

Medical Policy Bulletin

Title:

Lanreotide (Somatuline® Depot)

Policy #:

MA08.090g

The Company makes decisions on coverage based on the Centers for Medicare and Medicaid Services (CMS) regulations and guidance, benefit plan documents and contracts, and the member's medical history and condition. If CMS does not have a position addressing a service, the Company makes decisions based on Company Policy Bulletins. Benefits may vary based on contract, and individual member benefits must be verified. The Company determines medical necessity only if the benefit exists and no contract exclusions are applicable. Although the Medicare Advantage Policy Bulletin is consistent with Medicare's regulations and guidance, the Company's payment methodology may differ from Medicare.

When services can be administered in various settings, the Company reserves the right to reimburse only those services that are furnished in the most appropriate and cost-effective setting that is appropriate to the member's medical needs and condition. This decision is based on the member's current medical condition and any required monitoring or additional services that may coincide with the delivery of this service.

This Policy Bulletin document describes the status of CMS coverage, medical terminology, and/or benefit plan documents and contracts at the time the document was developed. This Policy Bulletin will be reviewed regularly and be updated as Medicare changes their regulations and guidance, scientific and medical literature becomes available, and/or the benefit plan documents and/or contracts are changed.

Policy

Coverage is subject to the terms, conditions, and limitations of the member's Evidence of Coverage.

MEDICALLY NECESSARY

Lanreotide (Somatuline® Depot) is considered medically necessary and, therefore, covered in individuals with any of the following indications when the corresponding criteria are met:

ACROMEGALY

- For the long-term treatment of individuals with acromegaly who have had an inadequate response to surgery and/or radiotherapy, or for whom surgery and/or radiotherapy is not an option.

NEUROENDOCRINE AND ADRENAL TUMORS

Gastroenteropancreatic Neuroendocrine Tumors (GEP-NETs)

- For the treatment of unresectable, well- or moderately differentiated, locally advanced or metastatic gastroenteropancreatic neuroendocrine tumors (GEP-NETs) to improve progression-free survival.

Neuroendocrine Tumors of the Gastrointestinal Tract (Well-Differentiated Grade 1/2), Lung and Thymus (Carcinoid Tumors)

- For the treatment of adult individuals with carcinoid syndrome to reduce the frequency of short-acting somatostatin analog rescue therapy.
- For the treatment of neuroendocrine tumors of the gastrointestinal tract, lung and thymus (carcinoid tumors) for any of the following indications:
 - Primary treatment for symptom and/or tumor control of unresected primary gastrinoma
 - As primary therapy for symptom and/or tumor control of multiple lung nodules or tumorlets and evidence of diffuse idiopathic pulmonary neuroendocrine cell hyperplasia (DIPNECH) if chronic cough/dyspnea is not responsive to inhalers or conventional treatment
- For symptom and/or tumor control of recurrent, locoregional advanced disease and/or distant metastases* of the gastrointestinal tract as a single agent for any of the following:

- For unresectable and a low tumor burden
- For disease progression (if not already receiving) following resection of primary + metastases
- For disease progression (if not already receiving) following observation for unresectable low tumor burden
- Following resection of primary tumor if unresectable and locally symptomatic from primary tumor
- As a single agent or in combination with alternative front-line therapy if unresectable and clinically significant tumor burden
- As subsequent therapy at above label dosing after clinical, symptomatic, or radiographic progression (if SSTR-positive) on standard doses (useful in certain circumstances)
- For symptom and/or tumor control of recurrent and/or locoregional unresectable bronchopulmonary/thymic disease* if SSTR-positive and/or hormonal symptoms for one of the following regimens:
 - As primary therapy
 - As subsequent therapy (as alternate primary therapy) if progression on primary therapy
- For symptom and/or tumor control of recurrent and/or distant metastatic bronchopulmonary/thymic disease* if SSTR-positive and/or hormonal symptoms for one of the following regimens:
 - As primary therapy
 - As subsequent therapy (as alternate primary therapy) if progression on primary therapy
- For symptom and/or tumor control of recurrent and/or distant metastatic bronchopulmonary/thymic disease* if SSTR-positive and/or hormonal symptoms for one of the following regimens:
 - As primary therapy (NCCN preferred if clinically significant tumor burden and low grade [typical carcinoid], evidence of disease progression, intermediate grade [atypical carcinoid], or symptomatic)
 - As subsequent therapy (as alternate primary therapy) if progression on primary therapy if clinically significant tumor burden and low grade (typical carcinoid), evidence of disease progression, intermediate grade (atypical carcinoid), or symptomatic (NCCN preferred)
- Treatment of carcinoid syndrome for any of the following regimens:
 - As a single agent
 - In combination with telotristat for persistent diarrhea due to poorly controlled carcinoid syndrome
 - In combination with other systemic therapy options (based on disease site) with or without telotristat for persistent symptoms (i.e., flushing, diarrhea) due to poorly controlled carcinoid syndrome

