Reimbursement Resource Guide

SOMATULINE® DEPOT (LANREOTIDE)

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



Hours: 8:00 AM - 8:00 PM ET, Monday - Friday Phone: 1-888-435-5677 Fax: 1-888-525-2416 Mail: 11800 Weston Parkway, Cary, NC 27513 www.ipsencares.com

Please see Indications and Important Safety Information on page 3 and accompanying full <u>Prescribing Information</u> and <u>Patient Information</u>.



IPSEN CARES



Please see Indications and Important Safety Information on page 3 and accompanying full
<u>Prescribing Information</u> and <u>Patient Information</u>.

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.



IPSEN CARES OVERVIEW

Indications

SOMATULINE® DEPOT (lanreotide) 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 shortacting 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.

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.

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 >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 occurring 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

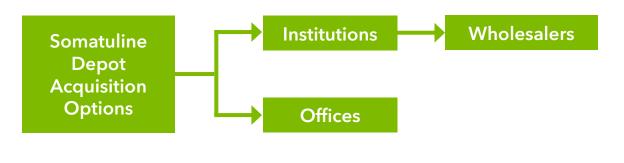
- **Lactation:** Advise women not to breastfeed during treatment and for 6 months after the last dose.
- Moderate to Severe Renal and Hepatic Impairment: See full prescribing information for dosage adjustment in patients with acromegaly.

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/medwatch.





Acquiring Somatuline Depot



If Somatuline Depot Is Covered Under the Medical Benefit

Purchase Somatuline Depot Directly (Buy and Bill)

- Requires an upfront financial investment
- Your office acquires Somatuline Depot directly from a group of approved specialty distributors
- Your office collects copay/coinsurance directly from the patient
- Your office seeks reimbursement from the patient's payer(s)
- It is important to verify with each patient's insurance plan to determine if buy and bill is allowed

Specialty Pharmacy Assignment of Benefit (AOB)

- 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 1-888-435-5677

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 1-888-435-5677





Please see Indications and Important Safety Information on page 3 and accompanying full <u>Prescribing Information</u> and <u>Patient Information</u>. ACQUIRING SOMATULINE DEPOT

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 ам - 6:30 рм ЕТ Fri: 7:00 ам - 6:00 рм ЕТ
Besse® Medical	1-800-543-2111 www.besse.com	1-800-543-2111 https://www.besse.com/create- an-account	Mon - Thu: 8:30 ам - 7:00 рм ЕТ Fri: 8:30 ам - 5:00 рм ЕТ 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 ам - 7:00 рм ЕТ
CuraScript SD®	1-877-599-7748 www.curascriptsd.com	1-877-599-7748 www.curascriptsd.com/ new-ac- counts	Mon - Fri: 8:30 ам - 7:00 рм ЕТ
McKesson Specialty Health	1-800-482-6700 Other: 1-855-477-9800 https://mscs.mckesson. com/CustomerCenter/ MckessonWebStore. html#PRELOGIN_VIEW	Oncology: 1-800-482-6700 Other: 1-855-477-9800	Mon - Fri: 8:00 ам - 8:00 рм ЕТ
Oncology Supply®	1-800-633-7555 www.oncologysupply.com	1-800-633-7555 https://www.oncologysupply.com/ create-an-account	Mon - Thu: 9:00 ам - 8:30 рм ЕТ Fri: 9:00 ам - 8:00 рм ЕТ

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.





Please see Indications and Important Safety Information on page 3 and accompanying full 5 <u>Prescribing Information</u> and <u>Patient Information</u>.

Acquiring Somatuline Depot (Continued)

Product Information

HCPCS Code

J1930, Injection, lanreotide, 1 mg

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.

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. When shipping Somatuline Depot, a foam or gel refrigerant ice that has been frozen hard at -18°C (0°F) for a minimum of 24 hours should be used. 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 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.





Please see Indications and Important Safety Information on page 3 and accompanying full
<u>Prescribing Information</u> and <u>Patient Information</u>.

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, "15054-1120-03"). This is consistent with Red Book and First DataBank listings.

Single-Dose Sterile Prefilled Syringe	Current NDC "Legacy"	New NDC
120 mg⁵	15054-1120-03	15054-1120-04
90 mg	15054-1090-03	15054-1090-04
60 mg	15054-1060-03	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, 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.

