Clinical Policy: Lanreotide (Somatuline Depot)

Reference Number: ERX.SPA.272
Effective Date: 12.01.18
Last Review Date: 11.21
Line of Business: Commercial, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

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.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ 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. 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*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

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*);
   b. Thymic NET;
   c. Bronchopulmonary NET;
   d. Pheochromocytoma or paraganglioma (adrenal NETs);
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*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 6 months

D. Other diagnoses/indications
1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Acromegaly (must meet all)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
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. Carcinoid Syndrome and Neuroendocrine Tumors (must meet all)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions, or documentation supports that member is currently receiving Somatuline Depot for a covered indication and has received this medication for at least 30 days;
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*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 12 months

C. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
GEP: gastroenteropancreatic
NET: neuroendocrine tumor

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, somatostatinoma.
  - 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 August 11, 2021.
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 August 11, 2021.
5. National Comprehensive Cancer Network. Neuroendocrine and Adrenal Tumors Version 3.2021. Available at: https://www.nccn.org/professionals/physician_gls/pdf/neuroendocrine.pdf. Accessed August 11, 2021.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	08.14.18	11.18
4Q 2019 annual review: bronchopulmonary/thymic NETs: simplified I.D.1 to "unresectable or metastatic bronchopulmonary/thymic NET" and modified I.D.4 to only require somatostatin receptor positive imaging and/or hormonal symptoms per NCCN compendium; references reviewed and updated.	08.27.19	11.19
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.	08.11.20	11.20
4Q 2021 annual review: no significant changes; references reviewed and updated.	08.11.21	11.21

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.