Neuroendocrine and Adrenal Tumors - Well-Differentiated Grade 3 Neuroendocrine Tumors

- For the treatment and/or tumor control of somatostatin receptor-positive (if SSTR-positive and/or hormonal symptoms) for unresectable locally advanced/metastatic disease with favorable biology (e.g., relatively low Ki-67 [$<55\%$], slow growing, positive SSR-based PET imaging) at standard dose

Tumors of the Pancreas (Well Differentiated Grade 1/2)

- Management of symptoms and/or tumor control of locoregional disease with any of the following indications:
 - Gastrinoma (usually duodenal or head of the pancreas)
 - Glucagonoma (usually tail)
 - VIPoma
- As National Comprehensive Cancer Network (NCCN)-preferred regimen for symptom and/or tumor control* in individuals** with recurrent or locoregional advanced disease and/or distant metastatic disease if SSTR-positive with any of the following indications:
 - As a single agent for asymptomatic, low tumor burden, and stable disease
 - As a single agent for symptomatic, clinically significant tumor burden, or clinically significant progression (if not already receiving)
 - In combination with alternative front-line therapy for symptomatic, clinically significant tumor burden, or clinically significant progression
- For symptom and/or tumor control as subsequent therapy at above label dosing after clinical, symptomatic, or radiographic progression on standard doses (if SSTR-positive)

Pheochromocytoma/Paraganglioma

- As primary treatment for secreting tumors for hormone excess and symptom control of locally unresectable disease or distant metastases (if SSTR-positive)

NCCN note: *If clinically significant disease progression, treatment with lanreotide should be discontinued for nonfunctional tumors and continued in individuals with functional tumors and may be used in combination with any of the subsequent options.

NCCN note: **For individuals with insulinoma, lanreotide should be used only if SSTR-based imaging is positive.

EXPERIMENTAL/INVESTIGATIONAL

All other uses for lanreotide (Somatuline® Depot) are considered experimental/investigational and, therefore, not covered unless the indication is supported as an accepted off-label use, as defined in the Company medical policy on off-label coverage for prescription drugs and biologics.

REQUIRED DOCUMENTATION

The individual's medical record must reflect the medical necessity for the care provided. These medical records may include but are not limited to: records from the professional provider's office, hospital, nursing home, home health agencies, therapies, and test reports.

The Company may conduct reviews and audits of services to our members, regardless of the participation status of the provider. All documentation is to be available to the Company upon request. Failure to produce the requested information may result in a denial for the drug.

Guidelines

There is no Medicare coverage determination addressing lanreotide (Somatuline® Depot); therefore, the Company policy is applicable.

Lanreotide (Somatuline® Depot) is administered via deep subcutaneous injection.

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable Evidence of Coverage, lanreotide (Somatuline® Depot) is covered under the medical benefits of the Company's Medicare Advantage products when the medical necessity criteria listed in this medical policy are met.

US FOOD AND DRUG ADMINISTRATION (FDA) STATUS

Lanreotide (Somatuline® Depot) was approved by the FDA on August 30, 2007, for the long-term treatment of acromegalic patients who have had an inadequate response to or cannot be treated with surgery and/or radiotherapy.

Lanreotide (Somatuline® Depot) was approved by the FDA on December 16, 2014, for the treatment of individuals with unresectable, well- or moderately differentiated, locally advanced or metastatic gastroenteropancreatic neuroendocrine tumors to improve progression-free survival.

Description

Somatostatin is a naturally occurring hormone that has many biological actions because its receptors are found throughout the entire body. Some actions of somatostatin include inhibiting the secretion of growth hormones (GH), prolactin, glucagon, and insulin. Because somatostatin has a short half-life and targets many different hormones, somatostatin analogs were created (e.g., lanreotide [Somatuline® Depot]). Somatostatin analogs have a long half-life so they can be dosed less often, as well as greater inhibitory selectivity of GH secretion over insulin secretion.

Lanreotide (Somatuline® Depot) is indicated for the long-term treatment of acromegaly, a rare condition characterized by abnormal enlargement of bones in the extremities and head, as well as thickening of soft tissues, such as the heart, lips, and tongue. Acromegaly occurs when the pituitary gland produces too much GH, which in turn causes excess secretion of insulin-like growth factor-1 (IGF-1). Lanreotide (Somatuline® Depot) suppresses the secretion of GH and IGF-1 in individuals who have had inadequate response to or cannot be treated with other therapies, including surgery or radiotherapy, by binding to somatostatin receptors.

