

**Clinical Policy: Lanreotide (Somatuline Depot)**

Reference Number: CP.PHAR.391

Effective Date: 08.14.18

Last Review Date: 11.19

Line of Business: Commercial, HIM, Medicaid

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

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

**Description**

Lanreotide (Somatuline<sup>®</sup> 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<sup>®</sup> 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  $\geq$  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/HIM** – 6 months

**Commercial** – 6 months or to the member's renewal date, whichever is longer

**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. Age  $\geq$  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/HIM** – 6 months

**Commercial** – 6 months or to the member's renewal date, whichever is longer

**C. Gastroenteropancreatic Neuroendocrine Tumors (must meet all):**

2. Diagnosis of GEP-NETs;
3. Prescribed by or in consultation with an oncologist;
4. Age  $\geq$  18 years;
5. 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/HIM** – 6 months

**Commercial** – 6 months or to the member's renewal date, whichever is longer

**D. Thymic and Bronchopulmonary Neuroendocrine Tumors (off-label) (must meet all):**

1. Diagnosis of unresectable or metastatic thymic/bronchopulmonary NETs;
2. Prescribed by or in consultation with an oncologist;
3. Age  $\geq$  18 years;
4. Member has somatostatin receptor positive imaging and/or hormonal symptoms;
5. 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/HIM** – 6 months

**Commercial** – 6 months or to the member's renewal date, whichever is longer

**E. Other diagnoses/indications**

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid.

**II. Continued Therapy**

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

1. Currently receiving medication via Centene benefit 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:**

**Medicaid/HIM** – 12 months

**Commercial** – 6 months or to the member's renewal date, whichever is longer

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

1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Somatuline Depot for carcinoid syndrome, or gastroenteropancreatic, thymic or bronchopulmonary NET 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

**Commercial** – 6 months or to the member's renewal date, whichever is longer

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

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.

**Approval duration: Duration of request or 6 months (whichever is less); or**

2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and 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 – CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, 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

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*

- 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.
- Per the NCCN guidelines on NETs, 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	<p><u>Initial:</u> 90 mg SC every 4 weeks for 3 months</p> <p><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.</p>	Maintenance: 120 mg every 4 weeks
GEP-NETs, carcinoid syndrome	<p>120 mg SC every 4 weeks</p> <p>If patients are being treated with Somatuline Depot for both GEP-NET and carcinoid syndrome, do not administer an additional dose</p>	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 July 26, 2019.
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 1.2019. Available at: [https://www.nccn.org/professionals/physician\\_gls/pdf/neuroendocrine.pdf](https://www.nccn.org/professionals/physician_gls/pdf/neuroendocrine.pdf). Accessed July 26, 2019.
6. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: [http://www.nccn.org/professionals/drug\\_compendium](http://www.nccn.org/professionals/drug_compendium). Accessed July 26, 2019.

### **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.

<b>HCPSC Codes</b>	<b>Description</b>
J1930	Injection, lanreotide, 1 mg

<b>Reviews, Revisions, and Approvals</b>	<b>Date</b>	<b>P&amp;T Approval Date</b>
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

### **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.

**For Health Insurance Marketplace members**, when applicable, this policy applies only when the prescribed agent is on your health plan approved formulary. Request for non-formulary drugs must be reviewed using the non-formulary policy; HIM.PA.103.

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