Effective date: 04/01/2022
Review date:12/2021, 06/2022, 2/2023, 01/2024, 05/2024, 12/2024 Commercial, Medicare-Medicaid Plan (MMP)

SPECIALTY GUIDELINE MANAGEMENT

SOMATULINE DEPOT (LANREOTIDE) NON-ONCOLOGY POLICY

I. INDICATIONS

FDA-Approved Indications

Somatuline Depot (lanreotide) 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. 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. SUMMARY OF EVIDENCE

Somatuline Depot (lanreotide) is a somatostatin analog indicated for long term treatment of acromegalic patients who cannot be treated with radiotherapy. The effect of Somatuline depot to reduce GH and IGF-levels in patients with acromegaly was studied in one long term study, Study 1. Study 1 included a 4-week, double blind, placebo controlled, phase, a 16-week single blind, fixed dose phase and a 32-week, open label, dose-titration phase. Patients were randomized to receive Somatuline Depot 60 mg, 90 mg, or 120 mg or placebo. Four weeks later, patients entered a fixed dose phase where they received 4 injections of Somatuline Depot followed by a dose-titration phase of 8 injections for a total of 13 injections over 52 weeks. In the double-blind phase of study 1, a total of 52 (63%) of the 83 lanreotide-treated patients had a > 50% decrease in mean GH from baseline to Week 4, including 52%, 44%, and 90% of patients in the 60 mg, 90 mg, and 120 mg groups, respectively, compared to placebo (0%, 0/25). In the fixed-dose phase at Week 16, 72% of all 107 lanreotide-treated patients had a decrease from baseline in mean GH of > 50%, including 68% (23/34), 64% (23/36), and 84% (31/37) of patients in the 60 mg, 90 mg, and 120 mg lanreotide treatment groups, respectively. Adverse effects include abdominal pain, musculoskeletal pain, vomiting, headache, injection site reaction, hyperglycemia, hypertension, and cholelithiasis

IV. 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. If the member is requesting Somatuline Depot, they must have an inadequate treatment response, intolerance or contraindication to lanreotide.

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

V. 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.

VI. DOSAGE/ADMINISTRATION

Indication	Dose
Acromegaly	• 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: o GH >1 to ≤ 2.5 ng/mL, IGF-1 normal and clinical symptoms controlled: maintain Somatuline Depot dose at 90 mg every 4 weeks o GH > 2.5 ng/mL, IGF-1 elevated and/or clinical symptoms uncontrolled, increase Somatuline Depot dose to 120 mg every 4 weeks o GH ≤ 1 ng/mL, IGF-1 normal and clinical symptoms controlled: reduce Somatuline Depot dose to 60 mg every 4 weeks

Investigational use: All therapies are considered investigational when used at a dose or for a condition other than those that are recognized as medically accepted indications as defined in any one of the following standard reference compendia: American Hospital Formulary Service Drug information (AHFS-DI), Thomson Micromedex DrugDex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs, or Peer-reviewed published medical literature indicating that sufficient evidence exists to support use. Neighborhood does not provide coverage for drugs when used for investigational purposes.

Applicable Codes:
Below is a list of billing codes applicable for covered treatment options. The below tables are provided for reference purposes and may not be all inclusive. Requests received with codes from tables below do not guarantee coverage. Requests must meet all criteria provided in the procedure section.

The following HCPCS/CPT code is:

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

Per §§ 42 CFR 422.101, this clinical medical policy only applies to INTEGRITY in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD)

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Policy Rationale:
Somatuline Depot (lanreotide) was reviewed by the Neighborhood Health Plan of Rhode Island Pharmacy & Therapeutics (P&T) Committee. Neighborhood adopted the following clinical coverage criteria to ensure that its members use Somatuline Depot according to Food and Drug Administration (FDA) approved labeling and/or relevant clinical literature. Neighborhood worked with network prescribers and pharmacists to draft these criteria. These criteria will help ensure its members are using this drug for a medically accepted indication, while minimizing the risk for adverse effects and ensuring more cost-effective options are used first, if applicable and appropriate. For INTEGRITY (Medicare-Medicaid Plan) members, these coverage criteria will only apply in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD) criteria. Neighborhood will give individual consideration to each request it reviews based on the information submitted by the prescriber and other information available to the plan.

VII. REFERENCES

1. Somatuline Depot [package insert]. Basking Ridge, NJ: Ipsen Biopharmaceuticals, Inc.; November2023. Accessed May 2024.
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.