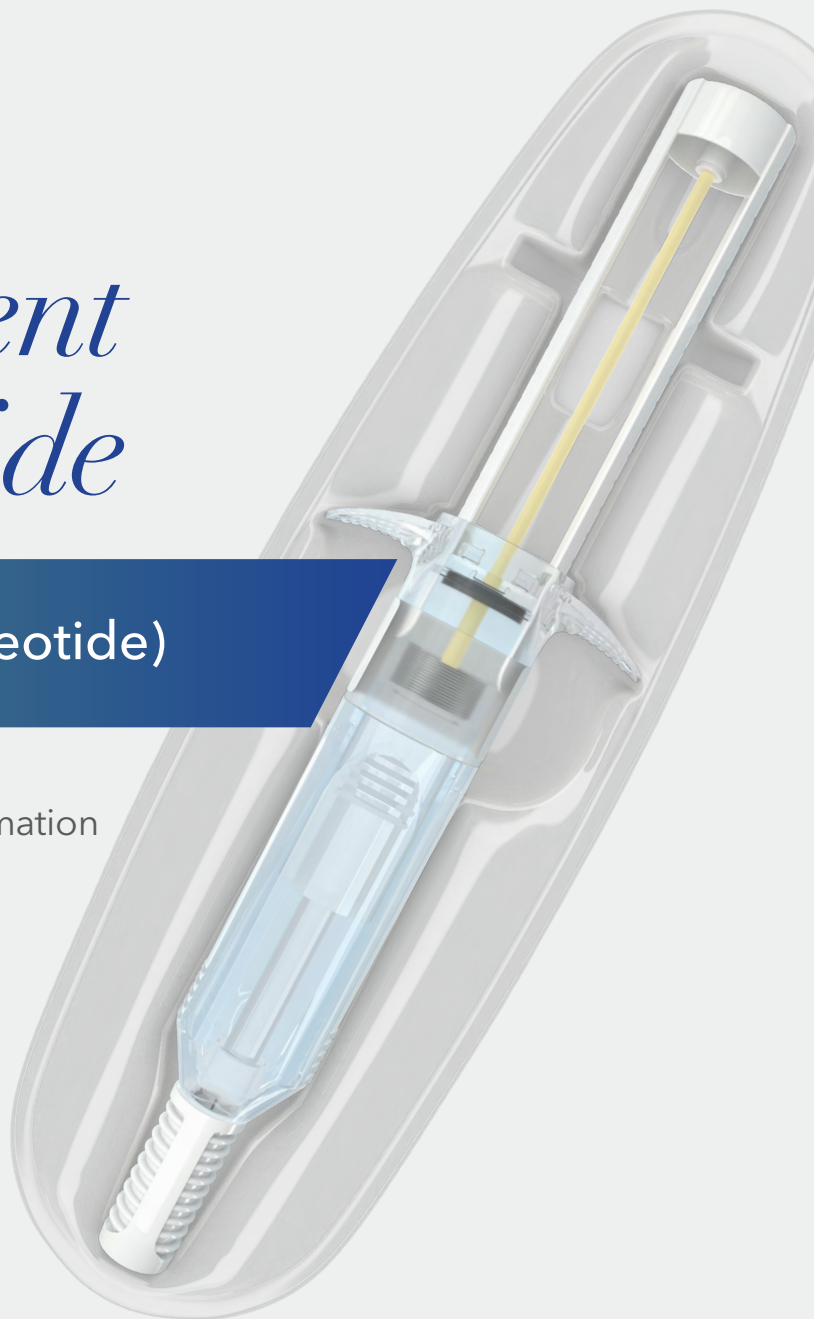


Reimbursement Resource Guide

SOMATULINE® DEPOT (lanreotide)

- Indications and Important Safety Information
- Acquiring Somatuline Depot
- Somatuline Depot Billing and Coding
- IPSEN CARES® Overview



IPSENCARES®

Coverage, Access, Reimbursement & Education Support

Hours: Monday - Friday, 8:00 AM - 8:00 PM ET

Phone: 1-866-435-5677

Fax: 1-888-525-2416

Mail: 2250 Perimeter Park Dr #300,
Morrisville, NC 27560

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Please see Indications and Important Safety Information on page 3 and accompanying full [Prescribing Information](#) and [Patient Information](#).



Somatuline® Depot
(lanreotide) Injection

This guide is provided for informational purposes only. Correct coding is the responsibility of the provider submitting the claim for the item or service. Please check with the payer to verify codes and specific billing requirements. Ipsen Biopharmaceuticals, Inc. (Ipsen) does not make any representation or guarantees concerning reimbursement or coverage for any service or item, nor does Ipsen guarantee patient assistance to the limits described.

