



Somatuline Depot® (lanreotide)

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Definition

Somatuline Depot is an octapeptide analog of natural somatostatin, behaves similarly to that of natural somatostatin and inhibits secretion of various endocrine, neuroendocrine, exocrine and paracrine functions; thereby, normalizing growth hormones (GH) and/or insulin-like growth factor-1 (IGF-1) levels in acromegalic patients.

Length of Authorization

Coverage will be provided for 12 months and may be renewed.

Dosing Limits

Max Units (per dose and over time) [Medical Benefit]:

- 120 billable units per 28 days

I. INITIAL APPROVAL CRITERIA

Somatuline Depot may be considered medically necessary if one of the below conditions are met **AND** use is consistent with the medical necessity criteria that follows:

- Individual is 18 years of age or older
- Individual has not received a long-acting somatostatin analogue (e.g., Octreotide LAR, Lanreotide SR, Lanreotide Autogel) within the last 4 weeks
- Diagnosis of **ANY ONE** of the following:
 1. **Acromegaly**; with **ALL** of the following:
 - a. Diagnosis confirmed by elevated (age-adjusted) or equivocal serum IGF-1; **AND**
 - b. Inadequate suppression of GH after a glucose load; **AND**
 - c. Prior treatment/assessment of inadequate response to surgery and/or radiotherapy **OR** surgery and/or radiotherapy is not an option; **AND**

- d. Baseline growth hormone (GH) and IGF-I blood levels (renewal will require reporting of current levels); **AND**
- e. Tumor (i.e., growth hormone-secreting pituitary adenoma) is visualized on imaging studies (MRI or CT-scan)

2. Carcinoid Syndrome

- a. To reduce the frequency of short-acting somatostatin analog rescue therapy; **OR**
- b. Treatment and/or control of symptoms

3. Neuroendocrine tumor

- a. Gastroenteropancreatic neuroendocrine tumors (GEP-NETs)
 - i. Disease is unresectable, locally advanced or metastatic; **AND**
 - ii. Disease is a non-functioning tumor without hormone-related symptoms; **AND**
 - iii. Disease is well or moderately differentiated.
- b. Any of the following tumors of the GI tract, lung, thymus, or Pancreas
 - i. Treatment of unresectable primary gastrinoma; **OR**
 - ii. Treatment of symptoms related to hormone hypersecretion and/or Carcinoid syndrome; **OR**
 - iii. Tumor control in individuals with unresectable and/or metastatic disease.

II. RENEWAL CRITERIA

- Patient continues to meet INITIAL APPROVAL CRITERIA.
- Absence of unacceptable toxicity including gallstones, cardiovascular abnormalities (bradycardia, sinus bradycardia, and hypertension), uncontrolled blood glucose abnormalities (hyperglycemia or hypoglycemia) or thyroid disorders (hypothyroidism).
- Improved disease response in the above indications

Dosage/Administration

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 – 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.
Gastroenteropancreatic neuroendocrine tumors, Carcinoid Syndrome	<ul style="list-style-type: none"> – 120 mg administered every 4 weeks by deep subcutaneous injection

Applicable Procedure Codes

J1930	Injection, somatuline depot, 1 mg, 1 billable unit = 1 mg
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Applicable NDCs

15054-1120-xx	Somatulane Depot single use subcutaneous solution
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Applicable Diagnosis Codes

ICD-10	ICD-10 Description
C25	Malignant Neoplasm Of Pancreas, unspecified
C25.0	Malignant Neoplasm Of Head of pancreas
C25.1	Malignant neoplasm of body of pancreas
C25.2	Malignant neoplasm of tail of pancreas
C25.3	Malignant neoplasm of pancreas
C25.4	Malignant neoplasm of endocrine pancreas
C25.7	Malignant neoplasm of other parts of pancreas
C25.8	Malignant neoplasm of overlapping sites of pancreas
C25.9	Malignant neoplasm of pancreas
C37	Malignant neoplasm of thymus
C74	Malignant neoplasm of adrenal gland
C74.0	Malignant neoplasm of cortex of adrenal gland
C74.00	Malignant neoplasm of cortex of unspecified adrenal gland
C74.01	Malignant neoplasm of cortex of right adrenal gland
C74.02	Malignant neoplasm of cortex of left adrenal gland
C74.1	Malignant neoplasm of medulla of adrenal gland
C74.10	Malignant neoplasm of medulla of unspecified adrenal gland
C74.11	Malignant neoplasm of medulla of right adrenal gland
C74.12	Malignant neoplasm of medulla of left adrenal gland
C74.9	Malignant neoplasm of unspecified part of adrenal gland
C74.90	Malignant neoplasm of unspecified part of adrenal gland
C74.91	Malignant neoplasm of unspecified part of left adrenal gland
C74.92	Malignant neoplasm of unspecified part of left adrenal gland
C7A	Malignant neuroendocrine tumors
C7A.0	Malignant carcinoid tumors
C7A.00	Malignant carcinoid tumor of unspecified site
C7A.01	Malignant carcinoid tumors of the small intestine
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.02	Malig carcinoid tumors of the appendix, large intestine, and rectum
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.09	Malignant carcinoid tumors of other sites
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
C7B	Secondary neuroendocrine tumors
C7B.0	Secondary carcinoid tumors
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.1	Secondary merkel cell carcinoma
C7B.8	Other secondary neuroendocrine tumors
D13.7	Benign neoplasm of endocrine pancreas
D15.0	Benign neoplasm of thymus
D35.2	Benign neoplasm of pituitary gland
D35.3	Benign neoplasm of craniopharyngeal duct
D37.9	Neoplasm of uncertain behavior of digestive organ, unspecified
D3A	Benign neuroendocrine tumors
D3A.0	Benign carcinoid tumors
D3A.00	Benign carcinoid tumor of unspecified site
D3A.01	Benign carcinoid tumors of the small intestine
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.02	Benign carcinoid tumors of the appendix, large intestine, and rectum
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.09	Benign carcinoid tumors of other sites
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.093	Benign carcinoid tumor of the kidney
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

D3A.8	Other benign neuroendocrine tumors
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
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

References

1. Product Information: SOMATULINE(R) solution for IM injection, lanreotide acetate solution for IM injection. Tercica Inc., Brisbane, CA, 2011.