Clinical Criteria

Subject:	Lumoxiti (moxetumomab pasudotox-tdfk)		
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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.

Note: Lumoxiti has a black box warning for capillary leak syndrome and hemolytic uremic syndrome.

Definitions and Measures

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.

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. Individuals with severe renal impairment (CrCl ≤ 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

C9045	Injection, moxetumomab pasudotox-tdfk, 0.01 mg [Lumoxiti] (Delete 10/1/19)
J9999	Not Otherwise Classified, Antineoplastic Drugs when specified as [Lumoxiti] (Delete 10/1/9)
J9313	Injection, moxetumomab pasudotox-tdfk, 0.01 mg [Lumoxiti] (Effective 10/1/19)

ICD-10 Diagnosis

C91.4	Hairy cell leukemia
N25.0-N25.9	Disorders resulting from impaired renal tubular function
6A0-6AB	Systemic Therapies

Document History

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Document History:

- 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 C91.4, N25.0-N25.9, 6A0-6AB

References

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2019. URL: http://www.clinicalpharmacology.com. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: April 24, 2019.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2019 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on July 24, 2019.
    a. Hairy Cell Leukemia. V3.2019. Revised January 31, 2019.

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