INDICATIONS

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

- the treatment of adult patients with unresectable, well- or moderately-differentiated, locally advanced or metastatic gastroenteropancreatic neuroendocrine tumors (GEPNETs) to improve progression-free survival.
- the treatment of adults with carcinoid syndrome; when used, it reduces the frequency of short-acting somatostatin analog rescue therapy.
- 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.

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.

Warnings and Precautions

- **Cholelithiasis and Gallbladder Sludge**
 - SOMATULINE DEPOT may reduce gallbladder motility and lead to gallstone formation.
 - Periodic monitoring may be needed.
 - If complications of cholelithiasis are suspected, discontinue SOMATULINE DEPOT and treat appropriately.
- **Hypoglycemia or Hyperglycemia**
 - 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.
- **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 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.
- **Steatorrhea and Malabsorption of Dietary Fats**
 - New onset steatorrhea, stool discoloration and loose stools have been reported in patients receiving somatostatin analogs, including SOMATULINE DEPOT. Somatostatin analogs reversibly inhibit secretion of pancreatic enzymes and bile acids, which may result in malabsorption of dietary fats and subsequent symptoms of steatorrhea, loose stools, abdominal bloating, and weight loss.
 - If new occurrence or worsening of these symptoms are reported in patients receiving SOMATULINE DEPOT, evaluate patients for potential pancreatic exocrine insufficiency and manage accordingly.

Most Common Adverse Reactions

- **Acromegaly:** Adverse reactions in >5% of patients who received SOMATULINE DEPOT were diarrhea (37%), cholelithiasis (20%), abdominal pain (19%), nausea (11%) injection-site reactions (9%) constipation (8%) flatulence (7%) vomiting (7%) arthralgia (7%) headache (7%) and loose stools (6%).
- **GEP-NETs:** Adverse reactions in >10% of patients who received SOMATULINE DEPOT 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 in ≥5% of patients who received SOMATULINE DEPOT and 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).

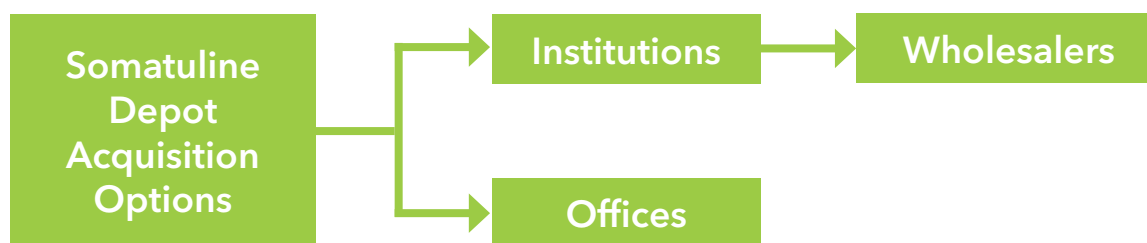
Special Populations

- **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.

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/safety/medwatch-fda-safetyinformation-and-adverse-event-reporting-program.

Acquiring Somatuline Depot



If Somatuline Depot Is Covered Under the Medical Benefit

Purchase Somatuline Depot Directly (Buy and Bill)

- Your office acquires Somatuline Depot directly from an authorized specialty distributor
- Your office collects copay/coinsurance directly from the patient
- Your office submits claim to patient's payer(s) for reimbursement
- It is important to verify with each patient's insurance plan to determine whether buy and bill is allowed

Specialty Pharmacy Assignment of Benefit (AOB)

- Your office submits prescription to specialty pharmacy for a specific patient
- Patient pays copay/coinsurance directly to specialty pharmacy
- Specialty pharmacy ships product directly to your office
- IPSEN CARES® can provide helpful information on selection of the appropriate specialty pharmacy for the patient by calling 1-866-435-5677

If Somatuline Depot Is Covered Under the Pharmacy Benefit

Specialty Pharmacy

- Does not require an upfront financial investment
- Your office orders Somatuline Depot from a specialty pharmacy for a specific patient
- Patient pays copay/coinsurance directly to specialty pharmacy
- Specialty pharmacy ships product directly to your office
- Specialty pharmacy seeks reimbursement from the patient's payer(s)
- IPSEN CARES® can provide helpful information on selection of the appropriate specialty pharmacy provider for the patient by calling 1-866-435-5677

Acquiring Somatuline Depot (Continued)

