HIGHMARK WHOLECARE

Updated: 04/2024
PARP Approved: 05/2024

Prior Authorization Criteria

Somatuline Depot (lanreotide acetate)

All requests for Somatuline Depot (lanreotide acetate) require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

For all requests the following criteria must be met in addition to the diagnosis specific criteria below:

- Must be 18 years of age or older
- Must be prescribed by or in consultation with an endocrinologist or oncologist
- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines

Coverage may be provided with a diagnosis of **acromegaly** and the following criteria is met:

- Must have had an inadequate response to surgery or radiotherapy, unless surgery and/or radiotherapy is not an option
- Documentation of **both** of the following:
  - Elevated serum IGF-1 level for member's gender and age range. Laboratory reference range must be provided.
  - Elevated growth hormone (GH) level defined as a GH level ≥1ng/mL following an oral glucose tolerance test (OGTT)
- **Initial Duration of Approval:** 6 months
- **Reauthorization criteria:**
  - Documentation of ALL of the following:
    - Chart documentation demonstrating clinical benefit and tolerance
    - IGF-1 level has decreased or stabilized since initiation of therapy
    - GH level has decreased or normalized since initiation of therapy
- **Reauthorization Duration of Approval:** 12 months

Coverage may be provided with a diagnosis of unresectable, well- or moderately-differentiated, locally advanced or metastatic **gastroenteropancreatic neuroendocrine tumors (GEP-NETs)**:

- **Initial Duration of Approval:** 6 months
- **Reauthorization criteria:**
  - Chart documentation demonstrating clinical benefit and tolerance
- **Reauthorization Duration of Approval:** 12 months

Coverage may be provided with a diagnosis of **carcinoid syndrome** when the following criteria is met:

- **Initial Duration of Approval:** 6 months
- **Reauthorization criteria**
  - Chart documentation demonstrating clinical benefit and tolerance
  - Member is showing a reduction in the frequency of short-acting somatostatin analog rescue therapy
- **Reauthorization Duration of approval:** 12 months

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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SOMATULINE DEPOT (LANREOTIDE)
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 Wholecare Pharmacy Services. **FAX:** (888) 245-2049
If needed, you may call to speak to a Pharmacy Services Representative. **PHONE**: (800) 392-1147 Mon – Fri 8:30am to 5:00pm

PROVIDER INFORMATION	
Requesting Provider:	Provider NPI:
Provider Specialty:	Office Contact:
State license #:	Office NPI:
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:	

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 Code:

For Acromegaly:

- Has the member had an inadequate response to surgery and/or radiotherapy? ☐ Yes ☐ No
- Does the member have an elevated IGF-1 level? ☐ Yes, *lab results attached* ☐ No
- Does the member have a growth hormone (GH) level ≥ 1mg/mL following an oral glucose tolerance test? ☐ Yes, *lab results attached* ☐ No

For GEP-NET:
Is it unresectable, well- or moderately-differentiated, locally advanced or metastatic? ☐ Yes ☐ No

REAUTHORIZATION
Has the member experienced clinical benefit and tolerance with treatment? ☐ Yes ☐ No
For acromegaly: Have the member's GH and IGF-1 level decreased or stabilized since initiation of therapy? ☐ Yes ☐ No
For carcinoid syndrome: Has there been a reduction in the frequency of short-acting somatostatin analog rescue therapy? ☐ Yes ☐ No

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date