Reference number(s)
4471-A

STANDARD MEDICARE PART B MANAGEMENT

LUMOXITI (moxetumomab pasudotox-tdfk)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications
Lumoxiti is a CD22-directed cytotoxin 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).

Limitations of use: Lumoxiti is not recommended in patients with severe renal impairment (CrCl ≤ 29 mL/min).

B. Compendial Uses
Hairy cell leukemia (HCL)

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. CRITERIA FOR INITIAL APPROVAL

Hairy Cell Leukemia
Authorization of 6 months may be granted for treatment of relapsed or refractory hairy cell leukemia as a single agent when all of the following criteria are met:
A. Member has received at least two prior systemic therapies, including treatment with a purine nucleoside analog.
B. Member has not previously received 6 or more cycles of treatment with the requested medication.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization up to 6 months may be granted when all of the following criteria are met:
A. The member is currently receiving therapy with Lumoxiti

B. Lumoxiti is being used to treat an indication enumerated in Section II
C. Member will receive a maximum of 6 cycles with Lumoxiti
D. The member is receiving benefit from therapy. Benefit is defined as:
   1. No evidence of unacceptable toxicity while on the current regimen AND
   2. No evidence of disease progression while on the current regimen

IV. REFERENCES

1. Lumoxiti [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; February 2022.
2. The NCCN Drugs & Biologics Compendium® © 2022 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed June 2, 2022.