Drug Policy:

Lumoxiti™ (moxetumomab pasudotox)

POLICY NUMBER UM ONC_1348	SUBJECT Lumoxiti™ (moxetumomab pasudotox)		DEPT/PROGRAM UM Dept	PAGE 1 of 3
DATES COMMITTEE REVIEWED 11/14/18, 11/13/19, 12/11/19, 10/14/20, 09/08/21, 11/15/21, 05/11/22, 08/10/22, 02/08/23	APPROVAL DATE February 8, 2023	EFFECTIVE DATE February 24, 2023	COMMITTEE APPROVAL DATES 11/14/18, 11/13/19, 12/11/19, 10/14/20, 09/08/21, 11/15/21, 05/11/22, 08/10/22, 02/08/23	
PRIMARY BUSINESS OWNER: UM		COMMITTEE/BOARD APPROVAL Utilization Management Committee		
URAC STANDARDS HUM v8: UM 1-2; UM 2-1	NCQA STANDARDS UM 2		ADDITIONAL AREAS OF IMPACT	
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS		APPLICABLE LINES OF BUSINESS Commercial, Exchange, Medicaid	

I. PURPOSE

To define and describe the accepted indications for Lumoxiti (moxetumomab pasudotox) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

New Century Health (NCH) is responsible for processing all medication requests from network ordering providers. Medications not authorized by NCH may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

II. INDICATIONS FOR USE/INCLUSION CRITERIA

A. PREFERRED MEDICATION GUIDANCE FOR INITIAL REQUEST:

1. When health plan Medicaid coverage provisions—including any applicable PDLs (Preferred Drug Lists)—conflict with the coverage provisions in this drug policy, health plan Medicaid coverage provisions take precedence per the Preferred Drug Guidelines OR
2. When health plan Exchange coverage provisions-including any applicable PDLs (Preferred Drug Lists)-conflict with the coverage provisions in this drug policy, health plan Exchange coverage provisions take precedence per the Preferred Drug Guidelines OR

3. When Health Plans utilize NCH UM Oncology Clinical Policies as the initial clinical criteria, and there is no Health Plan PDL applicable, the Preferred Drug Guidelines shall follow NCH recommended agents/regimens/preferred drugs AND
4. Continuation requests of previously approved, non-preferred medication are not subject to this provision AND
5. When applicable, generic alternatives are preferred over brand-name drugs AND
6. When there is a documented drug shortage, disease progression, contraindication, or confirmed intolerance to a preferred drug/regimen, per NCH Policy and Pathway, the available alternative product may be used if deemed medically appropriate and the indication is listed in a standard reference compendium or accepted peer review literature. For a list of current drug shortages, please refer to FDA drug shortage website in the reference section.

B. Hairy Cell Leukemia

1. NOTE: Per NCH Policy, Lumoxiti (moxetumomab pasudotox) is not preferred for the treatment of hairy cell leukemia. This recommendation is based on the voluntary withdrawal by the manufacturer of Lumoxiti. Lumoxiti will be discontinued, by August 31, 2023, due to low clinical utilization and the availability of alternative treatment options. Therefore, Lumoxiti's manufacturer advises healthcare providers not to initiate new treatments.

III. EXCLUSION CRITERIA

A. Lumoxiti (moxetumomab pasudotox) is being used after disease progression with the same regimen.

B. Concurrent use with other chemotherapy.

C. Dosing exceeds single dose limit of Lumoxiti (moxetumomab pasudotox) of 0.04 mg/kg.

D. Treatment exceeds the maximum months duration limit of 6 cycles.

E. Investigational use of Lumoxiti (moxetumomab pasudotox) with an off-label indication that is not sufficient in evidence or is not generally accepted by the medical community. Sufficient evidence that is not supported by CMS recognized compendia or acceptable peer reviewed literature is defined as any of the following:

1. Whether the clinical characteristics of the patient and the cancer are adequately represented in the published evidence.
2. Whether the administered chemotherapy/biologic therapy/immune therapy/targeted therapy/other oncologic therapy regimen is adequately represented in the published evidence.
3. Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients. Generally, the definitions of Clinically Meaningful outcomes are those recommended by ASCO, e.g., Hazard Ratio of less than 0.80 and the recommended survival benefit for OS and PFS should be at least 3 months.
4. Whether the experimental design, considering the drugs and conditions under investigation, is appropriate to address the investigative question. (For example, in some clinical studies, it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover).
5. That non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs.
6. That case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.

7. That abstracts (including meeting abstracts) without the full article from the approved peer-reviewed journals lack supporting clinical evidence for determining accepted uses of drugs.

IV. MEDICATION MANAGEMENT

A. Please refer to the FDA label/package insert for details regarding these topics.

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

A. Lumoxiti (moxetumomab pasudotox) prescribing information. AstraZeneca Pharmaceuticals LP, Wilmington, DE 2022.

B. Clinical Pharmacology Elsevier Gold Standard 2023.

C. Micromedex® Healthcare Series: Micromedex Drugdex Ann Arbor, Michigan 2023.

D. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium 2023.

E. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD 2023.

F. Ellis LM, et al. American Society of Clinical Oncology perspective: Raising the bar for clinical trials by defining clinically meaningful outcomes. J Clin Oncol. 2014 Apr 20;32(12):1277-80.

G. Medicare Benefit Policy Manual Chapter 15 Covered Medical and Other Health Services: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf.

H. Current and Resolved Drug Shortages and Discontinuations Reported to the FDA: http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm.

I. NCQA UM 2023 Standards and Elements.