

Lanreotide (somatuline depot)
Effective 03/01/2026

Plan	<input type="checkbox"/> MassHealth UPPL <input checked="" type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit		<input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	Medical Benefit Pharmacy Benefit	Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 Fax: 844-403-1029
Exceptions	N/A		

Overview

FDA-Approved Indications

1. Long-term treatment of acromegalic patients who have had an inadequate response to or cannot be treated with surgery and/or radiotherapy.
2. Treatment of adult patients with unresectable, well- or moderately-differentiated, locally advanced or metastatic gastroenteropancreatic neuroendocrine tumors (GEP-NETs) to improve progression-free survival.
3. Treatment of adults with carcinoid syndrome; when used, it reduces the frequency of short-acting somatostatin analog rescue therapy.

Compendial Uses

1. Neuroendocrine tumors (NETs):
 - a. Tumors of the gastrointestinal (GI) tract, lung, and thymus (carcinoid tumors)
 - b. Tumors of the pancreas (islet cell tumors)
 - c. Well-differentiated grade 3 NETs with favorable biology
2. Pheochromocytoma and paraganglioma
3. Zollinger-Ellison syndrome

Coverage Guidelines

Authorization may be granted for members new to the plan within the past 90 days who are currently receiving treatment with the requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

OR

Requests will be approved when the following diagnosis specific criteria are met:

Acromegaly

1. Diagnosis of acromegaly
2. Submission of laboratory report indicating member has a high pretreatment insulin-like growth factor-1 (IGF-1) level for age and/or gender based on the laboratory reference range.
3. Submission of chart notes indicating ONE of the following:
 - a. Member has an inadequate or partial response to surgery or radiotherapy

- b. Clinical reason why the member has not had surgery or radiotherapy.

Neuroendocrine Tumors

- 1. One of the following diagnoses:
 - a. Tumors of the gastrointestinal (GI) tract (carcinoid tumor)
 - b. Tumors of the thymus (carcinoid tumor)
 - c. Tumors of the lung (carcinoid tumor)
 - d. Tumors of the pancreas (islet cell tumors), including gastrinomas, glucagonomas, insulinomas, and VIPomas
 - e. Well-differentiated grade 3 Neuroendocrine tumors (NETs) with favorable biology (e.g., relatively low Ki-67 [less than 55%], somatostatin receptor [SSR] positive imaging)
 - f. Gastroenteropancreatic neuroendocrine tumors (GEP-NETs)

Carcinoid Syndrome

- 1. Diagnosis of carcinoid syndrome

Pheochromocytoma and Paranglioma

- 1. One of the following diagnoses:
 - a. Pheochromocytoma
 - b. Paranglioma

Zollinger-Ellison Syndrome

- 1. Diagnosis of Zollinger-Ellison syndrome.

All oncology criteria will be reviewed against Oncology Medication Review - NCCN guidelines with a Category of Evidence and Consensus of 1, 2A, or 2B.

Continuation of Therapy

Requests for reauthorization will be approved when the following diagnosis-specific criteria are met:

Acromegaly

- 1. Submission of laboratory reports or chart notes indicating the member’s IGF-1 level has decreased or normalized since initiation of therapy.

All Other Diagnoses:

- 1. Member is experiencing clinical benefit as evidenced by improvement or stabilization in clinical signs and symptoms since starting therapy.

Limitations

- 1. Initial approvals and reauthorizations will be granted for 12 months.
- 2. The following quantity limitations apply:

Drug Name and Dosage Form	Quantity Limit
Lanreotide (somatuline depot) prefilled syringe	1 syringe per 28 days



References

1. 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.
2. Caplin ME, Pavel M, Cwikla JB, et al. Lanreotide in metastatic enteropancreatic neuroendocrine tumors. *N Engl J Med.* 2014;371:224-233.
3. Katznelson L, Laws ER, Melmed S, et al. Acromegaly: an endocrine society clinical practice guideline. *J Clin Endocrinol Metab.* 2014;99:3933-3951.
4. Lanreotide Injection [prescribing information]. Warren, NJ: Cipla USA, Inc.; September 2024.
5. Somatuline Depot [package insert]. Signes, France: Ipsen Biopharmaceuticals, Inc.; July 2024.

Review History

12/13/2023 - Reviewed at December P&T, switched from SGM to Custom. Effective 1/1/2024

10/08/2025 – Reviewed and updated at October P&T. Updated policy to indicate it no longer applies to the medical benefit. Effective 01/01/2026.

02/11/2026 – Reviewed at February P&T. Added neuroendocrine tumors, carcinoid syndrome, pheochromocytoma and paraganglioma to the policy. Added quantity limitation. Effective 03/01/2026.

