

Somatuline Depot (lanreotide)

(Subcutaneous)

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I. Length of Authorization

Initial coverage will be for three months and is eligible for renewal for six months.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Somatuline Depot 60 mg/0.2 mL prefilled syringe: 1 syringe every 28 days
- Somatuline Depot 90 mg/0.3 mL prefilled syringe: 1 syringe every 28 days
- Somatuline Depot 120 mg/0.5 mL prefilled syringe: 1 syringe every 28 days

B. Max Units (per dose and over time) [HCPCS Unit]:

All Indications

- 120 billable units every 28 days

III. Initial Approval Criteria^{1,2}

Coverage is provided in the following conditions:

- Patient is at least 18 years old; **AND**
- Patient has not received a long-acting somatostatin analogue (e.g., Octreotide LAR, Lanreotide SR, and Lanreotide autogel) within the last 4 weeks; **AND**

Acromegaly † Φ

- Patient diagnosis confirmed by elevated (age-adjusted) or equivocal serum IGF-1 as well as inadequate suppression of GH after a glucose load; **AND**
- Patient has documented inadequate response to surgery and/or radiotherapy or it is not an option for the patient; **AND**
- Patient's tumor has been visualized on imaging studies (i.e., MRI or CT-scan); **AND**
- Baseline growth hormone (GH) and IGF-1 blood levels (renewal will require reporting of current levels)

Gastroenteropancreatic neuroendocrine tumors (GEP-NETs) †

- Patient has unresectable, locally advanced or metastatic disease; **AND**
- Patient has non-functioning tumors without hormone-related symptoms; **AND**
- Patient has well or moderately differentiated disease

Carcinoid Syndrome †

- Patient has documented neuroendocrine tumors with a history of carcinoid syndrome; **AND**
 - Used to reduce the frequency of short-acting somatostatin analog rescue therapy; **OR**
 - Used for treatment and/or control of symptoms

Neuroendocrine Tumors (GI Tract, Lung, Thymus, Pancreas, and Pheochromocytoma/Paraganglioma) ‡ Φ

- Used to treat unresectable primary gastrinoma; **OR**
- Used for treatment of symptoms related to hormone hypersecretion and/or Carcinoid syndrome; **OR**
- Used for tumor control in patients with unresectable, locally advanced, and/or metastatic disease

† FDA Approved Indication(s), ‡ Compendia Approved Indication(s); Φ Orphan Drug

IV. Renewal Criteria^{1,2}

Coverage can be renewed based upon the following criteria:

- Patient continues to meet universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: formation of gallstones; cardiovascular abnormalities (bradycardia, sinus bradycardia, and hypertension); uncontrolled blood glucose abnormalities (hyperglycemia, hypoglycemia); thyroid disorders (hypothyroidism); etc ; **AND**
- Disease response with improvement in patient's signs and/or symptoms: **AND**

Acromegaly:

- Disease response as indicated by an improvement in signs and symptoms compared to baseline; **AND**
 - Reduction of growth hormone (GH) by random testing to < 1.0 mcg/L; **OR**
 - Age-adjusted normalization of serum IGF-1

Carcinoid Syndrome:

- Disease response with treatment as indicated by reduction in use of short-acting somatostatin analog rescue medication (e.g., octreotide) and a decrease in the frequency of diarrhea and flushing events, when compared to baseline

Treatment of and/or symptoms secondary to Neuroendocrine tumors:

- Disease response with treatment as indicated by an improvement in symptoms including reduction in symptomatic episodes (such as diarrhea, rapid gastric dumping, flushing, bleeding, etc.) and/or stabilization of glucose levels and/or decrease in size of tumor or tumor spread

V. Dosage/Administration¹

Indication	Dose
Acromegaly	<ul style="list-style-type: none">▪ Recommended starting dose is 90 mg by deep subcutaneous injection every 4 weeks for 3 months, adjusted thereafter based on GH and/or IGF-1 levels:<ul style="list-style-type: none">– GH >1 to ≤ 2.5 ng/mL, IGF-1 normal and clinical symptoms controlled: maintain Somatuline Depot dose at 90 mg every 4 weeks– GH > 2.5 ng/mL, IGF-1 elevated and/or clinical symptoms uncontrolled, increase Somatuline Depot dose to 120 mg every 4 weeks– GH ≤ 1 ng/mL, IGF-1 normal and clinical symptoms controlled: reduce Somatuline Depot dose to 60 mg every 4 weeks– <i>Renal and Hepatic Impairment: Initial dose is 60 mg every 4 weeks for 3 months in moderate and severe renal or hepatic impairment, then adjust thereafter based on GH and/or IGF-1 levels.</i>
GEP-NETs; Carcinoid Syndrome	<ul style="list-style-type: none">▪ 120 mg administered every 4 weeks by deep subcutaneous injection
All other indications	<ul style="list-style-type: none">▪ Dose range of 60 mg to 120 mg every 4 weeks

VI. Billing Code/Availability Information

HCPCS code:

- J1930 – Injection, lanreotide, 1 mg; 1 billable unit = 1 mg

NDC:

- Somatuline Depot 60 mg/0.2 mL prefilled syringe: 15054-1060-xx
- Somatuline Depot 90 mg/0.3 mL prefilled syringe: 15054-1090-xx
- Somatuline Depot 120 mg/0.5 mL prefilled syringe: 15054-1120-xx

VII. References

1. Somatuline Depot [package insert]. Signes, France; Ipsen Pharma Biotech; June 2019. Accessed July 2020.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for lanreotide. National Comprehensive Cancer Network, 2020. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL

COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc.” To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed July 2020.