Per 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.





Please see Indications and Important Safety Information on page 3 and accompanying full 7 Prescribing Information and Patient Information.

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 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

^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





Please see Indications and Important Safety Information on page 3 and accompanying full 8 <u>Prescribing Information</u> and <u>Patient Information</u>.

IPSEN CARES OVERVIEW

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
С7В.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 © 2020 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.

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 Centers for Medicare and Medicaid Services (CMS) website at <u>www.cms.gov</u>.

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.





Please see Indications and Important Safety Information on page 3 and accompanying full
<u>Prescribing Information</u> and <u>Patient Information</u>.

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.

EALTH INSURANCE CLAIM FORM		
PROVED BY NATIONAL UNIFORM CLAIM COMMITTEE 08/05		PICA
MEDICARE MEDICAID TRICARE CHAM	MPVA GROUP FECA OTH	ER 1a. INSURED'S I.D. NUMBER (For Program in Item 1)
(Medicare #) (Medicaid #) (Sponsor's SSN) (Memi	ber ID#) (SSN or ID) (SSN) (ID)	
PATIENT'S NAME (Last Name, First Name, Middle Initial)	3. PATIENT'S BIRTH DATE SEX	4. INSURED'S NAME (Last Name, First Name, Middle Initial)
PATIENT'S ADDRESS (No., Street)	6. PATIENT RELATIONSHIP TO INSURED	7. INSURED'S ADDRESS (No., Street)
	Self Spouse Child Other	
TY STA		CITY STATE
P CODE TELEPHONE (Include Area Code)		ZIP CODE TELEPHONE (Include Area Code)
()	Employed Full-Time Part-Time Student Student	()
OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)	10. IS PATIENT'S CONDITION RELATED TO:	11. INSURED'S POLICY GROUP OR FECA NUMBER
OTHER INSURED'S POLICY OR GROUP NUMBER	a. EMPLOYMENT? (Current or Previous)	a. INSURED'S DATE OF BIRTH SEX
	YES NO	
MM DD YY MC F	b. AUTO ACCIDENT? PLACE (Stat	b. EMPLOYER'S NAME OR SCHOOL NAME
EMPLOYER'S NAME OR SCHOOL NAME	c. OTHER ACCIDENT?	C. INSURANCE PLAN NAME OR PROGRAM NAME
	YES NO	
INSURANCE PLAN NAME OR PROGRAM NAME	10d. RESERVED FOR LOCAL USE	d. IS THERE ANOTHER HEALTH BENEFIT PLAN?
READ BACK OF FORM BEFORE COMPLE	TING & SIGNING THIS FORM	YES NO If yes, return to and complete item 9 a-d. 13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize
PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE I authorize to process this claim. I also request payment of government benefits ei	the release of any medical or other information necessary	payment of medical benefits to the undersigned physician or supplier for services described below.
below.		
	DATE	SIGNED
INJURY (Accident) OR PREGNANCY(LMP)	15. IF PATIENT HAS HAD SAME OR SIMILAR ILLNES GIVE FIRST DATE MM DD YY	S. 16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION
NAME OF REFERRING PROVIDER OR OTHER SOURCE	17a.	18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES
RESERVED FOR LOCAL USE	17b. NPI	FROM TO 100000000000000000000000000000000000
DIAGNOSIS OR NATURE OF ILLNESS OR IN IURY (Belate Items 1	I, 2, 3 or 4 to Item 24E by Line)	22. MEDICAID RESUBMISSION CODE ORIGINAL REF. NO.
<u> </u>	3	23. PRIOR AUTHON ATION NUMBER
	4	
From To PLACEOF (E	CEDURES, SERVICES, OR SUPPLIES E. DIAGNOS	SIS F. G. H. I. J. DAYS FRUIT ID. RENDERING CR Farty ID. TO
MM DD YY SERVICE EMG CPT/		OR Family ID. HENDERING
4A	- 240 🕴 🕞	24E 🕞 🛏 24G 🚥
		NPI
		NPI
		NPI
		NPI
FEDERAL TAX I.D. NUMBER SSN EIN 26. PATIENT	TS ACCOUNT NO. 27. ACCEPT ASSIGNMENT	28. TOTAL CHARGE 29. AMOUNT PAID 30. BALANCE DUE
	YES NO	s s s s
INCLUDING DEGREES OR CREDENTIALS	FACILITY LOCATION INFORMATION	33. BILLING PROVIDER INFO & PH # ()
(I certify that the statements on the reverse		
apply to this bill and are made a part thereof.)		