Authorized Specialty Distributors

Specialty Distributor	Customer Service/Ordering	New Accounts	Order Times
ASD Healthcare®	1-800-746-6273 www.asdhealthcare.com	1-800-385-2368	Mon - Thu: 7:00 AM - 6:30 PM ET Fri: 7:00 AM - 6:00 PM ET
Besse® Medical	1-800-543-2111 www.besse.com	1-800-543-2111 https://www.besse.com/create-an-account	Mon - Thu: 8:30 AM - 7:00 PM ET Fri: 8:30 AM - 5:00 PM ET Sat: Delivery Available by Prior Arrangement
Cardinal Health Specialty Pharmacy	1-866-300-3838 Oncology: 1-877-453-3972 www.cardinalhealth.com/spd	1-866-300-3838 Oncology: 1-877-453-3972 www.cardinalhealth.com/spd	Mon - Fri: 8:00 AM - 7:00 PM ET
CuraScript SD®	1-877-599-7748 www.curascriptsd.com	1-877-599-7748 www.curascriptsd.com/new-accounts	Mon - Fri: 8:30 AM - 7:00 PM ET
Morris & Dickson Specialty Distribution	1-800-388-3833 www.mdspecialtydist.com	1-800-388-3833	Mon - Fri: 8:00 AM - 6:00 PM CST
McKesson Specialty Health	1-800-482-6700 Other: 1-855-477-9800 www.mckesson.com/	Oncology: 1-800-482-6700 Other: 1-855-477-9800	Mon - Fri: 8:00 AM - 8:00 PM ET
Oncology Supply®	1-800-633-7555 www.oncologysupply.com	1-800-633-7555 https://www.oncologysupply.com/create-an-account	Mon - Thu: 9:00 AM - 8:30 PM ET Fri: 9:00 AM - 8:00 PM ET

The specialty distributors listed above are not associated with Ipsen Biopharmaceuticals, Inc. ("Ipsen"), nor do they represent Ipsen. These specialty distributors have been selected by Ipsen to distribute Somatuline Depot given their reputation, capabilities, and customer satisfaction ratings. Our goal is to provide you with options to select the specialty distributors that will meet your needs. You are free to engage any of the above specialty distributors. You may also open an account with more than one of the above distributors if you wish.

Acquiring Somatuline Depot (Continued)

Product Information

HCPCS Code

J1930, Injection, lanreotide, 1 mg

Medically Unlikely Edit (MUE) is 120 mg dose per calendar day

Pack Dimensions

Approximate Dimensions - Unit

Depth: 4.25", height 1", width 12"

Storage and Handling Information

Store Somatuline Depot in the refrigerator at 2°C to 8°C (36°F to 46°F). Protect from light. Store in the original package. Product left in its sealed pouch at room temperature (not to exceed 104°F or 40°C) for up to 72 hours may be returned to the refrigerator for continued storage and use at a later time.

Sales Unit to Trade

One dispensing pack.

Product Expiration

The expiration date is printed on each dispensing pack and syringe label.

Special Shipping Requirements

Somatuline Depot is labeled with specific transportation and storage requirements. Care should be taken to ensure that temperature control at 2°C to 8°C (36°F to 46°F) is maintained during these activities. Product left in its sealed pouch at room temperature (not to exceed 104°F or 40°C) for up to 72 hours may be returned to the refrigerator for continued storage and use at a later time. Somatuline Depot should never be exposed to dry ice. Ipsen will ship Somatuline Depot in a manner that maintains its temperature to meet the requirements stated above during transport from Ipsen to the product destination. Specialty distributors and specialty pharmacies should also package and ship Somatuline Depot in a manner that maintains this same environment.

Customers should call 1-855-463-5127 if they have any questions pertaining to proper shipping.

Product Returns

Credit for returns is subject to Ipsen's current Return Goods Policy. Please contact [Returns.USA@Ipsen.com](mailto>Returns.USA@Ipsen.com) for more information or to receive a Return Goods Authorization.

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.



Somatuline Depot Billing and Coding

Somatuline Depot 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; the treatment of adults with carcinoid syndrome; when used, it reduces the frequency of short-acting somatostatin analog rescue therapy.

Coding

Please refer to the following tables to support appropriate claims processing for Somatuline Depot.^a

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

National Drug Codes (NDCs)

Drug products are identified and reported using a unique, 3-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. Therefore, a zero must be entered into the 10th position (eg, "15054-1120-04"). This is consistent with Red Book and First DataBank listings.

