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≤29 mL/min).

All other indications are considered experimental/investigational and not medically necessary.

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

Authorization of up to 6 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section II when all of the following criteria are met:
A. Member will receive a maximum of 6 cycles with the requested medication.
B. There is no evidence of disease progression or an unacceptable toxicity while on the current regimen.

IV. REFERENCES

1. Lumoxiti [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; April 2020.