

Lumoxiti[™] (moxetumomab pasudotox-tdfk) (Intravenous)

Document Number: IC-0393

Last Review Date: 10/24/2022

Date of Origin: 10/02/2018

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

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 single-dose vial: 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**
- 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, 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 ¹

Coverage cannot be renewed.

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

1. Lumoxiti [package insert]. Wilmington, DE; AstraZeneca; February 2022. Accessed September 2022.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for moxetumomab pasudotox. National Comprehensive Cancer Network, 2022. 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 2022.
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 1.2023. National Comprehensive Cancer Network, 2022. 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 2022.

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

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PCHP:

Provides free aids and services to people with disabilities to communicate effectively with us, such as:

- Qualified sign language interpreters
- Written information in other formats (large print, audio, accessible electronic formats, other formats)

Provides free language services to people whose primary language is not English, such as:

- Qualified interpreters
- Information written in other languages

If you need these services, contact a Grievance Specialist.

If you believe that PCHP has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:

Grievance Specialist
PreferredOne Community Health Plan
PO Box 59052
Minneapolis, MN 55459-0052
Phone: 1.800.940.5049 (TTY: 763.847.4013)
Fax: 763.847.4010
customerservice@preferredone.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, a Grievance Specialist is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>.

Language Assistance Services

ATTENTION: If you do not speak English, language assistance services, free of charge, are available to you. Call 1.800.940.5049 (TTY: 763.847.4013).

ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 1.800.940.5049 (TTY: 763.847.4013).

LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 1.800.940.5049 (TTY: 763.847.4013).

XIYYEEFFANNAA: Afaan dubbattu Oroomiffa, taiaailla qargaarsa afaanii, kanfaltiidhaan ala, ni argama. Bilbilaa 1.800.940.5049 (TTY: 763.847.4013).

CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 1.800.940.5049 (TTY: 763.847.4013).

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1.800.940.5049 (TTY: 763.847.4013).

ማስታወሻ: የሚናገሩት ቋንቋ አማርኛ ከሆነ የትርጉም እርዳታ ድርጅቶች፣ በነጻ ሊያግዝዎት ተዘጋጅተዋል፡ ወደ ሚከተለው ቁጥር ይደውሉ 1.800.940.5049 (መስማት ለተሳናቸው፡ 763.847.4013) .

ဟ်သုဉ်ဟ်သး- နမၢ်ကတိၤ ကသီၤ ကျိာ်အယံၤ, နမၢ်နီၤ ကျိာ်အတၢ်မၤစၢၤလၢ တလၢာ်ဘၣ်လၢာ်စၢၤ နီၤတမံၤဘၣ်သန့လီၤ. ကိး 1.800.940.5049 (TTY: 763.847.4013).

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Minneapolis, MN 55459-0212
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U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
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