

**HARVARD PILGRIM HEALTH CARE  
RECOMMENDED MEDICATION REQUEST GUIDELINES**

**LANREOTIDE (SOMATULINE DEPOT)**

Generic	Brand	HICL	GCN	Exception/Other
LANREOTIDE	SOMATULINE DEPOT	10781		

**GUIDELINES FOR USE**

1. Does the patient have a diagnosis of acromegaly?

If yes, continue to #2.

If no, continue to #5.

2. Is the request for a renewal?

If yes, continue to #4.

If no, continue to #3.

3. Does the patient meet **ALL** of the following conditions?

- Documentation of a high pre-treatment IGF-1 level for age and/or gender based on the laboratory reference range
- An inadequate or partial response to surgery or radiotherapy **OR** there is a clinical reason why the patient has not had radiotherapy or surgery, such as one of the following:
  - Medically unstable conditions (poor surgical candidate)
  - High risk for complications of anesthesia because of airway difficulties
  - Major systemic manifestations of acromegaly including cardiomyopathy, severe hypertension, and uncontrolled diabetes
  - Patient refuses surgery or prefers the medical option over surgery
  - Lack of an available skilled surgeon
  - Tumor cannot be localized

If yes, **approve for 12 months by HICL up to 120mg per 28 days.** [The quantity limit is hard-coded.] Please use status code #056 and the approval text provided.

**APPROVAL TEXT:** Your request for Somatuline Depot (lanreotide) has been approved for a quantity up to 120mg per 28 days for a 12-month period.

If no, do not approve. Please use status code #238 and the denial text provided:

**DENIAL TEXT:** Per your health plan's Somatuline Depot (lanreotide) guideline, this medication is only covered for the diagnosis of acromegaly for a patient who meets all of the following conditions:

- A high pre-treatment IGF-1 level for age and/or gender based on a submitted lab report
- An inadequate or partial response to surgery or radiotherapy **OR** there is a clinical reason why the patient has not had radiotherapy or surgery

Your provider did not indicate that you [**specify criteria not met**] and therefore your request was not approved.

**CONTINUED ON NEXT PAGE**

**HARVARD PILGRIM HEALTH CARE  
RECOMMENDED MEDICATION REQUEST GUIDELINES**

**LANREOTIDE (SOMATULINE DEPOT)**

**GUIDELINES FOR USE (CONTINUED)**

4. Is there documentation of an IGF-1 level that has decreased or normalized since initiation of therapy?

If yes, **approve for 12 months by HICL up to 120mg per 28 days.** [The quantity limit is hard-coded.] Please use status code #056 and the approval text provided.

**APPROVAL TEXT:** Your request for Somatuline Depot (lanreotide) has been approved for a quantity up to 120mg per 28 days for a 12-month period.

If no, do not approve. Please use status code #238 and the denial text provided:

**DENIAL TEXT:** Per your health plan's Somatuline Depot (lanreotide) guideline, authorization for renewal for the diagnosis of acromegaly requires documentation that your IGF-1 level has decreased or normalized since initiation of therapy. Your provider did not provide this information and therefore your request was not approved.

5. Does the patient have a diagnosis of neuroendocrine tumors (NETs)?

If yes, continue to #6.

If no, continue to #7.

6. Does the patient meet **ONE** of the following conditions?

- Tumors of the GI tract (carcinoid tumor)
- Tumors of the thymus (carcinoid tumor)
- Tumors of the lung (carcinoid tumor)
- Tumors of the pancreas
- Tumors of the adrenal gland

If yes, **approve for 12 months by HICL up to 120mg per 28 days.** [The quantity limit is hard-coded.] Please use status code #056 and the approval text provided.

**APPROVAL TEXT:** Your request for Somatuline Depot (lanreotide) has been approved for a quantity up to 120mg per 28 days for a 12-month period.

If no, do not approve. Please use status code #238 and the denial text provided.

**DENIAL TEXT:** Per your health plan's Somatuline Depot (lanreotide) guideline, this medication is only covered when prescribed for the diagnosis of Neuroendocrine Tumors (NETS) for a patient who meets one of the following conditions:

- Tumors of the GI tract (carcinoid tumor)
- Tumors of the thymus (carcinoid tumor)
- Tumors of the lung (carcinoid tumor)
- Tumors of the pancreas
- Tumors of the adrenal gland

Your provider did not indicate that you have one of these tumors and therefore your request was not approved.

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RECOMMENDED MEDICATION REQUEST GUIDELINES**

**LANREOTIDE (SOMATULINE DEPOT)**

**GUIDELINES FOR USE (CONTINUED)**

7. Does the patient have a diagnosis of carcinoid syndrome?

If yes, **approve for 12 months by HICL up to 120mg per 28 days.** [The quantity limit is hard-coded.] Please use status code #056 and the approval text provided.

**APPROVAL TEXT:** Your request for Somatuline Depot (lanreotide) has been approved for a quantity up to 120mg per 28 days for a 12-month period.

If no, do not approve. Please use status code #238 and the denial text provided.

**DENIAL TEXT:** Per your health plan's Somatuline Depot (lanreotide) guideline, this medication is only covered for patients with a diagnosis of acromegaly, neuroendocrine tumors (NETs), or carcinoid syndrome. Your provider did not indicate that you are being treated for one of these conditions and therefore your request was not approved.

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**RATIONALE**

Ensure appropriate utilization of Somatuline Depot for the treatment of acromegaly, carcinoid syndrome, and gastroenteropancreatic neuroendocrine tumors.

**FDA APPROVED INDICATIONS**

Somatuline Depot is indicated for:

- Acromegaly: Long-term treatment of acromegalic patients who have had an inadequate response to surgery and/or radiotherapy, or for whom surgery and/or radiotherapy is not an option.
- Gastroenteropancreatic neuroendocrine tumors: Treatment (to improve progression-free survival) of unresectable, well or moderately differentiated, locally advanced or metastatic gastroenteropancreatic neuroendocrine tumors (GEP-NETs).
- Carcinoid syndrome: Treatment of adults with carcinoid syndrome; when used, it reduces the frequency of short-acting somatostatin analog rescue therapy.

**REFERENCES**

- Somatuline Depot [package insert]. Basking Ridge, NJ: Ipsen Biopharmaceuticals, Inc.; February 2018.
- National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: <http://www.nccn.org>. Accessed February 8, 2018.
- Katznelson L, Laws ER, Melmed S, et al. Acromegaly: an endocrine society clinical practice guideline. *J Clin Endocrinol Metab.* 2014; 99(11):3933-51.
- American Association of Clinical Endocrinologists Acromegaly Guidelines Task Force. Medical guidelines for clinical practice for the diagnosis and treatment of acromegaly - 2011 update. *Endocr Pract.* 2011;17(suppl 4):1-44.
- The NCCN Clinical Practice Guidelines in Oncology® Neuroendocrine Tumors (Version 3.2017). <http://www.nccn.org>. Accessed February 8, 2018.
- Caplin ME, Pavel M, Cwikla JB, et al. Lanreotide in metastatic enteropancreatic neuroendocrine tumors. *N Engl J Med.* 2014; 371:224-33.

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