Reference number
2092-A

SPECIALTY GUIDELINE 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. Somatuline Depot is indicated for the 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. Somatuline Depot is indicated for the treatment of patients with unresectable, well- or moderately-differentiated, locally advanced or metastatic gastroenteropancreatic neuroendocrine tumors (GEP-NETs) to improve progression-free survival.
3. Somatuline Depot is indicated for the treatment of adults with carcinoid syndrome; when used, it reduces the frequency of short-acting somatostatin analog rescue therapy.

B. Compendial Uses
Neuroendocrine tumors (NETs):
1. Tumors of the gastrointestinal (GI) tract, lung, and thymus (carcinoid tumors)
2. Tumors of the pancreas

All other indications are considered experimental/investigational and are not a covered benefit.

II. 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. Neuroendocrine tumors (NETs)
1. Tumors of the gastrointestinal (GI) tract (carcinoid tumor)
Authorization of 12 months may be granted for treatment of NETs of the GI tract.
2. Tumors of the thymus (carcinoid tumor)
Authorization of 12 months may be granted for treatment of NETs of the thymus.
3. Tumors of the lung (carcinoid tumor)
Authorization of 12 months may be granted for treatment of NETs of the lung.
4. Tumors of the pancreas
Authorization of 12 months may be granted for treatment of NETs of the pancreas.

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

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

IV. REFERENCES

1. Somatuline Depot [package insert]. Basking Ridge, NJ: Ipsen Biopharmaceuticals, Inc.; December 2018.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org. Accessed January 29, 2019.
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 4.2018). © 2019 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed January 29, 2019.
6. Caplin ME, Pavel M, Cwikla JB, et al. Lanreotide in metastatic enteropancreatic neuroendocrine tumors. *N Engl J Med.* 2014;371:224-233.