Clinical Policy: Lanreotide (Somatuline Depot)

Reference Number: PA.CP.PHAR.391
Effective Date: 10.17.18
Last Review Date: 10.17.18

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 health plans affiliated with 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;
2. Prescribed by or in consultation with an endocrinologist;
3. Inadequate response to surgical resection or pituitary irradiation (*see Appendix D*), or member is not a candidate for such treatment;
4. 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 carcinoid tumors;
2. Prescribed by or in consultation with an oncologist;
3. Dose does not exceed 120 mg every 4 weeks.

Approval duration: 6 months

C. Gastroenteropancreatic Neuroendocrine Tumors (must meet all)**:**
1. Diagnosis of GEP-NETs;
2. Prescribed by or in consultation with an oncologist;
3. 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. Thymic and Bronchopulmonary Neuroendocrine Tumors (off-label) (must meet all)**:**

1. Diagnosis of neuroendocrine tumors of one of the following (a or b):
   a. Thymic disease that is unresectable, incompletely resected, or metastatic;
   b. Bronchopulmonary disease that is unresectable or metastatic;
2. Prescribed by or in consultation with an oncologist;
3. Meets one of the following (a, b, or c):
   a. Nonmetastatic low grade (typical) in histology and used without radiation;
   b. Nonmetastatic intermediate grade (atypical) in histology;
   c. Advanced disease and/or distant metastases, with somatostatin receptor positive imaging and/or hormonal symptoms;
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

E. 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 Pennsylvania Health and 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, new dose does not exceed 120 mg every 4 weeks.

Approval duration: 12 months

B. All Other Indications in Section I (must meet all)**:**

1. Currently receiving medication via Pennsylvania Health and 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 Pennsylvania Health and 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-NETs: gastroenteropancreatic neuroendocrine tumors

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

- Examples of response to acromegaly therapy (including somatostatin analogs, surgical resection or pituitary irradiation) include improvement from baseline in or normalization of growth hormone (GH) and/or age- and sex-adjusted insulin-like growth factor (IGF-1) serum concentrations, or tumor mass control.

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	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; February 2018. Available at: https://www.ipsenus.com/pdfs/Somatuline_Depot_Full_Prescribing_Information.pdf. Accessed August 14, 2018.
2. Melmed S, Colao A, Barkan A, et al. Guidelines for acromegaly management: An update. J Clin Endocrinol Metab; 2009; 94:1509-1517.
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. Katznelson L, Atkinson JLD, Cook DM, Ezzat SZ, Hamrahian AH, Miller KK. American Association of Clinical Endocrinologists medical guidelines for clinical practice for the diagnosis and treatment of acromegaly – 2011 update. Endocrine Practice. 2011;17(Suppl 4).
5. National Comprehensive Cancer Network. Neuroendocrine and Adrenal Tumors Version 2.2018. Available at: https://www.nccn.org/professionals/physician_gls/pdf/neuroendocrine.pdf. Accessed August 14, 2018.

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	10/18	