Clinical Policy: Lanreotide (Somatuline Depot)

Reference Number: MDN.CP.PHAR.391
Effective Date: 8.1.23
Last Review Date: 11.5.24
Line of Business: Meridian IL Medicaid

Coding Implications
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.

It is the policy of health plans affiliated with Centene Corporation® 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;
   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. Dose does not exceed 120 mg every 4 weeks.

Approval duration:
Medicaid – 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:
Medicaid– 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. Diffuse idiopathic pulmonary neuroendocrine cell hyperplasia (DIPNECH)
   c. Pheochromocytoma or paraganglioma (adrenal NETs);
   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%] or SSTR-positive);
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:
Medicaid– 6 months

D. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the PDL (Medicaid), CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.PMN.53 for Medicaid.

II. Continued Therapy

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

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B*);
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:
Medicaid – 12 months

B. Carcinoid Syndrome and Neuroendocrine Tumors (must meet all)**:**

1. Currently receiving medication via Centene benefit, 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:
Medicaid/HIM – 12 months

C. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.PMN.53 for Medicaid.

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 policies – and CP.PMN.53 for Medicaid 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 tumor
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 for all relevant lines of business 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 GH or IGF-I 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, and nonfunctioning pancreatic tumors.
    - 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/2024/022074s032lbl.pdf. Accessed July 25, 2024.
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 25, 2024.
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 July 25, 2024.
6. National Comprehensive Cancer Network. Neuroendocrine and Adrenal Tumors Version 1.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/neuroendocrine.pdf. Accessed July 26, 2024.
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	P&T Approval Date
Policy adapted from CP.PHAR.391 for migration to State PDL	6.21.23	
3Q2024 Annual Review: updated neuroendocrine tumor criteria Grade 3 NET examples and pancreatic tumor examples in Appendix D to align with current NCCN Neuroendocrine Tumors fo the Gastrointestinal Tract, Lung, and Thymus guideline and NCCN compendium; references reviewed and updated.	7.26.24	
R**T4: ad**ded 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; added HCPCS code J3490; references reviewed and updated.	11.5.24	

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. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. 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. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.