Reference number(s)
2092-A

Specialty Guideline Management lanreotide injection-Somatuline Depot

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Somatuline Depot	lanreotide acetate

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications[1,7]

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

Compendial Uses[2,5]

- Neuroendocrine tumors (NETs):
  - Tumors of the gastrointestinal (GI) tract, lung, and thymus (carcinoid tumors)
  - Tumors of the pancreas (islet cell tumors)
  - Gastroenteropancreatic neuroendocrine tumors (GEP-NETs)

- Pheochromocytoma and paraganglioma
- Zollinger-Ellison syndrome

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review for acromegaly:

- For initial approval: Laboratory report indicating high pretreatment insulin-like growth factor-1 (IGF-1) level and chart notes indicating an inadequate or partial response to surgery or radiotherapy or a clinical reason for not having surgery or radiotherapy.
- For continuation: Laboratory report indicating normal current IGF-1 levels or chart notes indicating that the member's IGF-1 level has decreased or normalized since initiation of therapy.

Coverage Criteria

Acromegaly[1,3,4,7]

Authorization of 12 months may be granted for the treatment of acromegaly when all of the following criteria are met:

- Member has a high pretreatment IGF-1 level for age and/or gender based on the laboratory reference range.
- Member had an inadequate or partial response to surgery or radiotherapy OR there is a clinical reason why the member has not had surgery or radiotherapy.

Neuroendocrine Tumors (NETs)[1,2,5,6,7]

- Authorization of 12 months may be granted for treatment of NETs of the gastrointestinal (GI) tract, lung and thymus (carcinoid tumors).
- Authorization of 12 months may be granted for treatment of NETs of the pancreas (islet cell tumors), including gastrinomas, glucagonomas, insulinomas, and VIPomas.
- Authorization of 12 months may be granted for treatment of gastroenteropancreatic neuroendocrine tumors (GEP-NETs).

Carcinoid Syndrome[1,2,5,7]

Authorization of 12 months may be granted for treatment of carcinoid syndrome.

Pheochromocytoma and Paraganglioma[2]

Authorization of 12 months may be granted for treatment of pheochromocytoma and paraganglioma.

Zollinger-Ellinson Syndrome[5]

Authorization of 12 months may be granted for treatment of Zollinger-Ellison syndrome.

Continuation of Therapy

Acromegaly

Authorization of 12 months may be granted for continuation of therapy for acromegaly when the member's IGF-1 level has decreased or normalized since initiation of therapy.

NETs, Carcinoid Syndrome, Pheochromocytoma/Paraganglioma, and Zollinger-Ellison Syndrome

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization when the member is experiencing clinical benefit as evidenced by improvement or stabilization in clinical signs and symptoms since starting therapy.

References

1. Somatuline Depot [package insert]. Cambridge, MA: Ipsen Biopharmaceuticals, Inc.; July 2024.
2. The NCCN Drugs & Biologics Compendium® © 2024 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed November 8, 2024.
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. 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.
5. The NCCN Clinical Practice Guidelines in Oncology® Neuroendocrine and Adrenal Tumors (Version 2.2024). © 2024 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed November 8, 2024.
6. Caplin ME, Pavel M, Cwikla JB, et al. Lanreotide in metastatic enteropancreatic neuroendocrine tumors. N Engl J Med. 2014;371:224-233.
7. Lanreotide Injection [package insert]. Warren, NJ: Cipla USA, Inc.; September 2024.