Updated: 07/2019
PARP Approved: 07/2019

Prior Authorization Criteria

Lutathera (lutetium Lu 177 dotatate)

All requests for Lutathera (lutetium Lu 177 dotatate) require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

Lutathera (lutetium Lu 177 dotatate) Prior Authorization Criteria:

Coverage may be provided with a diagnosis of gastroeneteropancreatic neuroendocrine tumors (GEP-NETs) and the following criteria is met:

- Must be 18 years of age or older
- Must be prescribed by or in consultation with an oncologist or a physician who specializes in the treatment of GEP-NETs
- Documentation of somatostatin receptor-positive foregut, midgut, or hindgut GEP-NETs on all target lesions confirmed by gallium-68 dotatate PET/CT or somatostatin receptor scintigraphy
- Must have metastatic or locally advanced and inoperable tumors
- Disease must have progressed during treatment with Sandostatin LAR Depot
- Must have low or intermediate grade NET (Ki-67 $\leq$ 20%)
- During Lutathera treatment, Sandostatin LAR Depot 30 mg will be administered intramuscularly between 4 to 24 hours after each Lutathera dose.
- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines
- **Duration of Approval:** 32 weeks up to a maximum of 4 doses in a lifetime

Coverage may be provided for any non-FDA labeled indication if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia or peer-reviewed medical literature for treatment of the diagnosis(es) for which it is prescribed. These requests will be reviewed on a case by case basis to determine medical necessity.

When criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must override criteria when, in their professional judgment, the requested medication is medically necessary.

Gateway Health

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LUTATHERA (lutetium lu 177 dotate)
PRIOR AUTHORIZATION FORM

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Gateway Health℠ Pharmacy Services. **FAX:** (888) 245-2049
If needed, you may call to speak to a Pharmacy Services Representative.
PHONE: (800) 392-1147 Monday through Friday 8:30am to 5:00pm

PROVIDER INFORMATION

Requesting Provider:	NPI:
Provider Specialty:	Office Contact:
Office Address:	Office Phone:
	Office Fax:

MEMBER INFORMATION

Member Name:	DOB:
Gateway ID:	Member weight: _____pounds or _____kg

REQUESTED DRUG INFORMATION

Medication:	Strength:
Frequency:	Duration:
Is the member currently receiving requested medication? ☐ Yes ☐ No	Date Medication Initiated:

Billing Information

This medication will be billed: ☐ at a pharmacy **OR**
☐ medically (if medically please provide a JCODE:_____

Place of Service: ☐ Hospital ☐ Provider's office ☐ Member's home ☐ Other

Place of Service Information

Name:	NPI:
Address:	Phone:

MEDICAL HISTORY (Complete for ALL requests)

Diagnosis: ☐ Gastroeneteropancreatic Neuroendocrine Tumors (GEP-NETs) ICD-10 Code: _____
☐ Other: _____ ICD-10 Code: _____

Does the member have somatostatin receptor-positive foregut, midgut, or hindgut GEP-NETs on all target lesions confirmed by gallium-68 dotatate PET/CT or somatostatin receptor scintigraphy? ☐ Yes ☐ No

Please select which applies to the member:
☐ the member has metastatic tumors
☐ the member has locally advanced and inoperable tumors

Does the member have low or intermediate grade NET (Ki-67 ≤ 20%)? ☐ Yes ☐ No

Has the member tried and failed Sandostatin LAR Depot? ☐ Yes ☐ No
If **YES**, did the member experience disease progression while on Sandostatin LAR Depot? ☐ Yes ☐ No

If approved, while on Lutathera treatment, will Sandostatin LAR Depot 30 mg will be administered intramuscularly between 4 to 24 hours after each Lutathera dose? ☐ Yes ☐ No

REAUTHORIZATION

How many doses of Lutathera has the patient received to date? _____

Has the member experienced a significant improvement with treatment? ☐ Yes ☐ No
Please describe:

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date