

Effective date: 04/01/2022
Review date:12/2021, 06/2022, 2/2023`
Scope: Medicaid, Commercial, Medicare-Medicaid Plan (MMP)

SPECIALTY GUIDELINE MANAGEMENT

SOMATULINE DEPOT (lanreotide) NON-ONCOLOGY

POLICY

Policy Statement:

Somatuline Depot (lanreotide) is covered under the Pharmacy Benefit for Medicaid members and covered under the Medical Benefit for Commercial and MMP members when used within the following guidelines. Use outside of these guidelines may result in non-payment unless approved under an exception process.

I. INDICATIONS

FDA-Approved Indications

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.

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.
3. MMP members who have previously received this medication within the past 365 days are not subject to StepTherapy Requirements

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.

IV. DOSAGE/ADMINISTRATION

Indication	Dose
Acromegaly	<ul style="list-style-type: none"> • Recommended starting dose is 90 mg by deep subcutaneous injection every 4 weeks for 3 months, adjusted thereafter based on GH and/or IGF-1 levels: <ul style="list-style-type: none"> ○ GH >1 to ≤ 2.5 ng/mL, IGF-1 normal and clinical symptoms controlled: maintain Somatuline Depot dose at 90 mg every 4 weeks ○ GH > 2.5 ng/mL, IGF-1 elevated and/or clinical symptoms uncontrolled, increase Somatuline Depot dose to 120 mg every 4 weeks ○ GH ≤ 1 ng/mL, IGF-1 normal and clinical symptoms controlled: reduce Somatuline Depot dose to 60 mg every 4 weeks

Effective date: 04/01/2022
Review date:12/2021, 06/2022, 2/2023`
Scope: Medicaid, Commercial, Medicare-Medicaid Plan (MMP)

V. The following HCPCS/CPT code is:

HCPCS/CPT code	Description
J1930	Injection, lanreotide, 1mg; 1 billable unit = 1mg

VI. REFERENCES

1. Somatuline Depot [package insert]. Basking Ridge, NJ: Ipsen Biopharmaceuticals, Inc.;April 2022.
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.