Clinical Policy: Lanreotide (Somatuline Depot and Unbranded)

Reference Number: PA.CP.PHAR.391
Effective Date: 10/2018
Last Review Date: 01/2026

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 µg/L 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. For Somatuline Depot requests, member must use generic lanreotide if available, unless contraindicated or clinically significant adverse effects are experienced;
7. Failure of both of the following^, unless clinically adverse effects are experienced or both are contraindicated (a and b):
   a. Generic octreotide acetate LAR (generic Sandostatin® LAR Depot), unless octreotide acetate LAR is unavailable due to shortage;
   b. If member is unable to use generic octreotide acetate LAR (generic Sandostatin LAR Depot) due to shortage: Sandostatin LAR Depot;

^Prior authorization may be required for generic and brand Sandostatin LAR Depot

8. Dose does not exceed 120 mg every 4 weeks.

Approval duration: 12 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 is for either Somatuline Depot or unbranded lanreotide;
5. For Somatuline Depot requests, member must use generic lanreotide if available, unless contraindicated or clinically significant adverse effects are experienced;
6. Member meets one of the following (a or b):
   a. Failure of both of the following^, unless clinically adverse effects are experienced or both are contraindicated (i and ii):
      i. Generic octreotide acetate LAR (generic Sandostatin LAR Depot), unless octreotide acetate LAR is unavailable due to shortage;
      ii. If member is unable to use generic octreotide acetate LAR (generic Sandostatin LAR Depot) due to shortage: Sandostatin LAR Depot;

      ^Prior authorization may be required for octreotide acetate LAR and Sandostatin LAR Depot
   b. Request is for Stage IV or metastatic cancer;
7. 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: 12 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. Diffuse idiopathic pulmonary neuroendocrine cell hyperplasia (DIPNECH);
   d. One of the following NETs which is SSTR-positive or has hormonal symptoms (i, ii, or iii):
      i. Thymic NET;
      ii. Lung 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 ≥ 18 years;
4. Request is for either Somatuline Depot or unbranded lanreotide;
5. For Somatuline Depot requests, member must use generic lanreotide if available, unless contraindicated or clinically significant adverse effects are experienced;
6. Member meets one of the following (a or b):

a. Failure of both of the following^, unless clinically adverse effects are experienced or both are contraindicated (i and ii):
   i. Generic octreotide acetate LAR (generic Sandostatin LAR Depot), unless octreotide acetate LAR is unavailable due to shortage;
   ii. If member is unable to use generic octreotide acetate LAR (generic Sandostatin LAR Depot) due to shortage: Sandostatin LAR Depot;

^Prior authorization may be required for octreotide acetate LAR and Sandostatin LAR Depot

b. Request is for Stage IV or metastatic cancer;

7. 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: 12 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. PHARM.01) applies;
2. For Somatuline Depot requests, member must use generic lanreotide if available, unless contraindicated or clinically significant adverse effects are experienced;
3. Member is responding positively to therapy (*see Appendix D*);
4. 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. PHARM.01) applies;
2. For Somatuline Depot requests, member must use generic lanreotide if available, unless contraindicated or clinically significant adverse effects are experienced;
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

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. PHARM.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

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Octreotide acetate (Sandostatin LAR deport) (IM)	**Acromegaly:** 20-40 mg IM every 4 weeks **Carcinoid tumors:** 20-30 mg IM every 4 weeks **Neuroendocrine Tumors:** 20-30 mg IM every 4 weeks	See dosing regimen

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

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, rectum, duodenum, gastric, jejunum/ileum/colon.
    - Pancreatic tumors include insulinoma, gastrinoma, VIPoma (vasoactive intestinal polypeptide), glucagonoma.
      - For patients with insulinoma, lanreotide should be considered only if the tumor expresses SSTR.
  - If clinically significant disease progression, treatment with lanreotide should be discontinued for non-functional tumors and continued in patients with functional tumors and may be used in combination with any of the subsequent 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; July 2024. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/022074s026lbl.pdf. Accessed July 10, 2025.
2. Lanreotide Prescribing Information. Warren, NJ: Cipla USA. Inc.; July 2024. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/215395s008lbl.pdf. Accessed July 10, 2025.
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 11, 2025.

6. National Comprehensive Cancer Network. Neuroendocrine and Adrenal Tumors Version 2.2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/neuroendocrine.pdf. Accessed August 11, 2025.
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.
9. Giustina A, Biermasz N, Casanueva FF, et al; Acromegaly Consensus Group (ACG). Consensus on criteria for acromegaly diagnosis and remission. Pituitary. 2024 Feb;27(1):7-22. doi: 10.1007/s11102-023-01360-1.

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, (cipla), 1 mg
J3490	Unclassified drugs

Reviews, Revisions, and Approvals	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 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.	10/2023
4Q 2024 annual review: for acromegaly, revised initial criteria from "(GH) level ≥ 1 µg/mL" to "(GH) level ≥ 1 µg/L" per PS/ES practice guidelines and	10/2024

Reviews, Revisions, and Approvals	Date
ACG; for neuroendocrine tumors, added to initial criteria "diagnosis of diffuse idiopathic pulmonary neuroendocrine cell hyperplasia" and revised "bronchopulmonary NET" to "lung NET" per NCCN compendium and guideline; updated Appendix D "NCCN guidelines - Neuroendocrine and Adrenal Tumors" supplemental information; removed inactive HCPCS code C9399 and added HCPCS code J3490; references reviewed and updated.	
4Q 2025 annual review: no significant changes; for initial therapy, extended approval duration from 6 months to 12 months; references reviewed and updated.	10/2025
Per December SDC, for all indications, added redirection to octreotide acetate LAR (generic Sandostatin LAR Depot), added redirection to brand Sandostatin LAR Depot if octreotide acetate LAR is unavailable due to shortage, added member must use generic lanreotide if available for Somatuline Depot requests.	01/2026