3. Giustina A, Chanson P, Kleinberg D, et al. Expert consensus document: A consensus on the medical treatment of acromegaly. *Nat Rev Endocrinol.* 2014 Apr; 10(4):243-8. doi: 10.1038/nrendo.2014.21. Epub 2014 Feb 25.
4. Katznelson L, Laws ER Jr, Melmed S, et al. Acromegaly: an endocrine society clinical practice guideline. *J Clin Endocrinol Metab.* 2014 Nov; 99(11):3933-51. doi: 10.1210/jc.2014-2700. Epub 2014 Oct 30.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C25.4	Malignant neoplasm of endocrine pancreas
C7A.00	Malignant carcinoid tumor of unspecified site
C7A.010	Malignant carcinoid tumor of the duodenum
C7A.011	Malignant carcinoid tumor of the jejunum
C7A.012	Malignant carcinoid tumor of the ileum
C7A.019	Malignant carcinoid tumor of the small intestine, unspecified portion
C7A.020	Malignant carcinoid tumor of the appendix
C7A.021	Malignant carcinoid tumor of the cecum
C7A.022	Malignant carcinoid tumor of the ascending colon
C7A.023	Malignant carcinoid tumor of the transverse colon
C7A.024	Malignant carcinoid tumor of the descending colon
C7A.025	Malignant carcinoid tumor of the sigmoid colon
C7A.026	Malignant carcinoid tumor of the rectum
C7A.029	Malignant carcinoid tumor of the large intestine, unspecified portion
C7A.090	Malignant carcinoid tumor of the bronchus and lung
C7A.091	Malignant carcinoid tumor of the thymus
C7A.092	Malignant carcinoid tumor of the stomach
C7A.093	Malignant carcinoid tumor of the kidney
C7A.094	Malignant carcinoid tumor of the foregut, unspecified
C7A.095	Malignant carcinoid tumor of the midgut, unspecified
C7A.096	Malignant carcinoid tumor of the hindgut, unspecified
C7A.098	Malignant carcinoid tumors of other sites
C7A.1	Malignant poorly differentiated neuroendocrine tumors
C7A.8	Other malignant neuroendocrine tumors

ICD-10	ICD-10 Description
C7B.00	Secondary carcinoid tumors, unspecified site
C7B.01	Secondary carcinoid tumors of distant lymph nodes
C7B.02	Secondary carcinoid tumors of liver
C7B.03	Secondary carcinoid tumors of bone
C7B.04	Secondary carcinoid tumors of peritoneum
C7B.09	Secondary carcinoid tumors of other sites
C7B.8	Other secondary neuroendocrine tumors
D3A.00	Benign carcinoid tumor of unspecified site
D3A.010	Benign carcinoid tumor of the duodenum
D3A.011	Benign carcinoid tumor of the jejunum
D3A.012	Benign carcinoid tumor of the ileum
D3A.019	Benign carcinoid tumor of the small intestine, unspecified portion
D3A.020	Benign carcinoid tumor of the appendix
D3A.021	Benign carcinoid tumor of the cecum
D3A.022	Benign carcinoid tumor of the ascending colon
D3A.023	Benign carcinoid tumor of the transverse colon
D3A.024	Benign carcinoid tumor of the descending colon
D3A.025	Benign carcinoid tumor of the sigmoid colon
D3A.026	Benign carcinoid tumor of the rectum
D3A.029	Benign carcinoid tumor of the large intestine, unspecified portion
D3A.090	Benign carcinoid tumor of the bronchus and lung
D3A.091	Benign carcinoid tumor of the thymus
D3A.092	Benign carcinoid tumor of the stomach
D3A.094	Benign carcinoid tumor of the foregut, unspecified
D3A.095	Benign carcinoid tumor of the midgut, unspecified
D3A.096	Benign carcinoid tumor of the hindgut, unspecified
D3A.098	Benign carcinoid tumors of other sites
E16.1	Other hypoglycemia
E16.3	Increased secretion of glucagon
E16.4	Increased secretion of gastrin
E16.8	Other specified disorders of pancreatic internal secretion
E22.0	Acromegaly and pituitary gigantism
E24.8	Other Cushing's syndrome
E34.0	Carcinoid syndrome

ICD-10	ICD-10 Description
E34.4	Constitutional tall stature
Z85.020	Personal history of malignant carcinoid tumor of stomach
Z85.030	Personal history of malignant carcinoid tumor of large intestine
Z85.040	Personal history of malignant carcinoid tumor of rectum
Z85.060	Personal history of malignant carcinoid tumor of small intestine
Z85.07	Personal history of malignant neoplasm of pancreas
Z85.110	Personal history of malignant carcinoid tumor of bronchus and lung
Z85.230	Personal history of malignant carcinoid tumor of thymus
Z85.858	Personal history of malignant neoplasm of other endocrine glands

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: <http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC