



## 5.21.115

---

<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	July 1, 2022
<b>Subsection:</b>	Antineoplastic Agents	<b>Original Policy Date:</b>	October 5, 2018
<b>Subject:</b>	Lumoxiti	<b>Page:</b>	1 of 4

---

**Last Review Date:** June 16, 2022

---

## Lumoxiti

### Description

Lumoxiti (moxetumomab pasudotox-tdfk)

### Background

Lumoxiti (moxetumomab pasudotox-tdfk) is a CD22-directed cytotoxin. Lumoxiti binds CD22 on the cell surface of B-cells and is internalized. Lumoxiti internalization results in ADP-ribosylation of elongation factor 2, inhibition of protein synthesis, and apoptotic cell death (1).

### Regulatory Status

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) (1).

Lumoxiti has a boxed warning regarding Capillary Leak Syndrome (CLS), including life-threatening cases. CLS is characterized by hypoalbuminemia, hypotension, symptoms of fluid overload, and hemoconcentration. Patient weight and blood pressure should be monitored prior to each Lumoxiti infusion and as clinically indicated during treatment. Patients who develop CLS should receive appropriate supportive measures, including concomitant oral or intravenous corticosteroids, and hospitalization as clinically indicated. Lumoxiti should be withheld for Grade 2 CLS until resolution, and permanently discontinued for Grade  $\geq$  3 CLS (1).

Lumoxiti also has a boxed warning that Hemolytic Uremic Syndrome (HUS) may occur, including life-threatening cases. HUS is characterized by the triad of microangiopathic hemolytic anemia, thrombocytopenia, and progressive renal failure. Prophylactic intravenous fluids should be administered before and after Lumoxiti infusions. Blood chemistries and blood counts should

---

<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	July 1, 2022
<b>Subsection:</b>	Antineoplastic Agents	<b>Original Policy Date:</b>	October 5, 2018
<b>Subject:</b>	Lumoxiti	<b>Page:</b>	2 of 4

---

be done prior to each dose and on day 8 of each treatment cycle, as well as mid-cycle. Lumoxiti should be discontinued in patients with HUS (1).

Renal toxicity can occur with Lumoxiti therapy. Renal function should be monitored prior to each infusion of Lumoxiti, and as clinically indicated throughout treatment (1).

The safety and effectiveness of Lumoxiti in pediatric patients have not been established (1).

---

## Related policies

### Policy

*This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.*

Lumoxiti may be considered **medically necessary** in patients 18 years of age and older with relapsed or refractory hairy cell leukemia and if the conditions indicated below are met.

Lumoxiti may be considered **investigational** in patients less than 18 years of age and for all other indications.

## Prior-Approval Requirements

**Age** 18 years of age and older

### Diagnosis

The patient must have the following:

Relapsed or refractory hairy cell leukemia (HCL)

**AND ALL** of the following:

1. Patient has received prior systemic therapy with a purine nucleoside analog (PNA)
2. Patient has received at least **ONE** other prior systemic therapy
3. Serum creatinine  $\leq$  1.5 mg/dL **OR** creatinine clearance  $\geq$  60 mL/min

## Prior – Approval *Renewal* Requirements

None

---

<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	July 1, 2022
<b>Subsection:</b>	Antineoplastic Agents	<b>Original Policy Date:</b>	October 5, 2018
<b>Subject:</b>	Lumoxiti	<b>Page:</b>	3 of 4

---

## Policy Guidelines

### Pre - PA Allowance

None

### Prior - Approval Limits

**Duration** 9 months

### Prior – Approval *Renewal* Limits

None

## Rationale

### Summary

Lumoxiti (moxetumomab pasudotox-tdfk) is a CD22-directed cytotoxin. Lumoxiti binds CD22 on the cell surface of B-cells and is internalized. Lumoxiti internalization results in ADP-ribosylation of elongation factor 2, inhibition of protein synthesis, and apoptotic cell death. The safety and effectiveness of Lumoxiti in pediatric patients have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate and cost-effective use of Lumoxiti while maintaining optimal therapeutic outcomes.

### References

1. Lumoxiti [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; February 2022.
2. NCCN Drugs & Biologics Compendium<sup>®</sup> Moxetumomab pasudotox-tdfk 2022. National Comprehensive Cancer Network, Inc. Accessed on April 22, 2022.

## Policy History

Date	Action
October 2018	Addition to PA
November 2018	Annual review
March 2019	Annual review
June 2020	Annual review and reference update
June 2021	Annual review and reference update
June 2022	Annual review and reference update

# 5.21.115

---

<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	July 1, 2022
<b>Subsection:</b>	Antineoplastic Agents	<b>Original Policy Date:</b>	October 5, 2018
<b>Subject:</b>	Lumoxiti	<b>Page:</b>	4 of 4

---

## Keywords

**This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 16, 2022 and is effective on July 1, 2022.**