Lumoxiti® (moxetumomab pasudotox-tdfk)

Policy Orgination date: January 1, 2019	Number: MG.MM.PH.118

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 ≤ 29 mL/min; **AND**
   d. Patient has a confirmed diagnosis of Hairy Cell Leukemia or a HCL variant; **AND**
   e. Patient must has 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.