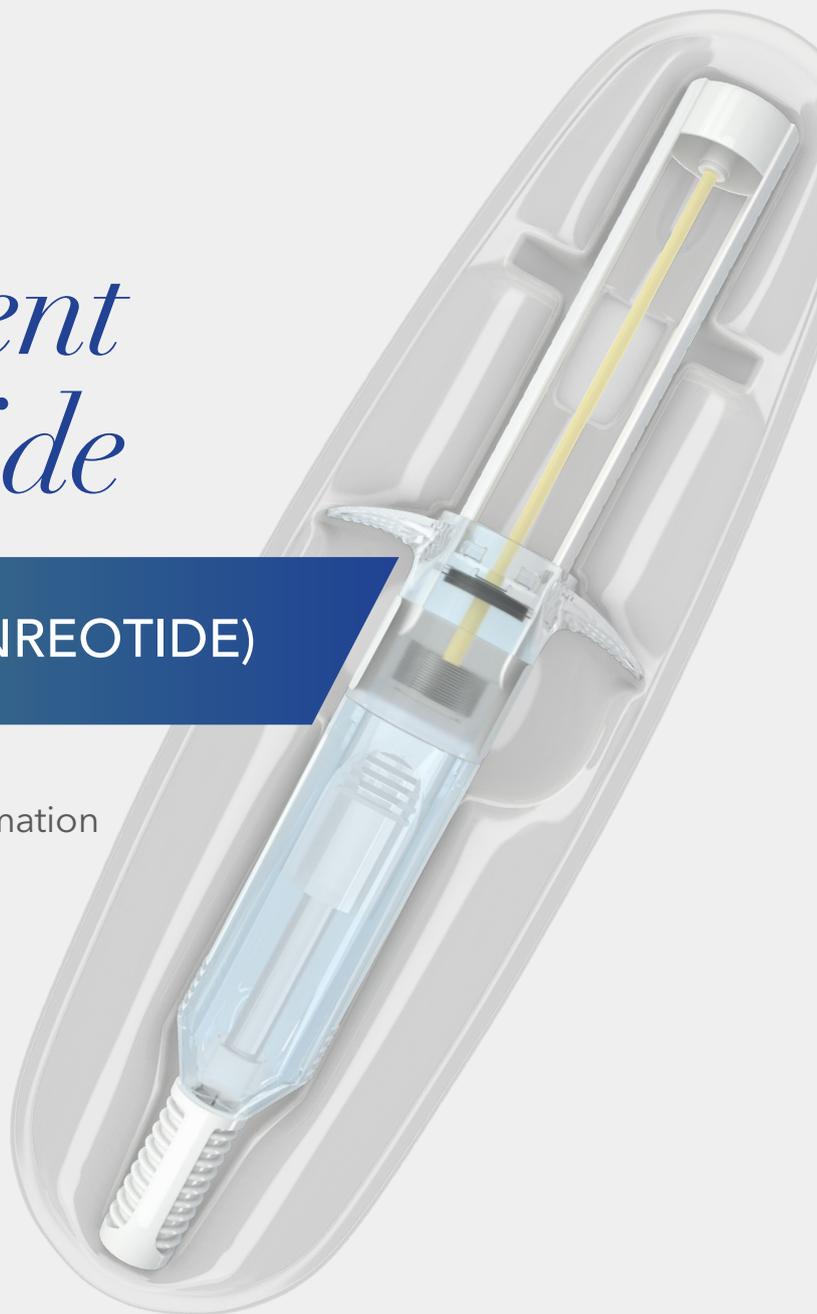


Reimbursement Resource Guide

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

Phone: 1-866-435-5677

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www.ipsencares.com

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 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.

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%).

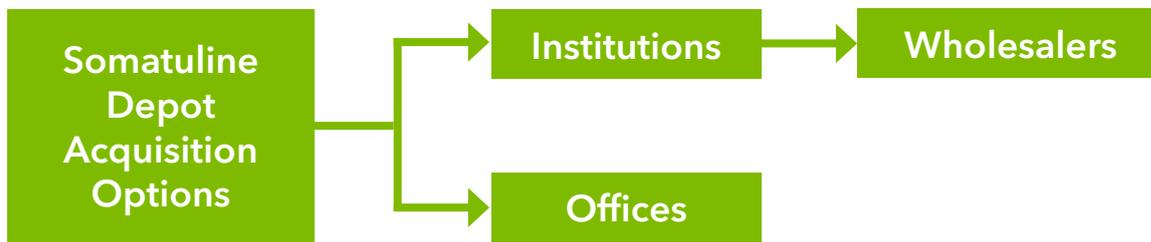
Drug Interactions: SOMATULINE DEPOT may decrease the absorption of cyclosporine (dosage adjustment may be needed); increase the absorption of bromocriptine; and require dosage adjustment for bradycardia-inducing drugs (e.g., beta-blockers).

