POLICY: Oncology (Injectable) – Lumoxiti

- Lumoxiti® (moxetumomab pasudotox-tdfk intravenous infusion – AstraZeneca)

EFFECTIVE DATE: 1/1/2021
LAST REVISION DATE: 09/16/2024

COVERAGE CRITERIA FOR: All Aspirus Medicare Plans

OVERVIEW

Lumoxiti, a CD22-directed cytotoxin, is indicated for the treatment of adults with relapsed or refractory **hairy cell leukemia** who received at least two prior systemic therapies, including treatment with a purine nucleoside analog.[1] AstraZeneca will permanently withdraw Lumoxiti from the market in July 2023. This is due to very low uptake of Lumoxiti and the availability of other treatment options. As such, physicians should not start new patients on Lumoxiti.

Limitations of Use: Lumoxiti is not recommended for use in patients with a creatinine clearance ≤ 29 mL/min.

Dosing Information

The recommended dose of Lumoxiti is 0.04 mg/kg given as a 30-minute intravenous infusion.[1] Lumoxiti is given on Days 1, 3, and 5 of each 28-day cycle. The recommended maximum duration of Lumoxiti therapy is 6 cycles, or until disease progression or unacceptable toxicity occurs.

Guidelines

The National Comprehensive Cancer Network guidelines for Hairy Cell Leukemia (version 1.2023 – August 30, 2022) recommend purine nucleoside analogs (cladribine or pentostatin) as first-line agents for hairy cell leukemia.[2,3] Lumoxiti is recommended as a single agent for the treatment of progression of hairy cell leukemia after therapy for relapsed/refractory disease.

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Lumoxiti. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indication. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. Because of the specialized skills required for evaluation and diagnosis of

patients treated with Lumoxiti, as well as the monitoring required for adverse events and long-term efficacy, approval requires Lumoxiti to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Lumoxiti is recommended in those who meet the following criteria:

FDA-Approved Indication

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1. **Hairy Cell Leukemia.** Approve for 6 months if the patient meets the following (A, B, C, D, and E):
   - **A)** Patient is currently receiving Lumoxiti; AND
   - **B)** Patient is ≥ 18 years of age; AND
   - **C)** Patient has received ≥ 2 prior systemic therapies, including therapy with a purine analog; AND
     Note: Purine analogs include cladribine and pentostatin.
   - **D)** Patient has an estimated creatinine clearance ≥ 30 mL/min; AND
   - **E)** The medication is prescribed by or in consultation with an oncologist.

   Dosing. Approve up to 0.04 mg/kg by intravenous infusion up to three times in each 28-day cycle.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Lumoxiti is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Lumoxiti® intravenous infusion [prescribing information]. Wilmington, DE: AstraZeneca; August 2020.
2. The NCCN Hairy Cell Leukemia Clinical Practice Guidelines in Oncology (version 1.2023 – August 30, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed October 5, 2023.
3. The NCCN Drugs and Biologics Compendium. © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on October 5, 2023. Search term: moxetumomab.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	10/19/2022
Selected Revision	**Hairy Cell Leukemia:** Due to the pending market withdrawal, a requirement was added that the patient is currently receiving Lumoxiti.	01/25/2023
Annual Revision	No criteria changes.	10/11/2023
Aspirus P&T Review	Policy reviewed and approved by Aspirus P&T committee. Annual review process	09/16/2024