^aPer CPT[®] coding guidelines, patients with any associated multiple endocrine neoplasia syndrome diagnosis will have codes E31.20 – E31.23 coded first and neuroendocrine diagnosis coded second.

Single-Dose Sterile Prefilled Syringe	NDC
120 mg ^b	15054-1120-04
90 mg	15054-1090-04
60 mg	15054-1060-04

^bGEP-NET and carcinoid syndrome: dosing is 120 mg administered every 4 weeks by deep subcutaneous injection. If patients are already being treated with Somatuline Depot for GEP-NETs, do not administer an additional dose for the treatment of carcinoid syndrome.

Acromegaly: the starting dose is 90 mg once every 4 weeks. For patients with moderate or severe renal or hepatic impairment, the 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 1 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.

Somatuline Depot Billing and Coding (Continued)

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 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

Diagnosis Codes for GEP-NETs^a

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
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.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
C7B.00	Secondary carcinoid tumors, unspecified site

^aPer CPT® coding guidelines, patients with any associated multiple endocrine neoplasia syndrome diagnosis will have codes E31.20 – E31.23 coded first and neuroendocrine diagnosis coded second.

Important Safety Information

Warnings and Precautions

• Cholelithiasis and Gallbladder Sludge

- SOMATULINE DEPOT may reduce gallbladder motility and lead to gallstone formation.
- Periodic monitoring may be needed.
- If complications of cholelithiasis are suspected, discontinue SOMATULINE DEPOT and treat appropriately.

IPSENCARES[®]
Coverage, Access, Reimbursement & Education Support

Somatuline[®] Depot
(lanreotide) Injection

8 Please see Indications and Important Safety Information on page 3 and accompanying full [Prescribing Information](#) and [Patient Information](#).

Somatuline Depot Billing and Coding (Continued)

Diagnosis Codes for GEP-NETs^a (Continued)

ICD-10-CM Code	Description
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 Code for Carcinoid Syndrome

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

^aPer CPT[®] coding guidelines, patients with any associated multiple endocrine neoplasia syndrome diagnosis will have codes E31.20 – E31.23 coded first and neuroendocrine diagnosis coded second.

CPT[®] is © 2023 American Medical Association (AMA). All rights reserved. No fee schedules, basic units, relative values, or related listings are included in CPT[®]. The AMA assumes no liability for the data contained herein.

JW Modifier

Effective January 1, 2017, Medicare requires providers to use the JW modifier (drug amount discarded/not administered to any patient) for all claims with unused drugs or biologicals from single-use vials that are appropriately discarded, and to document the discarded drug or biological in the patient's medical record.

Wastage-reporting requirements for payers other than Medicare may vary – providers should check with their specific plans about policies related to use of the JW modifier.

JZ Modifier

Effective July 1, 2023, providers and suppliers are required to report the JZ modifier on all claims that bill for drugs from single-dose containers that are separately payable under Medicare Part B when there are no discarded amounts.

Medicare Medically Unlikely Edits (MUEs)

Centers for Medicare and Medicaid Services (CMS) developed MUEs to reduce the paid claims error rate for Part B claims. A MUE for a HCPCS/CPT code is the maximum units of service that a provider would report under most circumstances for a single beneficiary on a single date of service. Not all HCPCS/CPT codes have a MUE.

Somatuline Depot has a MUE of 120 billing units.

Additional Information: Consult With Individual Payers as Appropriate

Always verify the patient's health insurance benefits prior to injecting Somatuline Depot. Medicare Administrative Contractors (MACs) may develop coverage policies for Somatuline Depot at some point. Coverage policies from MACs are publicly available on the CMS website at www.cms.gov.

Important Safety Information

Warnings and Precautions

• Hypoglycemia or Hyperglycemia

- 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.

IPSENCARES[®]
Coverage, Access, Reimbursement & Education Support

 **Somatuline[®] Depot**
(lanreotide) Injection

9 Please see Indications and Important Safety Information on page 3 and accompanying full [Prescribing Information](#) and [Patient Information](#).

Sample CMS-1500 Claim Form Physician Office Setting

Please note that all codes listed on the sample forms are representative examples only. Coding must be selected by the provider as appropriate based on diagnosis and treatment for the individual patient in each case.

