



Updated: 07/2024
Approved: 08/2024

Request for Prior Authorization for Lutathera (lutetium Lu 177 dotatate)

Website Form – www.wv.highmarkhealthoptions.com

Submit request via: Fax - 1-833-547-2030.

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:

- The member has ONE of the following:
 - A diagnosis of somatostatin-positive, gastroenteropancreatic neuroendocrine tumor (GEP-NETs) AND ALL of the following:
 - The member has locally advanced, inoperable, or metastatic carcinoid tumor; AND
 - Appropriate imaging study has been performed to document overexpression of somatostatin receptor of gastroenteropancreatic neuroendocrine tumor(s) (GEP-NETs) (i.e. somatostatin receptor scintigraphy; or 68-GaDotate PET/CT scan); AND
 - The tumor is well differentiated with a Ki-67 index of 20% or less as documented in a pathology report* AND
 - The member has received long-acting somatostatin analog (SSA therapy for a duration of at least 12 weeks) with disease progression noted during treatment; AND
 - Will discontinue long-acting somatostatin analog (e.g. octreotide LAR) for at least 4 weeks prior to initiating the requested agent, OR
 - Another FDA approved indication for the requested agent
- The member does NOT have any FDA labeled contraindications to the requested agent
- The member is 12 years of age or older
- The requested dose is within the FDA labeled dosing for the requested indication
- Must be prescribed by an Oncologist
- The member has adequate bone marrow, renal and hepatic function (the following would be contraindications: serum creatinine 1.7 mg/dL or creatinine clearance of 50 mL/minute; hemoglobin 8.0 g/dL; WBC < 2000/mm³; platelets < 75,000 mm³; total bilirubin > 3 x upper limit of normal)
- **Initial Duration of Approval:** 12 months; maximum of 4 doses per lifetime
- **Reauthorization criteria**
 - Treatment-related toxicities (e.g., anemia, hepatotoxicity, neutropenia, renal toxicity, thrombocytopenia) are resolved prior to re-starting the requested agent
- **Reauthorization Duration of Approval:** the member has NOT exceeded 4 treatment doses in a lifetime

* Well-differentiated neuroendocrine tumors include low grade (G1) and intermediate grade (G2) tumors, which correlate with a defined Ki-67 proliferation index, as determined by an immunohistochemical stain. Well-differentiated, low grade neuroendocrine tumors have a Ki-67 index of < 3%, and well-differentiated, intermediate grade neuroendocrine tumors have Ki-67 index of 3% to 20%.



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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.

**Lutathera (lutetium Lu 177 dotatate)
PRIOR AUTHORIZATION FORM**

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Highmark Health Options Pharmacy Services. **FAX: (833)-547-2030.**
If needed, you may call to speak to a Pharmacy Services Representative.
PHONE: (844) 325-6251 Monday through Friday 8:00am to 7:00pm

PROVIDER INFORMATION

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

MEMBER INFORMATION

Member Name:	DOB:
Member ID:	Member weight: Height:

REQUESTED DRUG INFORMATION

Medication:	Strength:
Directions:	Quantity: Refills:
Is the member currently receiving requested medication? <input type="checkbox"/> Yes <input type="checkbox"/> No Date Medication Initiated:	
Is this medication being used for a chronic or long-term condition for which the medication may be necessary for the life of the patient? <input type="checkbox"/> Yes <input type="checkbox"/> No	

Billing Information

This medication will be billed: at a pharmacy **OR** medically, 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: _____ ICD-10: _____
Does the member have somatostatin-positive, gastroenteropancreatic neuroendocrine tumor (GEP-NETs)? Please select all that apply:
 The member has locally advanced, inoperable, or metastatic carcinoid tumor
 Appropriate imaging study has been performed to document overexpression of somatostatin receptor of gastroenteropancreatic neuroendocrine tumor(s) (GEP-NETs) (i.e. somatostatin receptor scintigraphy; or 68-GaDotate PET/CT scan)
 The tumor is well differentiated with a Ki-67 index of 20% or less as documented in a pathology report*
 The member has received long-acting somatostatin analog (SSA therapy for a duration of at least 12 weeks) with disease progression noted during treatment
 Will discontinue long-acting somatostatin analog (e.g. octreotide LAR) for at least 4 weeks prior to initiating the requested agent
Does the member have any FDA labeled contraindications to the requested agent? Yes No
Does the member have adequate bone marrow, renal and hepatic function? Yes No

CURRENT or PREVIOUS THERAPY

Medication Name	Strength/ Frequency	Dates of Therapy	Status (Discontinued & Why / Current)

REAUTHORIZATION

Does the member have any treatment-related toxicities (e.g., anemia, hepatotoxicity, neutropenia, renal toxicity, thrombocytopenia) prior to re-starting the requested agent? Yes No
How many doses has the member received? 1 2 3 4

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date



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