

Clinical Policy: Lanreotide (Somatuline Depot and Unbranded)

Reference Number: PA.CP.PHAR.391

Effective Date: 10/2018

Last Review Date: 10/2023

[Coding Implications](#)
[Revision Log](#)

Description

Lanreotide (Somatuline® Depot) and unbranded lanreotide are somatostatin analogs.

FDA Approved Indication(s)

Somatuline Depot and unbranded lanreotide are 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
- Somatuline Depot is additionally indicated for:
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 lanreotide 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;
 - b. Serum growth hormone (GH) level ≥ 1 $\mu\text{g/mL}$ after a 2-hour oral glucose tolerance test;
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. Request is for either Somatuline Depot or unbranded lanreotide;
6. Failure of Sandostatin® LAR Depot, unless contraindicated or clinically adverse effects are experienced;
** Prior authorization may be required for Sandostatin LAR Depot*
7. 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 \geq 18 years;
4. Request is for either Somatuline Depot or unbranded lanreotide;
5. Failure of Sandostatin LAR Depot, unless contraindicated or clinically adverse effects are experienced;
** Prior authorization may be required for Sandostatin LAR Depot*
6. 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, or c):
 - 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%] slow growing, or SSTR-positive based PET imaging);
2. Prescribed by or in consultation with an oncologist;
3. Age \geq 18 years;
4. Request is for either Somatuline Depot or unbranded lanreotide;
5. Failure of Sandostatin LAR Depot, unless contraindicated or clinically adverse effects are experienced;
** Prior authorization may be required for Sandostatin LAR Depot*
6. 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	<u>Initial:</u> 90 mg SC every 4 weeks for 3 months <u>Maintenance:</u> 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; February 2023. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/022074s0261bl.pdf. Accessed August 4, 2023.
2. Lanreotide Prescribing Information. Warren, NJ: Cipla USA. Inc.; December 2021. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/215395s0001bl.pdf. Accessed August 17, 2023.
3. 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.

4. Katznelson L, Laws Jr. ER, Melmed S, et al. Acromegaly: an Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab.* 2014;99:3933-3951.
5. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed August 4, 2023.
6. National Comprehensive Cancer Network. Neuroendocrine and Adrenal Tumors Version 1.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/neuroendocrine.pdf. Accessed August 4, 2023.
7. Fleseriu M, Biller BMK, Freda PU, et al. A Pituitary Society update to acromegaly management guidelines. *Pituitary.* 2021; 24: 1-13.
8. 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
J1932	Injection, lanreotide, (cipl), 1 mg
C9399	Unclassified drugs or biologicals

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	
4Q 2023 annual review: updated Acromegaly, Carcinoid, Neuroendocrine Tumors criteria to include need for failure of Sandostatin LAR Depot prior to approval; updated neuroendocrine	10/2023	

Reviews, Revisions, and Approvals	Date	P&T Approval Date
tumor criteria Grade 3 NET examples and pancreatic tumor examples in Appendix D to align with current NCCN Neuroendocrine Tumors for the Gastrointestinal Tract, Lung, and Thymus guideline and NCCN compendium; references reviewed and updated.		