

Reference number(s)
2739-A

SPECIALTY GUIDELINE 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.

FDA-Approved Indication

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 ($CrCl \leq 29$ mL/min).

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

Hairy Cell Leukemia

Authorization of 6 months may be granted for treatment of relapsed or refractory hairy cell leukemia when all of the following criteria are met:

- A. The patient has received at least two prior systemic therapies, including treatment with a purine nucleoside analog.
- B. The patient has not previously received 6 or more cycles of treatment with Lumoxiti.

III. REFERENCES

1. Lumoxiti [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; September 2018.