1500
HEALTH INSURANCE CLAIM FORM
APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE 08/05

1. MEDICARE MEDICAID TRICARE CHAMPVA GROUP HEALTH PLAN FECA OTHER
(Medicare #) (Medicaid #) (Sponsor's SSN) (Member ID) (SSN or ID) (SSN) (ID)

2. PATIENT'S NAME (Last Name, First Name, Middle Initial) 3. PATIENT'S BIRTH DATE MM DD YY SEX M F
4. INSURED'S NAME (Last Name, First Name, Middle Initial)

5. PATIENT'S ADDRESS (No., Street) 6. PATIENT RELATIONSHIP TO INSURED
Self Spouse Child Other
7. INSURED'S ADDRESS (No., Street)

8. PATIENT STATUS
Single Married Other
9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial) 10. IS PATIENT'S CONDITION RELATED TO:
a. EMPLOYMENT? (Current or Previous) YES NO
b. AUTO ACCIDENT? YES NO PLACE (State)
c. OTHER ACCIDENT? YES NO
11. INSURED'S POLICY GROUP OR FECA NUMBER
a. INSURED'S DATE OF BIRTH MM DD YY SEX M F
b. EMPLOYER'S NAME OR SCHOOL NAME
c. INSURANCE PLAN NAME OR PROGRAM NAME
d. IS THERE ANOTHER HEALTH BENEFIT PLAN? YES NO # yes, return to and complete item 9 a-d.

12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment below. DATE SIGNED
13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below. DATE SIGNED

14. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION FROM TO
15. IF PATIENT HAS HAD SAME OR SIMILAR ILLNESS, GIVE FIRST DATE. MM DD YY
16. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES FROM TO
17. NAME OF REFERRING PROVIDER OR OTHER SOURCE 17a. NPI 17b. NPI
18. OUTSIDE \$ CHARGES
19. RESERVED FOR LOCAL USE
20. MEDICAID RESUBMISSION CODE ORIGINAL REF. NO.
21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY (Relate Items 1, 2, 3 or 4 to Item 24E by Line)
22. PRIOR AUTHORIZATION NUMBER
23. RESERVED FOR LOCAL USE

24. A. DATE(S) OF SERVICE FROM TO B. PLACE OF SERVICE C. EMERG D. PROCEDURES, SERVICES, OR SUPPLIES E. DIAGNOSIS POINTS F. CPT®/HCPCS CODE G. UNITS H. ICD-10-CM CODE I. RENDERING PROVIDER ID # J. RENDERING PROVIDER ID #

25. FEDERAL TAX ID. NUMBER SSN EIN 26. PATIENT'S ACCOUNT NO. 27. ACCEPT ASSIGNMENT? (For gov't. health care only) YES NO
28. TOTAL CHARGE \$ 29. AMOUNT PAID \$ 30. BALANCE DUE \$
31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof.) 32. SERVICE FACILITY LOCATION INFORMATION 33. BILLING PROVIDER INFO & PH # ()

SIGNED DATE a. NPI b. NPI

NUCC Instruction Manual available at: www.nucc.org PLEASE PRINT OR TYPE APPROVED OMB-093-0999 FORM CMS-1500 (08/05)

19
Reserved for local use. This area may be used to list the drug name.

21
Enter the appropriate ICD-10-CM diagnosis code (eg, C7A.092, malignant carcinoid tumor of the stomach). Code to the highest level of specificity. ICD-10-CM diagnosis codes contain 3-7 digits. It is recommended that providers verify each payer's specific coding requirements prior to injecting.

23
Input the authorization number if obtained from the insurance company.

24A
In the shaded area, list the N4 qualifier, the 11-digit drug NDC number, the unit of measurement qualifier, and dosage.
Example: N41504112004MG120.00 (Note: some payers may request the NDC number be listed in box 19).
In the nonshaded area, list the date of service.

24D
CPT®/HCPCS Code: Enter the appropriate CPT®/HCPCS code. For Somatuline Depot use J1930, Injection, lanreotide, 1 mg. Include the appropriate CPT® codes to report administration procedures (eg, 96372, therapeutic, prophylactic, or diagnostic injection, specify substance, or drug; subcutaneous, or intramuscular).
*Add JZ or JW modifier as appropriate

24E
For each code, insert the reference number corresponding to the appropriate diagnosis code in box 21.

24G
Report the appropriate number of units for the procedure and the appropriate number of milligrams for Somatuline Depot J1930 (120 mg, 90 mg, or 60 mg).

Note
For Somatuline Depot obtained through a specialty pharmacy, no charges for the drug should be billed by the provider. However, inclusion of the HCPCS code (J1930) is recommended to designate the drug administered and number of milligrams administered. Consult with the individual payer to determine the appropriate method of documenting and billing for drugs obtained through a specialty pharmacy.

