# Molina Clinical Policy
# Lutathera™ (lutetium Lu 177 dotatate)
# Policy Number: 322

**Last Approval: 8/09/2023**
**Next Review Due By: August 2024**

## POLICY SECTIONS



## DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment, and clinical recommendations for the Member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. 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 (e.g., will be paid for by Molina) for a particular Member. The Member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their Providers will need to consult the Member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid Members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

## POLICY DESCRIPTION

To define and describe the accepted indications for Lutathera (lutetium Lu 177 dotatate) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

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.

## INDICATIONS and/or LIMITATIONS OF COVERAGE

### A. Continuation requests for a not-approvable medication shall be exempt from this NCH policy provided:

1. The requested medication was used within the last year, **AND**
2. The member has not experienced disease progression and/or no intolerance to the requested medication, **AND**
3. Additional medication(s) are not being added to the continuation request.

### B. Gastrointestinal and pancreatic neuroendocrine tumors (GEP-NET):

1. The member has metastatic, locally advanced, or unresectable gastrointestinal **OR** pancreatic neuroendocrine tumor (GEP-NET); **AND**
2. Confirmed presence of somatostatin receptors on metastatic lesions documented by peptide receptor scintigraphy e.g., Ga-DOTA scan or similar test; **AND**
3. Lutathera (lutetium Lu 177 dotatate) may be used in members who have previously received Octreotide LAR and/or Lanreotide and experienced disease progression on either of the above agents.

## EXCLUSION CRITERIA

A. Dosing exceeds single dose limit of Lutathera (lutetium Lu 177 dotatate) 7.4 GBq (200 mCi).

B. Investigational use of Lutathera (lutetium Lu 177 dotatate) 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 definition of Clinically Meaningful outcomes are those recommended by ASCO, e.g., Hazard Ratio of < 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.

## MEDICATION MANAGEMENT

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

## APPLICABLE CPT / HCPCS PROCEDURE CODES

**CPT (Current Procedural Terminology) Code**

| CPT | Description |
|---|---|
| **79101** | Radiopharmaceutical therapy, by intravenous administration |

**HCPCS (Healthcare Common Procedure Coding System) Code**

| HCPCS | Description |
|---|---|
| **A9513** | Lutetium lu 177, dotatate, therapeutic, 1 mCi |

**AVAILABLE DOSAGE FORMS:** 370 MBq/mL (10 mCi/mL) in single-dose vial

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**CODING DISCLAIMER.** Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

## APPROVAL HISTORY

**8/09/2023** Changes to indications/inclusion criteria to remove reference to preferred drug listing. Reviewed by board certified Radiation Oncologist. Removed code 84307 and updated code description for code A9513.
**8/10/2022** Adopted NCH policy and retired MCP.

## REFERENCES


A. Strosberg J, et al. Peptide receptor radiotherapy re-treatment in patients with progressive neuroendocrine tumors: A systematic review and meta-analysis. Cancer Treat Rev. 2021 Feb;93:102141. doi: 10.1016/j.ctrv.2020.102141.
B. Liu T, et al. Treatments for patients with advanced neuroendocrine tumors: a network meta-analysis. Ther Adv Med Oncol. 2019;11:1758835919853673.
C. Lutathera prescribing information. Advanced Accelerator Applications USA, Inc., NJ 2023.
D. Clinical Pharmacology Elsevier Gold Standard 2023.
E. Micromedex® Healthcare Series: Micromedex Drugdex Ann Arbor, Michigan 2023.
F. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium 2023.
G. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD 2023.
H. 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.
I. Medicare Benefit Policy Manual Chapter 15 Covered Medical and Other Health Services: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf.
J. NCQA UM 2023 Standards and Elements.