

Lutathera (Lutetium Lu 177 dotatate)

Policy Number: 033

	Commercial and Qualified Health Plans	MassHealth	Medicare Advantage
Authorization required	X	X	X
No notification or authorization			

Criteria

1. Patient Population

Mass General Brigham Health Plan may authorize coverage of Lutathera (lutetium Lu 177 dotatate) for adult members, when the following criteria are met:

- Members have a documented diagnosis of a gastrointestinal or pancreatic neuroendocrine tumor (GEP-NETs) including foregut, midgut, and hindgut neuroendocrine tumors.
- The tumor has been shown to be somatostatin receptor-positive.
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Note: Requests for authorization for other indications supported by NCCN Compendia, including somatostatin-receptor positive carcinoid tumors of lung or thymus, will be reviewed on an individual basis.

2. Prescribing

- Prescribed by an oncologist.

3. Approval Duration:

- 4 doses at 8 week intervals

Exclusions

- Indications not supported by National Cancer Comprehensive Network (NCCN) category 2A or higher recommendations may not be considered medically necessary¹.
- The member has experienced disease progression on or following Lutathera.

Approved by Mass General Brigham Health Plan Medical Policy Committee

February 2024: Annual review.

February 2023: Annual Review. Medicare Advantage added to table. Statement regarding indications supported by NCC Compendia added. Medicare Variations language added. References updated.

March 2022: Annual Review. Added exclusions. References updated.

February 2021: Annual Review. References updated.

February 2020: Annual Review. References Updated.

February 2019: Annual Review. Added criteria requiring the tumor has been shown to be somatostatin receptor-positive. Revised approval of duration. Removed reauthorization criteria.

August 2018: Effective Date

Medicare Variations

Mass General Brigham Health Plan uses guidance from the Centers for Medicare and Medicaid Services (CMS) for coverage determinations for its Medicare Advantage plan members. National Coverage Determinations

¹Category 2A: Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate

(NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs) and documentation included in the Medicare manuals are the basis for coverage determinations. **When there is no guidance from CMS for the requested service, Mass General Brigham Health Plan’s medical policies are used for coverage determinations.**

Codes

The following codes are included below for informational purposes only; inclusion of a code does not constitute or imply coverage.

This list of codes applies to commercial and MassHealth plans only.

Authorized Codes	Code Description
A9513	Lutetium Lu 177, dotatate, therapeutic, 1 mCi

References

Baum RP, Kulkarni HR, Singh A, et al. Results and adverse events of personalized peptide receptor radionuclide therapy with 90Yttrium and 177Lutetium in 1048 patients with neuroendocrine neoplasms. *Oncotarget*. 2018 Feb 15;9(24):16932-16950. doi: 10.18632/oncotarget.24524. PMID: 29682195; PMCID: PMC5908296.

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Strosberg J, El-Haddad G, Wolin E, et al.; NETTER-1 Trial Investigators. Phase 3 Trial of (177)Lu-Dotatate for Midgut Neuroendocrine Tumors. *N Engl J Med*. 2017;376(2):125-135.

Zidan L, Irvani A, Oleinikov K. et al. Efficacy and Safety of 177Lu-DOTATATE in Lung Neuroendocrine Tumors: A Bicenter study. *J Nucl Med*. 2022 Feb;63(2):218-225. doi: 10.2967/jnumed.120.260760. Epub 2021 May 28. PMID: 34049983; PMCID: PMC8805789.

