

Lumoxiti® (moxetumomab pasudotox-tdfk)

Policy Origination date: January 1, 2019

Number: MG.MM.PH.118

Medical Guideline Disclaimer

Property of EmblemHealth. All rights reserved. The treating physician or primary care provider must submit to EmblemHealth the clinical evidence that the patient meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request for prior authorization. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer-reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes, and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary. If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication. EmblemHealth Services Company LLC, ("EmblemHealth") has adopted the herein policy in providing management, administrative and other services to, EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC and Health Insurance Plan of Greater New York (HIP), ConnectiCare, Inc., ConnectiCare Insurance Company, Inc. ConnectiCare Benefits, Inc., and ConnectiCare of Massachusetts, Inc. related to health benefit plans offered by these entities. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Definition

Moxetumomab pasudotox-tdfk (Lumoxiti) is a CD22-directed cytotoxin. Moxetumomab pasudotox-tdfk is indicated to treat relapsed or refractory HCL in adults who have previously been treated with at least 2 systemic therapies, one of which was a PNA. Moxetumomab pasudotox-tdfk targets binds to CD22 on the surface of B-cells and, once internalized, produces cell death via ADP-ribosylation of elongation factor 2 and inhibition of protein synthesis.

Length of Authorization

Coverage will be provided for 6 months and may not be renewed.

Dosing Limits

Max Units (per dose and over time) [Medical Benefit]:

- 5 mg on days 1, 3, and 5 of a 28-day cycle

I. INITIAL APPROVAL CRITERIA

Lumoxiti may be considered medically necessary if the below condition is met **AND** use is consistent with the medical necessity criteria that follows:

1. Hairy Cell Leukemia

- a. Patient is at least 18 years or older; **AND**
- b. Patient is pseudomonas-immunotoxin naïve (e.g., moxetumomab pasudotox, etc.); **AND**
- c. Patient does not have severe renal impairment defined as CrCl \leq 29 mL/min; **AND**
- d. Patient has a confirmed diagnosis of Hairy Cell Leukemia or a HCL variant; **AND**
- e. Patient must have relapsed or refractory disease; **AND**
- f. Patient has previously failed at least TWO prior systemic therapies as one of the following:

- i. Failure to two courses of purine analog therapy (e.g., cladribine, pentostatin, etc.); **OR**
- ii. Failure to at least one purine analog therapy AND one course of rituximab or a BRAF-inhibitor (e.g., vemurafenib, etc.)
- g. Lumoxiti will be used as a single agent

Limitations/Exclusions

Lumoxiti is not considered medically necessary for when any of the following selection criteria is met:

- 1) Lumoxiti is being used after disease progression with the same regimen.
- 2) Dosing exceeds single dose limit of Lumoxiti of 0.04mg/kg.

II. RENEWAL CRITERIA

- Coverage may not be renewed.

Dosage/Administration

Indication	Dose
Hairy Cell Leukemia (HCL)	– Infuse 0.04 mg/kg intravenously on days 1, 3, and 5 of a 28-day cycle. Continue Lumoxiti for a maximum of 6 cycles or until disease progression or unacceptable toxicity.

Applicable Procedure Codes

J9313	Injection, moxetumomab pasudotox-tdfk, 0.01 mg, effective 10/01/2019.
C9045	Injection, moxetumomab pasudotox-tdfk, 0.01 mg (Code Deleted 9/30/2019)

Applicable NDCs

0310-4700-01	Lumoxiti 1 mg single dose vial
0310-4715-11	IV solution stabilizer for use during administration

Applicable Diagnosis Codes

ICD-10	ICD-10 Description
C91.40	Hairy Cell Leukemia not having achieved remission
C91.42	Hairy Cell Leukemia, in relapse
Z92.21	Personal history of antineoplastic chemotherapy

Revision History

7/7/2021	Removed C Code
12/30/2020	
09/23/2019	Removed J9999, Added New code J9313 effective 10/01/2019.
3/26/2019	Added New Ccode C9045

References

1. Lumoxiti [package insert]. Wilmington, DE; Astra Zeneca Pharmaceuticals; January, 2019.
2. "FDA Approves New Kind of Treatment for Hairy Cell Leukemia." US Food and Drug Administration, US Department of Health and Human Services, 13 Sept. 2018, www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm620448.htm. Accessed November 20, 2018.
3. NCCN Clinical Practice Guidelines in Oncology (Hairy Cell Leukemia), Version 2.2019. National Comprehensive Cancer Network, 20 Sept. 2018, www.nccn.org/professionals/physician_gls/pdf/hairy_cell.pdf. Accessed November 20, 2018.
4. Clinical Pharmacology Elsevier Gold Standard. 2018.
5. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, Co. 2018.
6. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD. 2018.