Lanreotide (Somatuline® Depot) is also indicated for the treatment of unresectable, well- or moderately differentiated, locally advanced or metastatic gastroenteropancreatic neuroendocrine tumors. Data have shown that lanreotide (Somatuline® Depot) exhibits antiproliferative effects on these tumors, and improves progression-free survival. Neuroendocrine tumors are a heterogeneous group of neoplasms that arise from neuroendocrine cells and their precursors located throughout the body. Individuals with metastases from neuroendocrine tumors often become symptomatic due to hormone hypersecretion rather than tumor bulk. Lanreotide (Somatuline® Depot) is highly effective in controlling the symptoms associated with neuroendocrine tumors, such as flushing and diarrhea.

CLINICAL STUDIES

ACROMEGALY

The efficacy of lanreotide (Somatuline® Depot) on reducing growth hormone and IGF-1 was evaluated in two trials. The first was a three-phase trial that included a 4-week, double-blind, placebo-controlled phase; a 16-week, single-blind, fixed-dose phase; and a 32-week open-label dose titration phase. A total of 107 individuals completed the placebo-controlled phase, 105 completed the fixed-dose phase, and 99 completed the dose-titration phase. In the first (double-blind) phase of the trial, 52 of 83 (63 percent) of the lanreotide (Somatuline® Depot)–treated individuals had greater than 50 percent decrease in mean GH from baseline to week four, compared to 0 in the placebo group. In the fixed-dose phase, 72 percent of the 107 lanreotide (Somatuline® Depot)–treated individuals had a decrease from baseline in mean GH of greater than 50 percent. This efficacy was maintained for the duration of the trial.

The second trial was a 48-week, open-label, uncontrolled, multicenter study that enrolled individuals with an IGF-1 level equal to or greater than 1.3 times the upper limit of normal. This trial began with a 4-month fixed-dose phase in which individuals received four deep subcutaneous injections of lanreotide (Somatuline® Depot) at 4-week intervals. This was followed by a dose-titration phase in which the dose of lanreotide (Somatuline® Depot) was adjusted based on GH and IGF-1 levels. Sixty-three individuals started the fixed-dose phase and 57 completed 48 weeks of treatment. At the completion (48 weeks) of the trial, 43 percent (27/63) achieved normal age-adjusted IGF-1 levels, 38 percent (24/63) of individuals achieved both normal IGF-1 levels and GH levels less than or equal to 2.5 ng/mL, and 27 percent (17/63) had both normal IGF-1 levels and GH levels less than 1 ng/mL.

GASTROENTEROPANCREATIC NEUROENDOCRINE TUMORS

Efficacy of lanreotide (Somatuline® Depot) in the treatment of gastroenteropancreatic neuroendocrine tumors was evaluated in a multicenter, randomized, double-blind, placebo-controlled trial of 204 individuals. Individuals received either lanreotide (Somatuline® Depot) or placebo every 4 weeks until disease progression, unacceptable toxicity, or a maximum of 96 weeks. Primary outcome was progression-free survival. Individuals in the lanreotide (Somatuline® Depot) arm had statistically significant improvement in progression-free survival compared to those in the placebo arm. Median progression-free survival was not reached in the lanreotide (Somatuline® Depot) group, and was 16.6 months in the placebo group.

OFF-LABEL INDICATION

There may be additional indications contained in the Policy section of this document due to evaluation of criteria highlighted in the Company's off-label policy, and/or review of clinical guidelines issued by leading professional organizations and government entities.

References

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Coding

Inclusion of a code in this table does not imply reimbursement. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

The codes listed below are updated on a regular basis, in accordance with nationally accepted coding guidelines. Therefore, this policy applies to any and all future applicable coding changes, revisions, or updates.

In order to ensure optimal reimbursement, all health care services, devices, and pharmaceuticals should be reported using the billing codes and modifiers that most accurately represent the services rendered, unless otherwise directed by the Company.

The Coding Table lists any CPT, ICD-10, and HCPCS billing codes related only to the specific policy in which they appear.

CPT Procedure Code Number(s)

N/A

ICD - 10 Procedure Code Number(s)

N/A

ICD - 10 Diagnosis Code Number(s)

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 body of pancreatic duct
C25.4 Malignant neoplasm of endocrine pancreas
C25.7 Malignant neoplasm of other parts of pancreas
C25.8 Malignant neoplasm of overlapping sites pancreas
C25.9 Malignant neoplasm of pancreas, unspecified
C26.0 Malignant neoplasm of intestinal tract, part unspecified
C26.9 Malignant neoplasm of ill-defined sites within the digestive system
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.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.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
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
C74.90 Malignant neoplasm of unspecified part of unspecified adrenal gland
C74.91 Malignant neoplasm of unspecified part of right adrenal gland
C74.92 Malignant neoplasm of unspecified part of left adrenal gland
C75.5 Malignant neoplasm of aortic body and other paraganglia
D13.7 Benign neoplasm of endocrine pancreas
D37.8 Neoplasm of uncertain behavior of other specified digestive organs
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
 D3A.8 Other benign neuroendocrine tumors
 D49.0 Neoplasm of unspecified behavior of digestive system
 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
 E22.2 Syndrome of inappropriate secretion of antidiuretic hormone
 E34.00 Carcinoid syndrome, unspecified
 E34.01 Carcinoid heart syndrome
 E34.09 Other carcinoid syndrome

