Reference number
2092-A

SPECIALTY GUIDELINE MANAGEMENT

SOMATULINE DEPOT (lanreotide acetate injection)
LANREOTIDE INJECTION (lanreotide acetate injection)

POLICY

I. 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.

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

   2. Lanreotide Injection
      a. Long-term treatment of acromegalic patients who have had an inadequate response to or cannot be treated with surgery and/or radiotherapy.
      b. Treatment of adult patients with unresectable, well- or moderately-differentiated, locally advanced or metastatic gastroenteropancreatic neuroendocrine tumors (GEP-NETs) to improve progression-free survival.

B. 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

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

II. DOCUMENTATION

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

III. CRITERIA FOR INITIAL APPROVAL

A. Acromegaly

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

1. Member has a high pretreatment IGF-1 level for age and/or gender based on the laboratory reference range.
2. 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.

B. Neuroendocrine tumors (NETs)

1. Tumors of the gastrointestinal (GI) tract (carcinoid tumor)
   Authorization of 12 months may be granted for treatment of locoregional advanced or metastatic NETs of the GI tract or unresected primary gastrinoma.
2. Tumors of the thymus (carcinoid tumor)
   Authorization of 12 months may be granted for treatment unresectable or metastatic of NETs of the thymus.
3. Tumors of the lung (carcinoid tumor)
   Authorization of 12 months may be granted for treatment of unresectable or metastatic NETs of the lung.
4. Tumors of the pancreas (islet cell tumors)
   Authorization of 12 months may be granted for treatment of NETs of the pancreas, including gastrinomas, glucagonomas, insulinomas, and VIPomas.
5. Well-differentiated grade 3 NETs with favorable biology
   Authorization of 12 months may be granted for treatment of well-differentiated grade 3 unresectable locally advanced or metastatic NETs (not of gastroenteropancreatic origin) with favorable biology (e.g., relatively low Ki-67 [less than 55%], somatostatin receptor [SSR] positive imaging)
6. Gastroenteropancreatic neuroendocrine tumors (GEP-NETs)
   Authorization of 12 months may be granted for treatment of unresectable, well- or moderately-differentiated, locally advanced or metastatic GEP-NETs.

C. Carcinoid syndrome

Authorization of 12 months may be granted for treatment of carcinoid syndrome when it is used in any of the following clinical settings:

1. As a single agent.
2. In combination with telotristat for persistent diarrhea due to poorly controlled carcinoid syndrome.
3. In combination with other systemic therapy options for persistent symptoms such as flushing or diarrhea, or for progressive disease.

D. Pheochromocytoma and paraganglioma

Authorization of 12 months may be granted for treatment of locally unresectable or metastatic pheochromocytoma and paraganglioma.

E. Zollinger-Ellison syndrome

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

IV. CONTINUATION OF THERAPY

A. 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.

B. Carcinoid syndrome 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.

C. All other indications
Members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

V. REFERENCES

1. Somatuline Depot [package insert]. Cambridge, MA: Ipsen Biopharmaceuticals, Inc.; June 2019.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org. Accessed November 3, 2021.
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 3.2021). © 2021 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed November 3, 2021.
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.; December 2021.