Reference number(s)
2750-A

STANDARD MEDICARE PART B 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. NETs of the gastrointestinal (GI) tract, lung, and thymus (carcinoid tumors)
   b. NETs of the pancreas (islet cell tumors)
   c. Well-differentiated grade 3 NETs with favorable biology
2. Pheochromocytoma/paraganglioma
3. Hepatocellular carcinoma
4. Thyroid carcinoma
5. Thyroid stimulating hormone (TSH)-secreting pituitary adenoma
6. Uterine leiomyoma
7. Zollinger-Ellison syndrome

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. DOCUMENTATION

The following documentation must be available, upon request, for all submissions 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 insulin-like growth factor-1 (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. Carcinoid syndrome

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

C. Neuroendocrine tumors (NETs)

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

D. Pheochromocytoma and paraganglioma

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

E. Hepatocellular carcinoma

Authorization of 12 months may be granted for treatment of hepatocellular carcinoma.

F. Thyroid carcinoma

Authorization of 12 months may be granted for treatment of thyroid carcinoma.

G. Thyroid stimulating hormone (TSH)-secreting pituitary adenoma

Authorization of 12 months may be granted for treatment of TSH-secreting pituitary adenoma.

H. Uterine leiomyoma

Authorization of 12 months may be granted for treatment of uterine leiomyoma.

I. Zollinger-Ellison syndrome

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

IV. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

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

A. The member is currently receiving therapy with the requested medication.
B. The requested medication is being used to treat an indication enumerated in Section III.
C. The member is receiving benefit from therapy. Benefits are defined as:
    1. Acromegaly: decreased or normalized IGF-1 level since initiation of therapy.
    2. All other indications: improvement or stabilization of clinical signs and symptoms since initiation of therapy.

V. REFERENCES

1. Somatuline Depot [package insert]. Basking Ridge, NJ: Ipsen Biopharmaceuticals, Inc.; June 2019.
2. Lanreotide injection [package insert]. Warren, NJ: Cipla USA, Inc.; December 2021.
3. IBM Micromedex® DRUGDEX® (electronic version). Micromedex Truven Health Analytics, Greenwood Village, Colorado, USA. Available at: https://www.micromedexsolutions.com [available with subscription]. Accessed November 9, 2022.
4. The NCCN Drugs & Biologics Compendium® © 2022 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed November 9, 2022.
5. The NCCN Clinical Practice Guidelines in Oncology® Neuroendocrine and Adrenal Tumors (Version 1.2022). © 2022 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed November 9, 2022.
6. Katznelson L, Laws ER, Melmed S, et al. Acromegaly: an endocrine society clinical practice guideline. *J Clin Endocrinol Metab.* 2014;99:3933-3951.
7. 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.
8. Caplin ME, Pavel M, Cwikla JB, et al. Lanreotide in metastatic enteropancreatic neuroendocrine tumors. *N Engl J Med.* 2014;371:224-233.

