

Medical Policy:

SOMATULINE DEPOT™ (lanreotide) and lanreotide Injection

| POLICY NUMBER | LAST REVIEW | ORIGIN DATE |
|---------------|-----------------|-------------|
| MG.MM.PH.165 | January 4, 2024 | |

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Definitions

Somatuline Depot/lanreotide 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 [Medical Benefit]

Max Units (per dose and over time):

120 billable units per 28 days

Guideline

I. Initial Approval Criteria

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

1. Patient is 18 years of age or older
2. Patient has not tried a long-acting octreotide or lanreotide product within the last 4 weeks
3. Diagnosis of **ANY ONE** of the following:
 - A. **Acromegaly**; with **ALL** of the following:
 - i. Diagnosis confirmed by elevated (age-adjusted) or equivocal serum IGF-1; **AND**
 - ii. Inadequate suppression of GH after a glucose load; **AND**
 - iii. Prior treatment/assessment of inadequate response to surgery and/or radiotherapy **OR** surgery and/or radiotherapy is not an option; **AND**
 - iv. Baseline growth hormone (GH) and IGF-I blood levels (renewal will require reporting of current levels); **AND**
 - v. Tumor (i.e., growth hormone-secreting pituitary adenoma) is visualized on imaging studies (MRI or CT-scan); **AND**
 - vi. Will not be used in combination with oral octreotide
 - B. **Carcinoid Syndrome**
 - i. To reduce the frequency of short-acting somatostatin analog rescue therapy; **OR**
 - ii. Treatment and/or control of symptoms
 - C. **Neuroendocrine tumor**
 - i. Gastroenteropancreatic neuroendocrine tumors (GEP-NETs)
 - a. Disease is unresectable, locally advanced or metastatic; **AND**
 - b. Disease is a non-functioning tumor without hormone-related symptoms; **AND**
 - c. Disease is well or moderately differentiated.
 - ii. Any of the following **tumors of the GI tract, lung, thymus, or Pancreas**
 - a. Treatment of unresectable primary gastrinoma; **OR**
 - b. Treatment of symptoms related to hormone hypersecretion and/or Carcinoid syndrome; **OR**
 - c. Tumor control in individuals with unresectable and/or metastatic disease.

II. Renewal Criteria

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

Dosage/Administration

| Indication | Dose |
|------------|---|
| Acromegaly | 1. 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: <ol style="list-style-type: none">a. GH >1 to ≤ 2.5 ng/mL, IGF-1 normal and clinical symptoms controlled: maintain Somatuline Depot/lanreotide dose at 90 mg every 4 weeks |

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| | <p>b. GH > 2.5 ng/mL, IGF-1 elevated and/or clinical symptoms uncontrolled, increase Somatuline Depot/ lanreotide dose to 120 mg every 4 weeks</p> <p>c. GH ≤ 1 ng/mL, IGF-1 normal and clinical symptoms controlled: reduce Somatuline Depot/lanreotide dose to 60 mg every 4 weeks</p> <p>2. 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.</p> |
| Gastroenteropancreatic neuroendocrine tumors, Carcinoid Syndrome | 120 mg administered every 4 weeks by deep subcutaneous injection |

Applicable Procedure Codes

| Code | Description |
|-------|--|
| J1930 | Injection, somatuline depot, 1 mg, 1 billable unit = 1 mg (Somatuline Depot) |
| J1932 | Injection, lanreotide, (cipl), 1 mg |

Applicable NDCs

| Code | Description |
|---------------|---|
| 15054-1120-xx | Somatuline Depot single use subcutaneous solution |
| 15054-1090-xx | Somatuline Depot 90 mg/0.3 mL prefilled syringe |
| 15054-1060-xx | Somatuline Depot 60 mg/0.2 mL prefilled syringe |
| 69097-0870-67 | LANREOTIDE ACETATE 120MG/0.5ML Solution |
| 69097-0890-xx | Lanreotide Depot 90 mg/0.3 mL prefilled syringe: |
| 69097-0880-xx | Lanreotide Depot 60 mg/0.2 mL prefilled syringe |

ICD-10 Diagnoses

| Code | 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 |

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| 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 |

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| 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 |

Revision History

| Company(ies) | DATE | REVISION |
|-----------------------------|------------|---|
| EmblemHealth & ConnectiCare | 1/4/2024 | Annual Review: Initial Criteria: Acromegaly: added "Will not be used in combination with oral octreotide" |
| EmblemHealth & ConnectiCare | 06/01/2023 | Annual Review: added NDC's: 15054-1060-xx, 15054-1090-xx, 69097-0880-xx, 69097-0890-xx |
| EmblemHealth & ConnectiCare | 09/08/2022 | Added generic lanreotide, J1932 |
| EmblemHealth & ConnectiCare | 6/13/2022 | Transferred policy to new template. |
| EmblemHealth & ConnectiCare | 2/18/2022 | Removal of examples- "Octreotide LAR, Lanreotide SR, Lanreotide Autogel" from long-acting somatostatin analogue in initial approval criterial |

References

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