



Lumoxiti™ (moxetumomab pasudotox-tdfk) (Intravenous)

Document Number: IC-0393

Last Review Date: 10/28/2019

Date of Origin: 10/02/2018

Dates Reviewed: 10/2018, 11/2019

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]:

- 500 billable units 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 CrCl \leq 29 mL/min; **AND**
- Must be used as a single agent; **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 consisting of 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

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

Jcode:

- 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; Astra Zeneca Pharmaceuticals; January 2019. Accessed September 2019.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for moxetumomab pasudotox. National Comprehensive Cancer Network, 2019. 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 2019.
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 |