Clinical Policy: Moxetumomab Pasudotox-tdfk (Lumoxiti)

Reference Number: LA.PHAR.398
Effective Date: 03.16.23
Last Review Date: 01.21.25
Line of Business: Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

****Please note: This policy is for medical benefit****

Description

Moxetumomab pasudotox-tdfk (Lumoxiti™) is a CD22-directed cytotoxin.

FDA Approved Indication(s)

Lumoxiti is indicated for the treatment of adult patients with relapsed or refractory hairy cell leukemia (HCL) who received at least two prior systemic therapies, including treatment with a purine nucleoside analog (PNA).

Limitation(s) of use: Not recommended in patients with severe renal impairment (CrCl ≤ 29 mL/min).

Policy/Criteria

.Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of Louisiana Healthcare Connections that Lumoxiti is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Hairy Cell Leukemia

1. Authorization is not permitted. Member may not initiate therapy with Lumoxiti. If member is currently using Lumoxiti, proceed to section II.A. Hairy Cell Leukemia for continued therapy (*see Appendix D).*

Approval duration: Not applicable

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy LA.PMN.53

II. Continued Therapy

A. Hairy Cell Leukemia (must meet all)**:**

1. Currently receiving medication via Louisiana Healthcare Connections benefit, or documentation supports that member is currently receiving Lumoxiti for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. Member has not received ≥ 6 treatment cycles;
4. If request is for a dose increase, request meets one of the following (a or b):*
   a. New dose does not exceed 0.04 mg/kg/dose (actual body weight) for three days of each 28-day cycle;
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN.*

Approval duration: 6 months (total of 6 cycles)

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy LA.PMN.53

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – LA.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

CLS: capillary leak syndrome
FDA: Food and Drug Administration
HCL: hairy cell leukemia
HUS: hemolytic uremic syndrome
NCCN: National Comprehensive Cancer Cancer

Appendix B: Therapeutic Alternatives

Not applicable

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): none reported
- Boxed warning(s): capillary leak syndrome (CLS) and hemolytic uremic syndrome (HUS)

Appendix D: Permanent Withdrawal of Lumoxiti from the US Market

- On November 18, 2022, AztraZeneca announced the decision to permanently discontinue Lumoxiti from the US market in July 2023. AztraZeneca advises distributors to stop all distribution in August 2023. Also starting in August 2023, AztraZeneca will request returns of Lumoxiti packs from distributors.

- The removal of Lumoxiti from the US market is not related to the safety or efficacy of the medicinal product. There has been very low clinical uptake of Lumoxiti since FDA approval, due to the availability of other treatment options and possibly due to the specialized complexity of administration, toxicity prophylaxis and safety monitoring needs for patients.
- Action required for prescribers: Physicians should not initiate new treatment with Lumoxiti with immediate effect. Physicians who are currently treating patinets with Lumoxiti will have adequate time to complete six cycles of treatment.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
HCL	0.04 mg/kg (actual body weight) IV on Days 1, 3, and 5 of each 28-day cycle. Continue treatment for maximum of 6 cycles, disease progression, or unacceptable toxicity.	See regimen

VI. Product Availability

Single-dose vial: 1 mg

VII. References

1. Lumoxiti Prescribing Information. Wilmington, DE: AstraZeneca Pharmaceuticals LP; February 2022. Available at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=d6510282-1a57-4614-9859-299a227a089c. Accessed July 17, 2024.
2. AztraZeneca. Important prescribing information update – permanent withdrawal of Lumoxiti from the US market. November 18, 2022. Available at: https://www.fda.gov/media/164425/download. Accessed August 5, 2024.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J9313	Injection, moxetumomab pasudotox-tdfk, 0.01 mg

Reviews, Revisions, and Approvals	Date	LDH Approval Date
Converted corporate to local policy	02.23	03.16.23
Updated criteria for other diagnoses/indications	06.25.23	10.05.23
Annual review: removed initial approval criteria for HCL due to manufacturer withdrawal, added Appendix E with details of market withdrawal; references reviewed and updated.	05.21.24	08.20.24

Reviews, Revisions, and Approvals	Date	LDH Approval Date
Annual review; removed Appendix D and drugs listed in Appendix B as they are not relevant to current criteria; references reviewed and updated.	01.21.25	

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. LHCC makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable LHCC administrative policies and procedures.

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This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

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