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 1-866-435-5677

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	1-800-710-6100 www.mdspecialtydist.com	1-800-710-6100	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. 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](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.

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, 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 .

^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.

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

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. OTHER INSURED'S POLICY OR GROUP NUMBER
b. OTHER INSURED'S DATE OF BIRTH (MM/DD/YY) SEX (M/F)
c. EMPLOYER'S NAME OR SCHOOL NAME
d. INSURANCE PLAN NAME OR PROGRAM NAME

11. INSURED'S POLICY GROUP OR FECA NUMBER
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.)
13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE (I authorize payment of medical benefits to the undersigned physician or supplier for services described below.)

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
18. OUTSIDE \$ CHARGES
19. RESERVED FOR LOCAL USE
20. MEDICAID RESUBMISSION CODE
21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY (Relate Items 1, 2, 3 or 4 to Item 24E by Line)
22. MEDICAID RESUBMISSION ORIGINAL REF. NO.
23. PRIOR AUTHORIZATION NUMBER

24. A. DATE(S) OF SERVICE (From MM/DD/YY To MM/DD/YY) B. PLACE OF SERVICE (EMG) C. PROCEDURES, SERVICES, OR SUPPLIES (Specify-Report and Code) D. DIAGNOSIS POINTS E. RENDERING PROVIDER ID #

25. FEDERAL TAX I.D. NUMBER SSN EIN 26. PATIENT'S ACCOUNT NO. 27. ACCEPT ASSIGNMENT? (For Spcl. Pharm. use back) 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, respectively.
- 44**, **45**, and **46** point to the **CPT®/HCPCS CODE**, **SERVICE DATE**, and **SERVICE UNITS** fields, respectively.
- 67** points to the **ICD-10-CM DIAGNOSIS CODE** field.

The form includes sections for patient information, insurance details, procedure codes, and charges. A 'TOTALS' row is visible at the bottom of the charges section.

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 Specialists who can assist in a variety of ways



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



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



Website:
www.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 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 1-866-435-5677)

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.
- **Medication Reminder Program**

HCP Portal

The HCP portal saves time and simplifies the interactions with IPSEN CARES on behalf of patients. The HCP portal allows you to track the status of your patients enrolled in IPSEN CARES.

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:

1. Send a message to the IPSEN CARES team
2. Upload relevant patient documents
3. Obtain Specialty Pharmacy dispensing information (if applicable)
4. Review case status notes for enrolled patients

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

^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

Most eligible^a patients with private insurance pay no copay (\$0 copay), subject to a \$20,000 annual maximum benefit

- Program exhausts after 13 injections, 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

- 1 Provider and patient complete enrollment form and send to IPSEN CARES.
- 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 (253-395-8028)
 - 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
 - Both documents must be submitted at the same time to be considered for reimbursement
- 5 IPSEN CARES processes eligible claim payment to patient's provider typically within 14 business days via either ACH (wire transfer) or check.

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

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 residing in Massachusetts, Minnesota, 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.

For patients with commercial insurance, 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 provided to the patient in the Somatuline® Depot Copay Program.

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/CoverMyMeds, 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.

Somatuline Depot Copay Assistance Program

Frequently Asked Questions

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®. Completion and submission of the Enrollment Form is the first step for enrolling in IPSEN CARES. The form can be completed online or 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 can be completed online or printed, filled out completely by the Provider and the Patient/Legal Guardian, signed, and faxed back to IPSEN CARES.

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 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.

*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
www.ipsecares.com

IPSENCARES®
Coverage, Access, Reimbursement & Education Support

 **Somatuline® Depot**
(lanreotide) Injection

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 can be completed online (at www.IpsenCares.com) or 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 can be completed online (at www.IpsenCares.com) or printed, filled out completely by the Provider and the Patient/Legal Guardian, signed, and faxed back to IPSEN CARES.

