Somatuline® Depot Billing and Coding

Somatuline® Depot (lanreotide) Injection 60mg, 90mg and 120mg

INDICATIONS

SOMATULINE® DEPOT (lanreotide) Injection is a somatostatin analog indicated for:

- the long-term treatment of patients with acromegaly who have had an inadequate response to surgery and/or radiotherapy, or for whom surgery and/or radiotherapy is not an option; the goal of treatment in acromegaly is to reduce growth hormone (GH) and insulin growth factor-1 (IGF-1) levels to normal;
- the treatment of adult patients with unresectable, well- or moderately-differentiated, locally advanced or metastatic gastroenteropancreatic neuroendocrine tumors (GEP-NETs) to improve progression-free survival; and
- the treatment of adults with carcinoid syndrome; when used, it reduces the frequency of short-acting somatostatin analog rescue therapy.

IMPORTANT SAFETY INFORMATION

Contraindications

- SOMATULINE DEPOT is contraindicated in patients with hypersensitivity to lanreotide. Allergic reactions (including angioedema and anaphylaxis) have been reported following administration of lanreotide.

Important Notice

This document is not intended to provide recommendations on clinical practice or legal advice. Laws, regulations, and policies concerning reimbursement are complex and are updated frequently. Although we have made an effort to be current as of the issue date of this document, the information may not be current or comprehensive when you view it. This document represents no statement, promise, or guarantee concerning coverage or levels of reimbursement. Similarly, all International Classification of Diseases, 10th edition; Clinical Modification (ICD-10-CM); Current Procedural Terminology (CPT®); and Health Care Procedure Coding System (HCPCS) codes for Somatuline® Depot are supplied for informational purposes. It is always the physician's or facility's responsibility to determine and submit appropriate codes, charges, and modifiers for services that are rendered. It is recommended that you contact your local payers with regard to local reimbursement policies and practices. Please consult your counsel or reimbursement specialist on reimbursement or billing questions specific to your practice.

Reimbursement Coding

When completing the CMS-1500 claim form, the UB-04 claim form, or submitting a prior authorization request for Somatuline® Depot, include accurate descriptions of the patient's diagnosis, route or mode of administration, and the drug used.

Healthcare Common Procedure Coding System (HCPCS) Level II Code

A permanent HCPCS code has been assigned to report use of Somatuline® Depot.

Somatuline® Depot HCPCS Code	Description
J1930	Injection, lanreotide, 1 mg

Please see accompanying full Prescribing Information and Patient Information.

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Reimbursement Coding (Continued)

National Drug Codes (NDCs)

Drug products are identified and reported using a unique, three-segment number, called the National Drug Code, which is a universal product identifier. The NDC is used primarily for pharmacy claims, but it may be required also when billing for physician-administered drugs to ensure crosswalk accuracy. When providers are required to include an NDC on an insurance claim, it typically must be in the required 11-digit format.

Single-Dose Sterile Prefilled Syringe	NDC
120 mg*	15054-1120-03
90 mg	15054-1090-03
60 mg	15054-1060-03

***GEP-NET and carcinoid syndrome: dosing is 120 mg administered every 4 weeks by deep subcutaneous injection.**
Acromegaly: the starting dose is 90 mg once every 4 weeks. For patients with moderate or severe renal or hepatic impairment, initial dose is 60 mg once every 4 weeks.

Current Procedural Terminology (CPT®) Drug Administration Codes

The following CPT® code may be appropriate to report Somatuline® Depot administration services. Evaluation and Management (E&M) codes for office visit services in addition to injection may be appropriate. Most payers require documentation of a separate and identifiable procedure. Some payers may not allow for a level one office visit and an injection code to be billed for the same date of service, and may only allow for other levels of office visits to be billed with an appropriate modifier.

CPT® Code	Description
96372	Therapeutic, prophylactic, or diagnosis injection; subcutaneous or intramuscular

Please consult the patient's specific plan or IPSEN CARES® for information on other CPT® codes that may be applicable and appropriate for billing the administration of Somatuline® Depot.

IMPORTANT SAFETY INFORMATION (CONTINUED)

Warnings and Precautions

- **Cholelithiasis and Gallbladder Sludge**
  - SOMATULINE DEPOT may reduce gallbladder motility and lead to gallstone formation.
  - Periodic monitoring may be needed.
- **Hypoglycemia or Hyperglycemia**
  - Pharmacological studies show that SOMATULINE DEPOT, like somatostatin and other somatostatin analogs, inhibits the secretion of insulin and glucagon. Patients treated with SOMATULINE DEPOT may experience hypoglycemia or hyperglycemia.
  - Blood glucose levels should be monitored when SOMATULINE DEPOT treatment is initiated, or when the dose is altered, and antidiabetic treatment should be adjusted accordingly.

Please see accompanying full Prescribing Information and Patient Information.

