AvMed

MEDICAL PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-877-535-1391**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization can be delayed**.

For Medicare Members: Medicare Coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Additional indications may be covered at the discretion of the health plan.

Drug Requested: Lutathera® (lutetium Lu 177 dotatate) **IV (A9513)**

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member Sentara #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight (if applicable): _____ **Date weight obtained:** _____

☐ Standard Review. In checking this box, the timeframe does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.

Quantity Limits:

A. Length of Authorization

- Coverage will be provided for 1 year (4 doses only) and may **NOT** be renewed.

B. Max Units (per dose and over time) [HCPCS Unit]:

- 200 billable units (7.4 GBq = 200 mCi) every 8 weeks for a total of 4 doses

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CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Approval Criteria – Coverage cannot be renewed

- ❑ Member is at least 12 years of age or older
- ❑ Requesting provider is an oncologist
- ❑ **For female members of reproductive potential**, a negative pregnancy test has been confirmed
- ❑ Member has progressive locally advanced or metastatic, somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs)
- ❑ Member's disease is somatostatin receptor-positive in all tumor lesions (OctreoScan uptake ≥ normal liver)
- ❑ Member has well-differentiated disease with a Ki67 labeling index score of ≤ 20%
- ❑ Member's condition has progressed on long-acting octreotide or lanreotide
- ❑ Member will discontinue any long-acting somatostatin analogues (e.g., octreotide LAR, pasireotide LAR, lanreotide depot) within the previous 4 weeks **OR** short-acting somatostatin analogues (e.g., octreotide, pasireotide) within 24 hours prior to therapy
- ❑ Requested medication will be used in combination with a long-acting somatostatin analog (e.g., octreotide LAR, lanreotide depot) given as a single-injection (between 4-24 hours) following each Lutathera infusion

  NOTE: Somatostatin analogs require separate prior authorization
- ❑ Provider will follow the recommended dosage per weight and timeline indication detailed in the table below:

Indication	Dose
Gastroenteropancreatic neuroendocrine tumors (GEP-NETs)	• 7.4 GBq (200 mCi) every 8 weeks for a total of 4 doses. Administer a single dose of long-acting somatostatin analog between 4 to 24 hours after each Lutathera dose. (Long-acting somatostatin analog may not be repeated until after the next scheduled dose of Lutathera to provide the 4-week drug-free interval. Short-acting octreotide may be administered up to 24 hours prior to each Lutathera dose) • Initiate recommended intravenous amino acid solution 30 minutes before Lutathera infusion; continue during and for 3 hours after infusion

Reauthorization Criteria – Coverage cannot be renewed

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Medication being provided by (check box below that applies):

- ❑ **Location/site of drug administration:** _____

  NPI or DEA # of administering location: _____

  OR

- ❑ **Specialty Pharmacy**

For urgent reviews: Practitioner should call Sentara Health Plans Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Sentara Health Plan's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.

Previous therapies will be verified through pharmacy paid claims or submitted chart notes.

***Approved by Pharmacy and Therapeutics Committee**: ~~7/21/2022;~~ **5/23/2024**
REVISED/UPDATED/REFORMATTED: ~~8/10/2022; 5/20/2024; 6/5/2024;~~ **6/4/2025**