemia	Administer 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: 00310-4715-xx

VII. References (STANDARD)

1. Lumoxiti [package insert]. Wilmington, DE; AstraZeneca; February 2022. Accessed October 2023.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for moxetumomab pasudotox. National Comprehensive Cancer Network, 2023. 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 October 2023.
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 Clinical Practice Guidelines in Oncology (NCCN Guidelines®) Hairy Cell Leukemia, Version 1.2025. National Comprehensive Cancer Network,

2023. 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 2024.

VIII. References (ENHANCED)

1e. Chihara D, Kantarjian H, O'Brien S, et al. Long-term durable remission by cladribine followed by rituximab in patients with hairy cell leukaemia: update of a phase II trial. Br J Haematol. 2016;174(5):760–766.

2e. Else M, Dearden CE, Matutes E, et al. Rituximab with pentostatin or cladribine: an effective combination treatment for hairy cell leukemia after disease recurrence. Leuk Lymphoma. 2011 Jun;52 Suppl 2:75-8.

3e. Nieva J, Bethel K, Saven A. Phase 2 study of rituximab in the treatment of cladribine-failed patients with hairy cell leukemia. Blood. 2003 Aug 1;102(3):810-3.

4e. Zenhäusern R, Simcock M, Gratwohl A, et al. Rituximab in patients with hairy cell leukemia relapsing after treatment with 2-chlorodeoxyadenosine (SAKK 31/98). Haematologica. 2008 Sep;93(9):1426-8.

5e. Goodman GR, Burian C, Koziol JA, Saven A. Extended follow-up of patients with hairy cell leukemia after treatment with cladribine. J Clin Oncol. 2003 Mar 1;21(5):891-6.

6e. Jones J, Andritsos L, Kreitman RJ, et al. Efficacy and Safety of the Bruton Tyrosine Kinase Inhibitor Ibrutinib in Patients with Hairy Cell Leukemia: Stage 1 Results of a Phase 2 Study. Blood. 2016;128:1215.

7e. Park JH, Lee JO, Stone RM, et al. Acquired Resistance to BRAF Inhibition in Hcl Is Rare and Retreatment with Vemurafenib at Relapse Can Induce High Response Rates: Final Results of a Phase II Trial of Vemurafenib in Relapsed Hcl. Blood. 2018;132:392.

8e. Tiacci E, De Carolis L, Zaja F, et al. The Chemotherapy-Free Combination of Vemurafenib and Rituximab Produces Deep and Durable Responses in Relapsed or Refractory Hairy Cell Leukemia (HCL) Patients. Blood. 2017;130:409.

9e. Kreitman RJ, Moreau P, Farhad Ravandi, et al. Dabrafenib plus trametinib in patients with relapsed/refractory *BRAF* V600E mutation–positive hairy cell leukemia. 2022;141(9):996-1006. doi:https://doi.org/10.1182/blood.2021013658

10e. Prime Therapeutics Management. Lumoxiti Clinical Literature Review Analysis. Last updated November 2024. Accessed November 2024.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C91.40	Hairy cell leukemia not having achieved remission

ICD-10	ICD-10 Description
C91.42	Hairy cell leukemia, in relapse

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

The preceding information is intended for non-Medicare coverage determinations. 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 Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied 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 GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
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