19

eserved for local use. This area may be used o 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).

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).

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

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.



Please see Indications and Important Safety Information on page 3 and accompanying full
 <u>Prescribing Information</u> and <u>Patient Information</u>.



ACQUIRING SOMATULINE DEPOT

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.



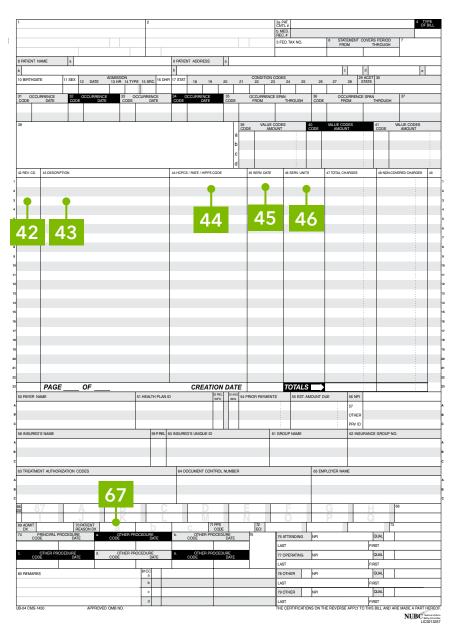
Please see Indications and Important Safety Information on page 3 and accompanying full 11 <u>Prescribing Information</u> and <u>Patient Information</u>.

Somatuline[®] Depot

(lanreotide) Injection 60mg, 90mg and 120mg

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.



42

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

the cost center where services were performed (eg, 0510, clinic, 500, outpatient services, etc).

43

Revenue Description: Enter the narrative 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

44

CPT ®/HCPCS Code: Enter the appropriate CPT ®/

therapeutic, prophylactic, or diagnostic injection, specify substance, or drug; subcutaneous or intramuscular).

45

Service Date: Enter the date on which the service

46

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

Code to the highest level of specificity. ICD-10-CM diagnosis codes contain 3 to 7 digits. It is recommended that providers verify each





Please see Indications and Important Safety Information on page 3 and accompanying full 12 Prescribing Information and Patient Information.

IPSEN CARES® Overview

IPSEN CARES Provides Support for Patients and Providers

The IPSEN CARES Patient Access Specialists are fully dedicated to:

- Facilitating patients' access to their prescribed medications
- Providing information and support for the interactions among offices, patients, and insurance companies for lpsen medications

IPSEN CARES provides a single point-of-contact dedicated to assisting patients, providers, and staff.



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

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



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-specific processes required to submit a level I or a level II appeal, as well as provides guidance as needed through the process.

Financial Support

- Copayment Assistance offers copayment assistance to eligible^a patients. This includes referring to the Somatuline Depot Commercial Copay Program or referring to an independent non-profit organization if available.
- 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 1-888-435-5677).

Patient Support

• 360° Communication – 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.

HCP Online Portal

Ipsen realizes that more work is now being done by computer rather than paper and fax machines. We hope this online portal will be a convenient resource for you and your office. After you register and create a profile, your profile will be validated within 1 business day.

Through the online portal you can:

- Submit enrollments and check their status
- Download additional forms and materials
- Send a message to the IPSEN CARES team
- Obtain Specialty Pharmacy dispensing information (if applicable)

Visit <u>www.ipsencares.com/hcp-resources</u> to learn more.

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

^bPatients may be eligible to receive free drug if they are experiencing financial hardship, are uninsured or functionally uninsured, are US residents, and received a prescription for an on-label use of Somatuline Depot, as supported by information provided in the Program application. 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.





Please see Indications and Important Safety Information on page 3 and accompanying full 13 Prescribing Information and Patient Information.

IPSEN CARES OVERVIEW

IPSEN CARES[®] Overview Somatuline Depot Copay Assistance Program

Eligible^a commercially insured patients pay as little as



- Program exhausts after 13 prescriptions and/or administrations of medication, or a maximum annual copay benefit of \$20,000, whichever comes first
- Program resets every January 1st
- IPSEN CARES will confirm with patient on an annual basis that patient still meets criteria for program

Simple Steps for Patients to Receive Their Somatuline Depot Assistance

Provider and patient complete enrollment form and send to IPSEN CARES.



