HIGHMARK HEALTH OPTIONS

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 intermediategrade (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%.

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.

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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? ☐ Yes ☐ 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? ☐ Yes ☐ 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