

Medical Drug Clinical Criteria

Subject:	Lumoxiti (moxetumomab pasudotox-tdfk)		
Document #:	CC-0144	Publish Date:	09/23/2024
Status:	Reviewed	Last Review Date:	08/16/2024

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Overview

This document addresses the use of Lumoxiti (moxetumomab pasudotox-tdfk), a CD22-directed cytotoxin. Moxetumomab pasudotox-tdfk binds CD22 on the cell surface of B-cell and is released into the malignant cells upon binding to cause cell death. It is used to treat Hairy Cell Leukemia (HCL).

Lumoxiti is FDA approved to treat relapsed or refractory HCL in patients who received at least two prior systemic therapies, including treatment with a purine nucleoside analog. Similarly, the National Comprehensive Cancer Network® (NCCN) provides recommendations with a category 2A level of evidence for the use of Lumoxiti for progression after therapy for relapsed/refractory disease.

Lumoxiti has a black box warning for capillary leak syndrome (CLS) and hemolytic uremic syndrome (HUS). CLS and HUS, including life-threatening cases, have occurred in patients receiving Lumoxiti. Monitor weight and blood pressure; if CLS is suspected, check labs, including albumin. Delay dosing or discontinue as recommended. Monitor hemoglobin, platelet count, serum creatinine, and ensure adequate hydration; discontinue in patients with HUS.

Definitions and Measures

Purine nucleoside analog: a type of cancer drug that blocks important enzymes needed to make DNA and RNA; examples include cladribine and pentostatin

Refractory Disease: Illness or disease that does not respond to treatment.

Relapse or recurrence: After a period of improvement, during which time a disease (for example, cancer) could not be detected, the return of signs and symptoms of illness or disease. For cancer, it may come back to the same place as the original (primary) tumor or to another place in the body.

Lumoxiti was withdrawn from the market by the manufacturer July 2023. Criteria will remain active until July 2025 as claims can adjudicate several years after agent discontinuation.

Clinical Criteria

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Lumoxiti (moxetumomab pasudotox-tdfk)

Requests for Lumoxiti (moxetumomab pasudotox-tdfk) may be approved if the following criteria are met:

- I. Individual has a diagnosis of relapsed or refractory hairy cell leukemia (HCL); **AND**
- II. Individual has received at least two prior systemic therapies, including treatment with a purine nucleoside analog (PNA).

Lumoxiti (moxetumomab pasudotox-tdfk) may not be approved for the following:

- I. All other indications not included above; **OR**
- II. Individuals with severe renal impairment (CrCl \leq 29 mL/min).

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS

J9313 Injection, moxetumomab pasudotox-tdfk, 0.01 mg [Lumoxiti]

ICD-10 Diagnosis

C91.40 Hairy cell leukemia, NOS
C91.41 Hairy cell leukemia, in remission
C91.42 Hairy cell leukemia, in relapse

Document History

Reviewed: 08/16/2024

Document History:

- 08/16/2024 – Annual Review: No Changes Coding Reviewed: No changes.
- 08/18/2023 – Annual Review: No changes.
- 08/19/2022 – Annual Review: No changes. Coding reviewed: Added ICD-10-CM C91.40, C91.41, C91.42. Removed ICD-10-CM C91.40-C91.42.
- 08/20/2021 – Annual Review: No changes. Coding reviewed: No changes.
- 08/21/2020 – Annual Review: Wording and formatting changes. Coding review: No changes.
- 08/16/2019 – Annual Review: Minor formatting changes. Coding Reviewed: Added HCPCS code J9313 Effective (10/1/19). Delete J9999, C9045 (Effective 10/1/19) Added ICD-10 codes C91.40-C91.42

References

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4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2024; Updated periodically.
5. Lumoxiti Prescribing Information. November 18, 2022. Available: <https://www.fda.gov/media/164425/download>. Accessed June 20, 2024.
6. NCCN Clinical Practice Guidelines in Oncology™. © 2024 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on June 20, 2024.
 - a. Hairy Cell Leukemia. V2.2024. Revised April 22, 2024.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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