Patient is administered Somatuline Depot.



Provider submits claim to patient's insurance company.



Once claim is paid; provider submits the following documents via fax (253-395-8028)

- a. Completed CMS-1500 or CMS-1450 form
- b. 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
- IPSEN CARES processes eligible claim payment to patient's provider typically within 7-10 business days via either ACH (wire transfer) or check.

^aSee Patient Eligibility & Terms and Conditions on page 15.





Please see Indications and Important Safety Information on page 3 and accompanying full 14 <u>Prescribing Information</u> and <u>Patient Information</u>. **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 residing in Massachusetts, Minnesota, Michigan, or 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.

Cash-pay patients are eligible to participate. "Cash-pay" patients are defined for purposes of this program as patients without insurance coverage or who have commercial insurance that does not cover Somatuline[®] Depot. Medicare Part D enrollees who are in the prescription drug coverage gap (the "donut hole") are not considered cash-pay patients and are not eligible for copay assistance through IPSEN CARES[®]. For patients with commercial insurance who are not considered to be cash-pay patients, the maximum copay benefit amount per prescription is an amount equal to the difference between the annual maximum copay benefit of \$20,000 and the total amount of copay benefit amount per prescription is \$1,666.66, subject to the annual maximum of \$20,000 in total. Patient pays any amount greater than the maximum copay savings amount per prescription.

Patient or guardian is 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 may not submit any benefit provided by this program for reimbursement through a Flexible Spending Account, Health Savings Account, or Health Reimbursement Account. Ipsen reserves the right to rescind, revoke, or amend these offers without notice at any time. Ipsen and/or RxCrossroads by McKesson, are not responsible for any transactions processed under this program where Medicaid, Medicare, or Medigap payment in part or full has been applied. 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.



Please see Indications and Important Safety Information on page 3 and accompanying full 15 <u>Prescribing Information</u> and <u>Patient Information</u>.



IPSEN CARES OVERVIEW

Q How does a patient enroll in the Somatuline Depot Copay Assistance Program?

A Enrollment for either the medical or pharmacy benefit program is accomplished via IPSEN CARES*. The patient and provider complete their respective sections of the Enrollment Form, and the provider submits the form to IPSEN CARES or the patient may choose to self-enroll via the Somatuline Depot Self-Enrollment Form found on www.ipsencares.com.

Q How will IPSEN CARES determine that the patient is eligible^a?

IPSEN CARES will perform a benefit verification to determine if the patient requires assistance with the pharmacy or medical benefit. The benefits verification will determine whether the patient meets the eligibility criteria for the program, and the appropriate offer will be given to the provider and the patient. If the patient qualifies for both benefits, IPSEN CARES will allow the patient and the physician to determine which program to use.

Q Can the patient switch between the two programs?

- A Yes, the patient may switch if the benefit need changes, but are subject to an aggregate annual maximum savings of \$20,000.
- Q How do patients know that they have been enrolled?
- A Patients can choose to self-enroll in the program or their physician can enroll them by submitting an IPSEN CARES Enrollment Form. IPSEN CARES will speak to the patient and physician to review eligibility and enrollment into the program. In addition, the patient and physician will be mailed letters welcoming them into the program.

Q Are cash-pay patients allowed to use the program?

A Yes, cash-pay patients may qualify for the Copay Assistance Program. Eligible cash-paying patients will receive up to \$1,666.66 of support per prescription, up to \$20,000 program annual maximum.

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

A The Somatuline Depot Copay Assistance Program is available to be used in the physician'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 via Specialty Pharmacy.

Q A patient is enrolled in Medicaid. Are they eligible for the Somatuline Depot Assistance Copay 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 A patient has multiple Explanation of Benefits (EOBs) that need payment. Can multiple EOB submissions be sent for payment at one time?