HCPCS Level II Code Number(s)

J1930 Injection, lanreotide, 1 mg
 J1932 Injection, lanreotide, (cipra), 1 mg

Revenue Code Number(s)

N/A

Policy History

Revisions From MA08.090g:

12/15/2025	This policy has been reissued in accordance with the Company's annual review process.
12/16/2024	This policy has been identified for the ICD-10 code update, effective 12/16/2024. The following ICD-10 code has been removed from Attachment A of this policy: - E34.0 Carcinoid syndrome The following ICD-10 codes have been added to Attachment A of this policy: - E34.00 Carcinoid syndrome, unspecified - E34.01 Carcinoid heart syndrome - E34.09 Other carcinoid syndrome

Revisions From MA08.090f

05/07/2024	This version of the policy will become effective 05/07/2024. This policy was updated to communicate the coverage position changes for neuroendocrine tumors of the gastrointestinal tract, lung and thymus [carcinoid tumors], neuroendocrine tumors of the pancreas, Pheochromocytoma/Paraganglioma in accordance with the National Comprehensive Cancer Network (NCCN).
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	The following ICD-10 codes have been added to the coding policy: C74.90 Malignant neoplasm of unspecified part of unspecified adrenal gland C74.91 Malignant neoplasm of unspecified part of right adrenal gland C74.92 Malignant neoplasm of unspecified part of left adrenal gland C75.5 Malignant neoplasm of aortic body and other paraganglia
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Revisions From MA08.090e

10/01/2022	This version of the policy will become effective 10/01/2022 Inclusion of a policy in a Code Update memo does not imply that a full review of the policy was completed at this time. The following HCPCS code has been added to this policy: J1932 Injection, lanreotide (ciplia), 1 mg
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Revisions From MA08.090d:

06/20/2022	This version of the policy will become effective 06/20/2022 This policy was updated to communicate the coverage position changes for neuroendocrine and adrenal tumors (pheochromocytoma/paraganglioma, neuroendocrine tumors of the gastrointestinal tract, lung and thymus [carcinoid tumors], neuroendocrine tumors of the pancreas) in accordance with the National Comprehensive Cancer Network (NCCN). The following ICD- 10 codes have been added to the policy: C25.0 Malignant neoplasm of head of pancreas C25.1 Malignant neoplasm of body of pancreas C25.2 Malignant neoplasm of body of pancreas C25.3 Malignant neoplasm of body of pancreatic duct C25.7 Malignant neoplasm of other parts of pancreas C25.8 Malignant neoplasm of overlapping sites pancreas C25.9 Malignant neoplasm of pancreas, unspecified C26.0 Malignant neoplasm of intestinal tract, part unspecified C26.9 Malignant neoplasm of ill-defined sites within the digestive system D37.8- Neoplasm of uncertain behavior of other specified digestive organs D49.0- Neoplasm of unspecified behavior of digestive system D37.8- Neoplasm of uncertain behavior of other specified digestive organs D49.0- Neoplasm of unspecified behavior of digestive system
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Revisions From MA08.090c:

03/01/2021	This version of the policy will become effective 03/01/2021 This policy was updated to communicate the coverage position changes for neuroendocrine and adrenal tumors (pheochromocytoma/paraganglioma, neuroendocrine tumors of the gastrointestinal tract, lung and thymus [carcinoid tumors], neuroendocrine tumors of the pancreas) in accordance with the National Comprehensive Cancer Network (NCCN).
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Revisions From MA08.090b:

12/30/2019.	This version of the policy will become effective 12/30/2019. This policy was updated to communicate the coverage position changes for neuroendocrine and adrenal tumors (pheochromocytoma/paraganglioma, neuroendocrine tumors of the gastrointestinal tract, lung, and thymus [carcinoid tumors], neuroendocrine tumors of the pancreas) in accordance with the National Comprehensive Cancer Network (NCCN).
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Revisions From MA08.090a:

11/19/2018	This version of the policy will become effective 11/19/2018. This policy has been updated to communicate changes based on National Comprehensive Cancer Network (NCCN) compendium. Included criteria for neuroendocrine tumors
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Revisions From MA08.090:

01/01/2018	This version of the policy will become effective 01/01/2018. This new policy has been developed to communicate the Company's coverage criteria for lanreotide (Somatuline® Depot).
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12/15/2025

Version Issued Date:

12/15/2025

Version Reissued Date:

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