Reference number(s)
2750-A

STANDARD MEDICARE PART B MANAGEMENT

SOMATULINE DEPOT (lanreotide)

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. 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.
   2. Treatment of 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.

B. Compendial Uses
   1. Neuroendocrine tumors (NETs):
      a. NETs of the gastrointestinal (GI) tract, lung, and thymus (carcinoid tumors) or unresected primary gastrinoma
      b. NETs of the pancreas
   2. Pheochromocytoma/paraganglioma
   3. Hepatocellular carcinoma
   4. Thyroid carcinoma
   5. Pituitary adenoma
   6. Uterine leiomyoma

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:

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, thymus (carcinoid tumors) or unresected primary gastrinoma.
2. Authorization of 12 months may be granted for treatment of NETs of the pancreas.

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. Pituitary adenoma
Authorization of 12 months may be granted for treatment of pituitary adenoma.

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

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:
1. The member is currently receiving therapy with Somatuline Depot.
2. Somatuline Depot is being used to treat an indication enumerated in Section II.
3. The member is receiving benefit from therapy.

V. REFERENCES

1. Somatuline Depot [package insert]. Basking Ridge, NJ: Ipsen Biopharmaceuticals, Inc.; April 2019.
2. IBM Micromedex® DRUGDEX® (electronic version). IBM Watson Health, Greenwood Village, Colorado. Updated periodically. https://www.micromedexsolutions.com [available with subscription]. Accessed November 13, 2020.
3. The NCCN Drugs & Biologics Compendium® © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed November 13, 2020.

4. The NCCN Clinical Practice Guidelines in Oncology® Neuroendocrine and Adrenal Tumors (Version 1.2019). © 2020 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed November 13, 2020.
5. Katznelson L, Laws ER, Melmed S, et al. Acromegaly: an endocrine society clinical practice guideline. *J Clin Endocrinol Metab.* 2014;99:3933-3951.
6. 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.