Clinical Policy: Lanreotide (Somatuline Depot)

Reference Number: PA.CP.PHAR.391
Effective Date: 10/2018
Last Review Date: 10/2022

Coding Implications
Revision Log

Description
Lanreotide (Somatuline® Depot) is a somatostatin analog.

FDA Approved Indication(s)
Somatuline Depot is indicated for:

- Long-term treatment of acromegalic patients who have had an inadequate response to or cannot be treated with surgery and/or radiotherapy
- Treatment of adult patients with unresectable, well- or moderately-differentiated, locally advanced or metastatic gastroenteropancreatic neuroendocrine tumors (GEP-NETs) to improve progression-free survival
- Treatment of adults with carcinoid syndrome; when used, it reduces the frequency of short-acting somatostatin analog rescue therapy

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of PA Health & Wellness® that Somatuline Depot is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Acromegaly (must meet all)**:**

1. Diagnosis of acromegaly as evidenced by one of the following (a or b):
   a. Pre-treatment insulin-like growth factor-I (IGF-I) level above the upper limit of normal based on age and gender for the reporting laboratory;
2. Serum growth hormone (GH) level ≥ 1 µg/mL after a 2-hour oral glucose tolerance test;Prescribed by or in consultation with an endocrinologist;
3. Age ≥ 18 years;
4. Inadequate response to surgical resection or pituitary irradiation (*see Appendix D*), or member is not a candidate for such treatment;
5. Dose does not exceed 120 mg every 4 weeks.

Approval duration: 6 months

B. Carcinoid Syndrome (must meet all)**:**

1. Diagnosis of carcinoid syndrome (associated with NETs of the gastrointestinal tract, lung, and thymus, otherwise known as carcinoid tumors);
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Request meets one of the following (a or b):
   a. Dose does not exceed 120 mg every 4 weeks;

b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 6 months

C. Neuroendocrine Tumors (must meet all)**:**

1. Diagnosis of one of the following (a, b, c, or d):
   a. GEP-NET (*see Appendix D for tumor types*), and:
      i. If insulinoma, disease is somatostatin receptor (SSTR)-positive;
   b. Pheochromocytoma or paraganglioma (adrenal NETs);
   c. One of the following NETs which is SSTR-positive or has hormonal symptoms (i, ii, or iii):
      i. Thymic NET;
      ii. Bronchopulmonary NET;
      iii. Grade 3 NET with favorable biology (i.e., relatively low Ki-67 [< 55%] or SSTR-positive);
   d. Multiple lung nodules or tumorlets and evidence of diffuse idiopathic pulmonary neuroendocrine cell hyperplasia (DIPNECH) and one of the following (i or ii):
      i. SSTR-positive;
      ii. Chronic cough/dyspnea is not responsive to inhalers as primary therapy;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Request meets one of the following (a or b):
   a. Dose does not exceed 120 mg every 4 weeks;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 6 months

D. Other diagnoses/indications

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53.

II. Continued Therapy

A. Acromegaly (must meet all)**:**

1. Currently receiving medication via PA Health & Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy (*see Appendix D*);
3. If request is for a dose increase, request meets one of the following (a or b):
   a. New dose does not exceed 120 mg every 4 weeks.
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 12 months

B. Carcinoid Syndrome and Neuroendocrine Tumors (must meet all)**:**
1. Currently receiving medication via PA Health & Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies;
2. If request is for a dose increase, request meets one of the following (a or b):
   a. New dose does not exceed 120 mg every 4 weeks.
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 12 months

C. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via PA Health & Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – PA.CP.PMN.53 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
GEP: gastroenteropancreatic
GH: growth hormone
IGF-I: insulin-like growth factor
NET: neuroendocrine tumors
SSTR: somatostatin receptor

Appendix B: Therapeutic Alternatives
Not applicable

Appendix C: Contraindications/Boxed Warnings
- Contraindication(s): hypersensitivity to lanreotide
- Boxed warning(s): none reported

Appendix D: General Information
- Response to acromegaly therapy (e.g., somatostatin analogs, surgical resection, pituitary irradiation) may include:
  - Improved growth hormone (GH) or insulin-like growth factor (IGF-1) serum concentrations
  - Improved tumor mass control
- NCCN guidelines - Neuroendocrine and Adrenal Tumors

- GEP-NETs
  - Gastrointestinal tract tumors include the appendix, stomach, colon and rectum, duodenum, gastric, jejunum and ileum.
  - Pancreatic tumors include insulinoma, gastrinoma, VIPoma (vasoactive intestinal polypeptide), glucagonoma.
    - For patients with insulinoma, lanreotide should be considered only if the tumor expresses SSTR.
- Patients experiencing disease progression on lanreotide should continue treatment with lanreotide if the tumor is functional. Lanreotide may be used in combination with other systemic therapy options.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Acromegaly	Initial: 90 mg SC every 4 weeks for 3 months Maintenance: 90 to 120 mg SC every 4 weeks Dose should be adjusted according to reduction in serum GH or IGF-1 levels and/or changes in symptoms.	Maintenance: 120 mg every 4 weeks
GEP-NETs, carcinoid syndrome	120 mg SC every 4 weeks If patients are being treated with Somatuline Depot for both GEP-NET and carcinoid syndrome, do not administer an additional dose	120 mg every 4 weeks

**Intended for administration by a healthcare provider*

VI. Product Availability

Single-dose prefilled syringes: 60 mg/0.2 mL, 90 mg/0.3 mL, 120 mg/0.5 mL

VII. References

1. Somatuline Depot Prescribing Information. Signes, France: Ipsen Pharma Biotech; June 2019. Available at: http://www.somatulinedepot.com. Accessed July 20, 2022.
2. Melmed S, Bronstein MD, Chanson P. A Consensus Statement on acromegaly therapeutic outcomes. Nat Rev Endocrinol. 2018 Sep;14(9):552-561. doi: 10.1038/s41574-018-0058-5.
3. Katznelson L, Laws Jr. ER, Melmed S, et al. Acromegaly: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab. 2014;99:3933-3951.
4. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed July 20, 2022.
5. National Comprehensive Cancer Network. Neuroendocrine and Adrenal Tumors Version 1.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/neuroendocrine.pdf. Accessed July 20, 2022.

6. Fleseriu M, Biller BMK, Freda PU, et al. A Pituitary Society update to acromegaly management guidelines. Pituitary. 2021; 24: 1-13.
7. Guistina A, Barkhoudarian G, Beckers A, et al. Multidisciplinary management of acromegaly: A consensus. Rev Endocr Metab Disord. 2020; 21(4): 667-678.

Coding Implications
Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J1930	Injection, lanreotide, 1 mg

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	10/2018	
4Q 2019 annual review: No changes per Statewide PDL implementation 01-01-2020	10/2019	
4Q 2020 annual review: NET criteria consolidated into one section - off-label pheochromocytoma added; somatostatin receptor positive imaging and/or hormonal symptoms removed to include other uses per NCCN; examples of tumor types added to criteria and appendix D; references reviewed and updated.	08/2020	
4Q 2021 annual review: no significant changes; references reviewed and updated.	10/2021	
4Q 2022 annual review: for acromegaly, added confirmatory diagnostic requirements (IGF-I or GH) per PS/ES practice guidelines; per NCCN, specified that thymic/ bronchopulmonary NETs and insulinomas must be SSTR-positive or have hormonal symptoms and added that any grade 3 NETs with favorable biology are also coverable; references reviewed and updated.	10/2022	