PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Lumoxiti PA Policy (moxetumomab pasudotox-tdfk injection for intravenous use - AstraZeneca)

APPROVAL DATE: 09/25/2019

OVERVIEW

Lumoxiti is a CD22-directed cytotoxin.[1] Lumoxiti is produced in *E. coli* via recombinant DNA technology and consists of a recombinant, murine immunoglobulin variable region fused to a shortened form of the *Pseudomonas* endotoxin, E38. Lumoxiti binds to the CD22 antigen on the cell surface and is internalized by the B-cell which results in ADP-ribosylation of elongation factor 2, inhibition of protein synthesis and apoptotic cell death.

Lumoxiti is indicated for the treatment of adult patients with relapsed or refractory hairy cell leukemia who received at least two prior systemic therapies, including treatment with a purine nucleoside analog.[1] Limitations of Use: Lumoxiti is not recommended for use in patients with a creatinine clearance ≤ 29 mL/min.

Guidelines

The National Comprehensive Cancer Network (NCCN) guidelines on Hairy Cell Leukemia (version 3.2019 – January 31, 2019) recommends purine nucleoside analogs (cladribine and/or pentostatin) as first-line agents and Lumoxiti as a single agent for progression of hairy cell leukemia after therapy for relapsed/refractory disease.[2,3]

POLICY STATEMENT

Prior authorization is recommended for prescription benefit coverage of Lumoxiti. 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 Indications

1. Hairy Cell Leukemia.

Criteria. Approve for 6 months if the patient meets the following criteria (A, B, C, and D):
A) Patient is ≥ 18 years of age; AND
B) Patient has received ≥ 2 prior systemic therapies, including therapy with a purine analog. (Note: Purine analogs include cladribine and pentostatin); AND
C) Patient has an estimated creatinine clearance ≥ 30 mL/min; AND
D) Lumoxiti is prescribed by or in consultation with an oncologist.[1-3]

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Lumoxiti has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions.

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™ injection for intravenous use [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals; January 2019.
2. The NCCN Hairy Cell Leukemia Clinical Practice Guidelines in Oncology (Version 3.2019 – January 31, 2019). © 2019 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed August 16, 2019.
3. The NCCN Drugs and Biologics Compendium. © 2019 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on August 16, 2019. Search term: moxetumomab.