RXADVANCE
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Clinical Policy Title:	lanreotide
Policy Number:	RxA.492
Drug(s) Applied:	Somatuline® Depot
Original Policy Date:	03/06/2020
Last Review Date:	12/07/2020
Line of Business Policy Applies to:	All line of business

Background

Lanreotide (Somatuline® Depot) is a somatostatin analog. It 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.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
lanreotide (Somatuline® Depot)	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

Dosage Forms

- Single-dose prefilled syringes: 60 mg/0.2 mL, 90 mg/0.3 mL, 120 mg/0.5 mL

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

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
Commercial: 6 months
Medicaid: 6 months

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 ≥ 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
Commercial: 6 months
Medicaid: 6 months

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

1. Diagnosis of GEP-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
Commercial: 6 months
Medicaid: 6 months

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 ≥ 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
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

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

1. Currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy;
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
Commercial: 12 months
Medicaid: 12 months

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

1. Currently receiving medication that has been authorized by RxAdvance 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
Commercial: 12 months
Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
GEP: gastroenteropancreatic
NET: neuroendocrine tumor
NCCN: National Comprehensive Cancer Network

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 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.

References

1. Somatuline® Depot Prescribing Information. Cambridge, MA: Ipsen Biopharmaceuticals, Inc.; June 2019. Available at: http://www.somatulinedepot.com. Accessed September 15, 2020.
2. Melmed S, Colao A, Barkan A, et al. Guidelines for acromegaly management: an update. J Clin Endocrinol Metab; 2009; 94(5):1509-1517. Accessed September 15, 2020.
3. Katznelson L, Laws Jr. ER, Melmed S, et al. Acromegaly: an endocrine society clinical practice guideline. J Clin Endocrinol Metab. 2014; 99(11):3933-3951. Accessed September 15, 2020.
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). Accessed September 15, 2020.
5. National Comprehensive Cancer Network. Neuroendocrine and Adrenal Tumors Version 2. 2020 Available at: https://www.nccn.org/professionals/physician_gls/pdf/neuroendocrine.pdf. Accessed September 15, 2020.
6. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed September 15, 2020.
7. Lanreotide, Lexi-Drug. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Accessed with subscription at: http://online.lexi.com. Accessed September 15, 2020.
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Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/01/2020	03/06/2020
Policy was reviewed: 1. Policy title table was updated: Line of business policy applies was updated to All lines of business. 2. Continued therapy criteria II.A.1 and II.B.1 was rephrased to “Currently receiving medication that has been authorized by RxAdvance…”. 3. Commercial approval duration was updated from Length of benefit to 6 months for Initial and 12 months for continued approval criteria. 4. References were updated.	09/15/2020	12/07/2020