- A Yes. Subject to the maximum annual cap and other program restrictions, multiple EOBs can be submitted for consideration at one time, including EOBs 90 days prior to the patient's enrollment date.
- Q I have a patient who has two separate documentations (ie, an EOB and a Specialty Pharmacy receipt) for the same date of service. Will this patient be paid for both documents?
- A This depends on which services were provided to the patient. Subject to the maximum annual benefit and other restrictions, the Somatuline Depot Copay Assistance Program will cover the cost of the drug and injections (this also includes the physician's visit the same day of injection) where allowable by the state. Our processors will calculate the associated Somatuline Depot costs and reimburse accordingly. Any surgical, physician, and/or laboratory expenses will be excluded from payment.

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

For additional information about the Somatuline Depot Program, call:

1-888-435-5677

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

For additional information, visit us online at www.ipsencares.com





Please see Indications and Important Safety Information on page 3 and accompanying full 16 <u>Prescribing Information</u> and <u>Patient Information</u>.

Overview of Important IPSEN CARES Forms

ENROLLMENT FORM

Completion and submission of the Enrollment Form is the first step for enrolling in IPSEN CARES. The form needs to be printed, filled out completely by the Provider and the Patient/Legal Guardian, signed, and faxed back to IPSEN CARES. The step-by-step instructions ensure that all relevant sections are completed and signed.

A Self-Enrollment Form is available for Somatuline Depot. The form needs to be printed, filled out completely by the Provider and the Patient/Legal Guardian, signed, and faxed back to IPSEN CARES.

PATIENT AUTHORIZATION FORM

Once a patient is enrolled in IPSEN CARES, a Patient Authorization Form needs to be completed by the Patient/Legal Guardian every 3 years* in order to maintain participation in IPSEN CARES. The form needs to be printed, filled out completely by the Patient/Legal Guardian, signed, and faxed back to IPSEN CARES. It is important that the Patient/Legal Guardian review the original IPSEN CARES Enrollment Form prior to signing the Authorization Form.

*NOTE: The patient authorization will expire sooner than 3 years where required by state law.

	PATIENT INFORMATION		
	Patient Name (First & Last)	Home Phone #	Mobile Phone #
	Patient Address	 Caregiver/Legal Guardian 	n (First & Last Name)
	City State Zip		
P 1	Male Female Date of Birth (MM/DD/YY)//	Relationship to Patient	1 Phone #
STEP	Would you like to evrol in the ipson adherence text messaging program information if ipsore permission to space to contact me by SMS;text m data neters may apply. $\$ like $\$ Nould you like to receive marketing information from ipsore as descrit if ipso permission to jacen to contact me with information via mail, advertisionents, discusse tates wareness materials and educations. Automatic dailing may be used. Carrier, text, and data neters may apply of purchasing any public of services.	essage for the Ipsen adherenc bed on Page 5, in Step 8 under email, phone or SMS/text mes I material about SOMATUI INI	e text messaging program. Carrier, to Additional Product and Support Info isage, all of which may include telem == DFPOT and programs that suppor
	INSURANCE INFORMATION Complete or attach front and back copy of p	patient's primary and secondary in	nsurance cards for pharmacy and medical
	Is patient insured? Yes No		dary insurance? 🗌 Yes 🔲 No
2		Secondary Insurance Co.	
STEP		Insurance Co. Phone #	
57		Subscriber Policy ID #	
	Policy/Employer/Group #	Policy/Employer/Group #	·
	Is Physician a Participating Provider? (check one) Participating	☐ Non-Participating	
l h th	NTIENT AUTHORIZATION AND ADDITIONAL PRODUCT AND SUPPOR ave read and understand the IPSEN CARES Patient Authorization and Ac e terms. gnature of Patient or Caregiver/Legal Guardian		Information on Page 5, in Step 8 and
	PRESCRIBER INFORMATION		
	Prescriber Name	Street Address	
	DEA # State License #	City	State Zip
۲S	Tax ID # NPI #	Office Contact and Title	
SE	Medicaid Provider # (Required if Medicaid Patient)	Phone #	Fax#
	Medicare PTAN # (Required if Medicare Patient)	Email	
	Office/Institution	 Preferred Method of Con 	tact 🗌 Phone 🗌 Fax 🔲 Email
	Specialty Oncology Endocrinology Other	Best time to contact	Morning 🗌 Afternoon 🗌 Evenin
2	Would you like to request Nurse Home Health Administration of Somatuline Depot for your patient by an IPSEN CARES nurse if the patient is eligible? Yes No	If yes, requested location	r for training is Prescriber's Office (Please Specify) IPSEN CA
	N CARES' PATIENT AUTHORIZATION FORM		
eas SEN PL	IN CARES [®] PATIENT AUTHORIZATION FORM are primt the form, fill it out completely, sign it, and fax to CARES must receive pages 1 and 2 in order for the form to be co EASE BE SURE TO REVIEW ORIGINAL IPSEN CARES ENRO ATTIENT AUTHORIZATION IPSEN CARES [®] PRO	0: 1-888-525-2416. mplete. DLLMENT FORM	at 1-866-435-5677 Somatuline' I Ganrootdel Ispetso of