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Diagnosis Codes

All claim forms should include an accurate and appropriately documented diagnosis code. Physicians should select the code that most closely and appropriately represents the diagnosis of the patient. The following codes below are provided as examples. Physicians should select codes that most accurately reflect a patient's condition and corresponding utilization of Somatuline® Depot.

Diagnosis Codes for Acromegaly

ICD-10-CM Code	Description
E22.0	Acromegaly and pituitary gigantism

IMPORTANT SAFETY INFORMATION (CONTINUED)

Warnings and Precautions (Continued)

- **Cardiovascular Abnormalities**
  - SOMATULINE DEPOT may decrease heart rate.
  - In cardiac studies with acromegalic patients, the most common cardiac adverse reactions were sinus bradycardia, bradycardia, and hypertension.
  - In patients in the GEP-NET pivotal trial, 23% of SOMATULINE DEPOT-treated patients had a heart rate of less than 60 bpm compared to 16% of placebo-treated patients. The incidence of bradycardia was similar in the treatment groups. Initiate appropriate medical management in patients with symptomatic bradycardia.
  - In patients without underlying cardiac disease, SOMATULINE DEPOT may lead to a decrease in heart rate without necessarily reaching the threshold of bradycardia. In patients suffering from cardiac disorders prior to treatment, sinus bradycardia may occur. Care should be taken when initiating treatment in patients with bradycardia.
- **Thyroid Function Abnormalities**
  - Slight decreases in thyroid function have been seen during treatment with lanreotide in acromegalic patients.
  - Thyroid function tests are recommended where clinically appropriate.
- **Monitoring/Laboratory Tests:** In acromegaly, serum GH and IGF-1 levels are useful markers of the disease and effectiveness of treatment.

Diagnosis Codes (Continued)

Diagnosis Codes for GEP-NETs

Note: This list is not exhaustive.

ICD-10-CM Code	Description
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.020	Malignant carcinoid tumor of the appendix
C7A.021	Malignant carcinoid tumor of the cecum

IMPORTANT SAFETY INFORMATION (CONTINUED)

Adverse Reactions

- **Acromegaly:** Adverse reactions occurring in greater than or equal to 9% of patients who received SOMATULINE DEPOT in the overall pooled safety studies in acromegaly were diarrhea (37%), cholelithiasis (20%), abdominal pain (19%), nausea (11%), and injection-site reactions (9%).
- **GEP-NETs:** Adverse reactions occurring in greater than 10% of patients who received SOMATULINE DEPOT in the GEP-NET trial were abdominal pain (34%), musculoskeletal pain (19%), vomiting (19%), headache (16%), injection site reaction (15%), hyperglycemia (14%), hypertension (14%), and cholelithiasis (14%).
- **Carcinoid Syndrome:** Adverse reactions occurring in the carcinoid syndrome trial were generally similar to those in the GEP-NET trial. Adverse reactions occurring in greater than 5% of patients who received SOMATULINE DEPOT in the carcinoid syndrome trial and occurring at least 5% greater than placebo were headache (12%), dizziness (7%) and muscle spasm (5%).

Drug Interactions: SOMATULINE DEPOT may decrease the absorption of cyclosporine (dosage adjustment may be needed); increase the absorption of bromocriptine; and require dosage adjustment for bradycardia-inducing drugs (e.g., beta-blockers).

Special Populations

- **Lactation:** Advise women not to breastfeed during treatment and for 6 months after the last dose.
- **Moderate to Severe Renal and Hepatic Impairment:** See full prescribing information for dosage adjustment in patients with acromegaly.

Please see accompanying full Prescribing Information and Patient Information.

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Diagnosis Codes for GEP-NETs (Continued)

ICD-10-CM Code	Description
C7A.023	Malignant carcinoid tumor of the transverse colon
C7A.024	Malignant carcinoid tumor of the descending colo
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.092	Malignant carcinoid tumor of the stomach
C7A.094	Malignant carcinoid tumor of the foregut NOS
C7A.095	Malignant carcinoid tumor of the mid-gut NOS
C7A.096	Malignant carcinoid tumor of the hindgut NOS
C7B.00	Secondary carcinoid tumors, unspecified site
C7B.01	Secondary carcinoid tumors of distant lymph nodes
C7B.04	Secondary carcinoid tumors of peritoneum
C7B.09	Secondary carcinoid tumors of other sites
C7B.8	Other secondary neuroendocrine tumors
C24.1	Malignant neoplasm of ampulla of Vater
C25.4	Malignant neoplasm of endocrine pancreas

Diagnosis Codes for Carcinoid Syndrome

ICD-10-CM Code	Description
E34.0	Carcinoid syndrome

IMPORTANT SAFETY INFORMATION (CONTINUED)

To report SUSPECTED ADVERSE REACTIONS, contact Ipsen Biopharmaceuticals, Inc. at 1-855-463-5127 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see accompanying full Prescribing Information and Patient Information.

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