IPSEN CARES ENROLLMENT FORM Questions? Call IPSEN CARES at 1-866-435-5677 

Please print the form, fill it out completely, sign it, and fax to: 1-888-525-2416
IPSEN CARES must receive pages 2, 3, 4, & 5 in order for the Enrollment Form to be complete.

STEP 1 PATIENT INFORMATION

Patient Name (First & Last) _____ Home Phone # _____
 Patient Address _____ Mobile Phone # _____
 City _____ Caregiver/Legal Guardian Name (First & Last) _____
 State _____ Zip _____
 Date of Birth (MM/DD/YY) ____/____/____ Caregiver/Legal Guardian Phone # _____
 Email _____ Relationship to Patient _____

Would you like to enroll in the Ipsen adherence text messaging program as outlined on Page 6, in Step 8 under *Additional Product and Support Information*? I give permission to Ipsen to contact me by SMS/text message for the Ipsen adherence text messaging program. Carrier, text, and data rates may apply. Yes No

Would you like to receive marketing information from Ipsen as described on Page 6, in Step 8 under *Additional Product and Support Information*? I give permission to Ipsen to contact me with information via mail, email, phone, or SMS/text message, all of which may include marketing, advertisements, disease state awareness materials and educational material about Somatuline Depot and programs that support patients. Automatic dialing may be used. Carrier, text, and data rates may apply. I understand that I am not required to provide this consent as a condition of purchasing any goods or services. Yes No

STEP 2 INSURANCE INFORMATION

Complete or attach front and back copy of patient's primary and secondary insurance cards for pharmacy and medical benefits.

Is patient insured? Yes No Does patient have secondary insurance? Yes No

Primary Insurance Co. _____ Secondary Insurance Co. _____
 Insurance Co. Phone # _____ Insurance Co. Phone # _____
 Subscriber Policy ID # _____ Subscriber Policy ID # _____
 Policy/Employer/Group # _____ Policy/Employer/Group # _____

Is Physician a Participating Provider? (check one) Participating Non-Participating

STEP 3 IPSEN CARES COPAY PROGRAM

Eligible patients using commercial insurance can save on out-of-pocket Ipsen medication costs. Please see Patient Eligibility & Terms and Conditions.

I attest that I am not enrolled in any health insurance plan from any state or federally funded programs (including, but not limited to, Medicare or Medicaid, VA, DOD, or TRICARE) and agree to the Terms and Conditions of the Copay Program. Yes No

I would like IPSEN CARES to check my eligibility for, and enroll me into, the Somatuline Depot Copay Program if the results of this benefit verification determine that I have commercial or private health insurance.

PATIENT AUTHORIZATION AND ADDITIONAL PRODUCT AND SUPPORT INFORMATION

I have read and understand the IPSEN CARES Patient Authorization and Additional Product and Support Information on Pages 5 and 6, in Step 8 and agree to the terms.

Signature of Patient/Legal Guardian _____ Date _____

Please see accompanying full Prescribing Information and Patient Information.  2 of 6

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 can be completed online or 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.

IPSEN CARES PATIENT AUTHORIZATION FORM Questions? Call IPSEN CARES at 1-866-435-5677 

Please print the form, fill it out completely, sign it, and fax to: 1-888-525-2416.
IPSEN CARES must receive pages 1 and 2 in order for the form to be complete.

PLEASE BE SURE TO REVIEW ORIGINAL IPSEN CARES ENROLLMENT FORM

PATIENT AUTHORIZATION AND SIGNATURE - IPSEN CARES® PROGRAM

I authorize my healthcare providers (including those pharmacies that may receive my prescription for Somatuline® Depot), to disclose personal health information ("PHI") about me, including health information relating to my medical condition, prescription, and insurance coverage, to Ipsen Biopharmaceuticals, Inc., its affiliates, and its agents that have been hired to administer the Ipsen Coverage, Access, Reimbursement & Education Support (IPSEN CARES®) program on its behalf (collectively, "Ipsen") in order for Ipsen to (1) enroll me in IPSEN CARES®; (2) establish my benefit eligibility and potential out-of-pocket costs for Somatuline® Depot; (3) communicate with my healthcare providers and health plans about my treatment plan; (4) provide support services including patient education and financial assistance for Somatuline® Depot; (5) help get Somatuline® Depot shipped to me or my healthcare providers; (6) evaluate my eligibility for home health administration if requested by my physician; and (7) facilitate my participation in Somatuline® Depot patient programs that I have elected to receive information about, as indicated below. I agree that, using the contact information I provide, Ipsen may contact me for reasons related to the IPSEN CARES® program and support services and may leave messages for me that may disclose that I am on Somatuline® Depot therapy. I consent to being contacted by an IPSEN CARES® program representative in order for the program to obtain further information or clarification regarding any adverse event I may experience.