The initiality of the standard standard by Caling in State Orkey and State Ork

Patient Name (First & Last) _____ Legal Guardian (First & Last Name
Patient Date of Birth (mm/dd/yy) ____/ ____/ ____

Phone #_____

Signature of Patient or Legal Guardian

IPSENCARES Coverage, Access, Reinforcement & Education Support



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

Please see Indications and Important Safety Information on page 3 and accompanying full 17 <u>Prescribing Information</u> and <u>Patient Information</u>.

Overview of Important IPSEN CARES Forms (Continued)

PATIENT ASSISTANCE PROGRAM APPLICATION

The Patient Assistance Program (PAP) is designed to provide Somatuline Depot at no cost to eligible patients. Patients may be eligible to receive free drug if they are experiencing financial hardship, have no insurance coverage, and received a prescription for an on-label use of Somatuline Depot, as supported by information provided in the Program application. 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.

		e print the form, fill it out completely, sign it, and fax to: 1-88 I CARES must receive pages 1, 2, and 3 in order for the form to be or		Somatuline Depot
n fe	nay or a uar	Patient Assistance Program (PAP) is designed to provide Somatulin be eligible to receive free drug if they are experiencing financial ha non-label use of Somatuline Deport, as supported by information p antee approval for participation in the program. The PAP provides lously purchased product or medical services.	rdship, have no insurance coverage rovided in the Program application	, and received a prescription Eligibility does not
		PATIENT INFORMATION		
		First Name MI	Last Name	
		Date of Birth (MM/DD/YYYY)/ Gende	r 🗋 Male 📋 Female	
		Mailing Address		Apt #
		CityState	Zip	
		Phone # Are ye	au a US resident? 🔲 Yes 🗌 No	
		Email Address		
ent	STEP 1	Prescribing Physician	Treating Facility	
Completed by the patient	s	INSURANCE INFORMATION Complete or attach front and back copy of patient's primary and see	ondary insurance cards for pharmacy	and medical benefits.
Comp		Primary Insurance Co	Secondary Insurance Co.	
		Insurance Co. Phone #	Insurance Co. Phone #	
		Subscriber Policy ID #	Subscriber Policy ID #	
		Policy/Employer/Group #		
		Is Physician a Participating Provider (check one) Participatin		
		□ Uninsured - Patient does not have commercial health insurance limited to Medicare or Medicaid, or has been denied coverage by the		insurance, including but not
		PROOF OF INCOME'		
	STEP 2	My estimated annual household income currently is \$	come. Supplemental Security Income. Aid fr	rom the Department of Public Welfare.
			Cev	PSENCARES 1

Somatuline[®] Depot

(lanreotide) Injection 60mg, 90mg and 120mg



Please see Indications and Important Safety Information on page 3 and accompanying full 18 Prescribing Information and Patient Information.

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

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



Please see Indications and Important Safety Information on page 3 and accompanying full 19 Prescribing Information and Patient Information.





Hours: 8:00 AM - 8:00 PM ET, Monday - Friday Phone: 1-888-435-5677 Fax: 1-888-525-2416 Mail: 11800 Weston Parkway Cary, NC 27513 www.ipsencares.com

To learn more about Somatuline Depot, visit <u>SOMATULINEDEPOT.com</u>

Please see accompanying full <u>Prescribing Information</u> and <u>Patient Information</u>.

SOMATULINE DEPOT is a registered trademark of IPSEN PHARMA S.A.S. IPSEN CARES is a registered trademark of Ipsen S.A. All other trademarks and registered trademarks are property of their

All other trademarks and registered trademarks are property of their respective owners.



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