Somatuline Depot Billing and Coding (Continued)

Payer Coverage

Contacting the payer directly is the best way to determine how the physician may obtain reimbursement for Somatuline Depot. This may be done as part of an insurance benefit verification effort. Benefit verification provides the physician with important reimbursement information, such as benefit structure and coverage, and is typically performed prior to treatment. To ensure accuracy, benefit verifications should be conducted on a patient-specific basis.

Contact IPSEN CARES® or your Ipsen Regional Reimbursement Director for more information regarding coding coverage and reimbursement, including local medical policies.

Medicare

Medicare may cover Somatuline Depot Injection under the Part B benefit when provided and administered by a healthcare provider and under the Part D benefit when dispensed in an outpatient setting. When covered as a Part B benefit, claims for Somatuline Depot are billed to Medicare Administrative Contractors (MACs).

Local MACs manage Medicare Part A/B Benefits. MACs may make specific coverage decisions for Somatuline Depot through Local Coverage Decisions (LCDs) and may issue other coverage instructions through articles and bulletins. The absence of a published coverage policy does not mean that there is no coverage for Somatuline Depot.

The Part D drug benefit provides beneficiaries with coverage for outpatient prescription drugs. The Part D benefit is administered by private health plans, such as stand-alone prescription drug plans (PDPs) or Medicare Advantage prescription drug (MA-PD) plans. The standard benefit design for Medicare Part D coverage includes an annual deductible.

Medicaid

Most state Medicaid programs cover and reimburse Somatuline Depot. Medicaid coverage and payment for Somatuline Depot varies from state to state. Providers should check with the state program or may contact IPSEN CARES for more specific coverage information.

Private Payers

Private payers vary in the payment methods they use to reimburse the sites of service where Somatuline Depot is administered. Some private payers may require that physicians obtain Somatuline Depot through a specialty pharmacy. Specialty pharmacies may bill the payer through the medical or pharmacy benefit, depending on the payer's requirements.

Sample CMS-1450 Claim Form Hospital Outpatient Setting

Please note that all codes listed on the sample forms are representative examples only. Coding must be selected by the provider as appropriate based on diagnosis and treatment for the individual patient in each case.

The image shows a sample CMS-1450 claim form for a hospital outpatient setting. Several fields are highlighted with green callouts:

- 42** and **43** point to the **REVENUE CODE** and **REVENUE DESCRIPTION** fields in the procedure section.
- 44**, **45**, and **46** point to the **CPT®/HCPCS CODE**, **SERVICE DATE**, and **SERVICE UNITS** fields.
- 67** points to the **ICD-10-CM DIAGNOSIS CODE** field.

42 Revenue Code: Enter the appropriate numeric code to identify specific accommodations and/or ancillary service in ascending numeric order by date of service if applicable.
For Somatuline Depot, the most commonly used revenue code is 0636. Use revenue code 0250, General Pharmacy, for payers who do not recognize the 0636 revenue code.
For the administration, list the revenue code for the cost center where services were performed (eg, 0510, clinic; 500, outpatient services; etc).

43 Revenue Description: Enter the narrative description of the related room and board and/or ancillary categories shown in box 42. For payers that require a detailed drug description, a drug description can be inserted. The N4 indicator is listed first, the 11-digit NDC number is listed second, a code describing the unit of measurement qualifier is listed third, and the unit quantity is listed at the end.

44 CPT®/HCPCS Code: Enter the appropriate CPT®/HCPCS code.
For Somatuline Depot, use J1930, Injection, lanreotide, 1 mg.
For the administration, use the CPT® code representing the administration route (eg, 96372, therapeutic, prophylactic, or diagnostic injection; specify substance or drug; subcutaneous or intramuscular).

45 Service Date: Enter the date on which the service was performed, using an MMDDYY format.

46 Service Units: Enter the total number of units of service as appropriate and the appropriate number of milligrams for Somatuline Depot (120 mg, 90 mg, or 60 mg).

67 Enter the complete ICD-10-CM diagnosis code, (eg, C7A.092, malignant carcinoid tumor of the stomach). Code to the highest level of specificity. ICD-10-CM diagnosis codes contain 3 to 7 digits. It is recommended that providers verify each payer's specific coding requirements prior to injecting.

IPSEN CARES® Overview

Helping Patients Get Access to Their Prescribed Medications With the Information They Need

IPSEN CARES serves as a central point of contact between patients/caregivers, healthcare providers, insurance companies, and specialty pharmacies.