I understand that once my PHI has been disclosed to Ipsen, it is no longer protected by federal privacy laws and Ipsen may re-disclose it; however, Ipsen has agreed to protect my PHI by using and disclosing it only for the purposes described above or as required by law. I understand that my healthcare providers may receive remuneration from Ipsen in exchange for my PHI and/or for any therapy support services provided to me.

I can withdraw this authorization by calling IPSEN CARES® at 1-866-435-5677 or mailing a letter requesting such revocation to IPSEN CARES®, 11800 Weston Parkway, Cary, NC 27513, but it will not change any actions taken before I withdraw authorization. Withdrawal of authorization will end further uses and disclosures of PHI by the parties identified in this form except to the extent those uses and disclosures have been made in reliance upon my authorization. I understand that I may refuse to sign this form and, if I do so, I will not be able to participate in IPSEN CARES® programs, but it will not affect my eligibility to obtain medical treatment, my ability to seek payment for this treatment, or affect my insurance enrollment or eligibility for insurance coverage. This authorization expires three years from the date signed unless a shorter time is required by law or unless I revoke my authorization before that time. I understand that I will receive a copy of the signed authorization.

 1 of 2



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

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 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 Patient Assistance Program Application
Questions? Call IPSEN CARES at 1-888-435-5677

Please print the form, fill it out completely, sign it, and fax to: 1-888-525-2416



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, are uninsured or functionally uninsured, are US residents, and received a valid 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.

Completed by the patient/legal guardian

STEP 1

PATIENT INFORMATION

Patient Name (First & Last) _____ Home Phone # _____
 Patient Address _____ Mobile Phone # _____
 City _____ Caregiver/Legal Guardian Name (First & Last) _____
 State _____ Zip _____
 Date of Birth (MM/DD/YY) ____/____/____ Caregiver/Legal Guardian Phone # _____
 Email _____ Relationship to Patient _____

INSURANCE INFORMATION

Complete the information below or fax a copy of the front and back of patient's primary and secondary insurance cards for pharmacy and medical benefits.

Primary Insurance Co. _____ Secondary Insurance Co. _____
 Insurance Co. Phone # _____ Insurance Co. Phone # _____
 Subscriber Policy ID # _____ Subscriber Policy ID # _____
 Policy/Employer/Group # _____ Policy/Employer/Group # _____

Is Physician a Participating Provider (check one) Participating Non-Participating

Uninsured - Patient does not have commercial health insurance and is not eligible for public health insurance, including but not limited to Medicare or Medicaid, or has been denied coverage by their health insurance.

STEP 2

PROOF OF INCOME*

My estimated annual household income currently is \$ _____ Number of people in household _____

*IPSEN CARES will conduct a soft credit check as part of the process of confirming income and determining eligibility for the program.

STEP 3

THIRD PARTY VERIFICATION AUTHORIZATION

I understand that I am providing "written instructions" under the Fair Credit Reporting Act ("FCRA") authorizing the IPSEN CARES® Patient Assistance Program (the "Program"), Ipsen Biopharmaceuticals, Inc. ("Ipsen"), and its vendor, on an ongoing basis as needed for the duration of my participation in Program, under the Fair Credit Reporting Act ("FCRA"), to obtain information from my credit profile or other information from a credit reporting agency (including, without limitation, Experian Health), for the purpose of determining financial qualifications and eligibility for programs administered by Ipsen and the Program.

 1 of 4

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[®]

Coverage, Access, Reimbursement & Education Support

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

Phone: 1-866-435-5677

Fax: 1-888-525-2416

Mail: 11800 Weston Parkway Cary, NC 27513

www.ipsencares.com

To learn more about Somatuline Depot, visit SOMATULINEDEPOT.com

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

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Somatuline[®] Depot
(lanreotide) Injection