The IPSEN CARES Program is staffed by dedicated Patient Access Managers who can assist in a variety of ways:



Phone: 1-866-435-5677
Fax: 1-888-525-2416



Hours: Monday - Friday
8:00 AM - 8:00 PM ET



Website:
IPSENCARES.com

Reimbursement Assistance

- **Benefits Verification** – Verifies patients' coverage, restrictions (if applicable), and copayment/coinsurance amounts
- **Prior Authorization (PA)/Appeals**
 - Provides information on documentation required by payers on PA specifics and recommendations for next steps based on payer policy
 - Provides information on the payer appeals process
- **Billing and Coding Information**

Financial Support

- **Copay Assistance** – Offers copay assistance to eligible^a commercially-insured patients
- **Patient Assistance Program (PAP)** – Determines patients' eligibility^b for PAP and dispenses free product to eligible patients

Product Distribution

- **Institutions** – Somatuline Depot can be acquired from wholesaler
- **Private Practices**
 - Direct (buy-and-bill) acquisition from a group of approved specialty distributors
 - Specialty pharmacy delivery (IPSEN CARES can provide helpful information on selection of the appropriate specialty provider for the patient by calling 1-866-435-5677)

Patient Support

- **Communication with providers and patients** – Conducts calls to both healthcare provider and patient with status updates about patient's IPSEN CARES enrollment, benefits verification results, coverage status, dispense date, etc.

^aPlease see Patient Eligibility & Terms and Conditions on page 15.

^bPatients may be eligible for free medication through our PAP. Patients may be eligible to receive free drug if they 1) are experiencing financial hardship, 2) are uninsured or functionally uninsured, 3) are US residents, 4) received a prescription for an on-label use of an Ipsen medication as supported by information provided in the program application, and 5) meet income criteria based on Experian soft credit check. Eligibility does not guarantee approval for participation in the program. The PAP provides Somatuline Depot product only, and does not cover the cost of previously purchased product or medical services.

IPSEN CARES® Overview

Somatuline Depot Copay Assistance Program

Somatuline Depot Copay Assistance Program eligible^a patients may pay as little as \$0 per prescription

Steps for Patients to Receive Somatuline Depot Assistance

- 1 Provider and patient complete Enrollment Form and send to IPSEN CARES.
 - Patients can also enroll via the copay website
- 2 Patient is administered Somatuline Depot.
- 3 Provider submits claim to patient's insurance company.
- 4 Once claim is paid, Provider submits the following documents via fax 1-833-671-1086 or via the upload function at IPSENCARES.com.
 - Completed CMS-1500 or CMS-1450 form
 - Explanation of benefits (EOB)/remittance from the patient's primary private insurance showing itemized allowed charges and remaining cost share for the Somatuline Depot therapy
- 5 IPSEN CARES typically processes eligible claim payments to a patient's provider within 17-24 business days via EFT (wire transfer) or check.

^aPlease see Patient Eligibility & Terms and Conditions on page 15.

IPSENCARES®
Coverage, Access, Reimbursement & Education Support



If you have questions about the Somatuline Depot Copay Assistance Program, call 1-866-435-5677 Monday - Friday 8:00 am - 8:00 pm ET

For additional information, visit us online at

IPSENCARES.com

SCAN THE QR CODE to enroll into the Somatuline Depot Copay Assistance Program

IPSENCARES®
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 **Somatuline Depot**
(lanreotide) Injection

IPSEN CARES® Overview

Copay Assistance Program

Patient Eligibility & Terms and Conditions: Patients are not eligible for copay assistance through IPSEN CARES® if they are enrolled in any state or federally funded programs for which drug prescriptions or coverage could be paid in part or in full, including, but not limited to, Medicare Part B, Medicare Part D, Medicaid, Medigap, VA, DoD, or TRICARE (collectively, "Government Programs"), or where prohibited by law. Patients must be United States residents (including its territories) and enrolled in IPSEN CARES® to receive copay program benefits. Patients residing in Massachusetts and California are not eligible for copay assistance. Patients residing in Rhode Island can only receive assistance with the cost of Ipsen products but not the cost of related medical services (injection). Patients receiving assistance through another assistance program or foundation, free trial, or other similar offer or program, are not eligible for the copay assistance program during the current enrollment year.

An annual calendar year maximum copay benefit applies. Patients may remain enrolled in copay assistance as long as eligibility criteria is met.

Patients or guardians are responsible for reporting receipt of copay savings benefit to any insurer, health plan, or other third party who pays for or reimburses any part of the prescription filled through the program, as may be required. Additionally, patients or guardians may not submit any benefit provided by this program for reimbursement through a Flexible Spending Account, Health Savings Account, Health Reimbursement Account, or otherwise to a government or private payor. Ipsen reserves the right to rescind, revoke, or amend these offers without notice at any time. Ipsen and/or its copay assistance vendor are not responsible for any transactions processed under this program where Medicaid, Medicare, or Medigap payment in part or full has been applied. Claim reimbursement requests must be submitted within 180 days of treatment date. Data related to patient participation may be collected, analyzed, and shared with Ipsen for market research and other purposes related to assessing the program. Data shared with Ipsen will be de-identified, meaning it will not identify the patient. Void outside of the United States and its territories or where prohibited by law, taxed, or restricted. This program is not health insurance. No other purchase is necessary. Copay assistance cannot be sold, purchased, traded, or counterfeited. Void if reproduced.

Somatuline Depot Copay Assistance Program

Frequently Asked Questions

Q What is the Somatuline Depot Copay Assistance Program eligibility criteria?*

A Patients are not eligible for copay assistance through IPSEN CARES if they are enrolled in any state or federally funded programs for which drug prescriptions or coverage could be paid in part or in full, including, but not limited to, Medicare Part B, Medicare Part D, Medicaid, Medigap, VA, DoD, or TRICARE (collectively, "Government Programs"), or where prohibited by law. Patients must be United States residents (including its territories) and enrolled in IPSEN CARES to receive copay program benefits. Patients residing in Massachusetts and California are not eligible for copay assistance. Patients residing in Rhode Island can only receive assistance with the cost of Ipsen products but not the cost of related medical services (injection). Patients receiving assistance through another assistance program or foundation, free trial, or other similar offer or program, are not eligible for the copay assistance program during the current enrollment year.

Q What does the Somatuline Depot Copay Assistance Program cover?

A The Copay Assistance Program covers the patient's out-of-pocket cost for the prescription medicine and its applicable administration copay, where allowed by state law up to the annual calendar year maximum copay program benefit amount. Any surgical, physician, and/or laboratory expenses will be excluded from payment.

Q How do patients know that they have been enrolled?

A Patients will receive notification of copay enrollment and will be mailed a welcome letter. The provider will also be sent a welcome fax.

Q Where can the Somatuline Depot Copay Assistance Program be used?

A The Copay Assistance Program can be used in the provider's office/practice or hospital when using the patient's medical benefits. The Copay Assistance Program is also available when using the patient's pharmacy benefit and obtaining the prescription through a specialty pharmacy.

Q Are cash-pay patients allowed to use the Somatuline Depot Copay Assistance Program?

A No. Patients must be enrolled in a commercial insurance plan to be eligible for the Copay Assistance Program.

Q Are patients with government insurance eligible for the Somatuline Depot Copay Assistance Program?

A No. Patients are not eligible for copay assistance if they are enrolled in any state or federally funded programs for which drug prescription or coverage could be paid in part or in full, including but not limited to Medicare Part B, Medicare Part D, Medicaid, Medigap, VA, DoD, or Tricare (collectively, "Government Programs").

Q What is the timely filing submission requirement for reimbursement requests?

A Claim reimbursement requests must be submitted within 180 days of treatment date.

Q When does the program reset? What do the patient and provider have to do to remain enrolled?

A The program resets on January 1. Patients may remain enrolled in copay assistance as long as eligibility criteria is met.

*Please see Patient Eligibility & Terms and Conditions on page 15.

For additional information about the
Somatuline Depot Program, call:

1-866-435-5677

Monday - Friday, 8:00 AM - 8:00 PM ET



For additional information,
visit us online at
IPSENCARES.com

IPSENCARES[®]
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 **Somatuline**[®] Depot
(lanreotide) Injection

REGIONAL REIMBURSEMENT DIRECTORS ARE AVAILABLE TO EDUCATE HEALTHCARE PROFESSIONALS

- Increase healthcare professionals' knowledge about reimbursement of Ipsen products
- Provide information to help address complex reimbursement issues for healthcare professionals
- Explain IPSEN CARES services and support offerings for patients and healthcare professionals



IPSENCARES[®]
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Hours: Monday - Friday, 8:00 AM - 8:00 PM ET
Phone: 1-866-435-5677
Fax: 1-888-525-2416
Mail: 2250 Perimeter Park Dr #300,
Morrisville, NC 27560
IPSENCARES.com

To learn more about Somatuline Depot, visit SOMATULINEDEPOT.com

Please see accompanying full [Prescribing Information](#) and [Patient Information](#).

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