# 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:** 1-866-435-5677 **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 Patient Information.



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 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 1-866-435-5677

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 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 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 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.





## **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.





## 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.<sup>a</sup>

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 mg <sup>b</sup>	15054-1120-03	15054-1120-04
90 mg	15054-1090-03	15054-1090-04
60 mg	15054-1060-03	15054-1060-04

<sup>&</sup>lt;sup>b</sup>GEP-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.





## 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<sup>a</sup>

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

<sup>&</sup>lt;sup>a</sup>Per CPT<sup>®</sup> 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





## Somatuline Depot Billing and Coding (Continued)

### Diagnosis Codes for GEP-NETs<sup>a</sup> (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

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.

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## 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 www.cms.gov.

## **Important Safety Information**

### **Warnings and Precautions**

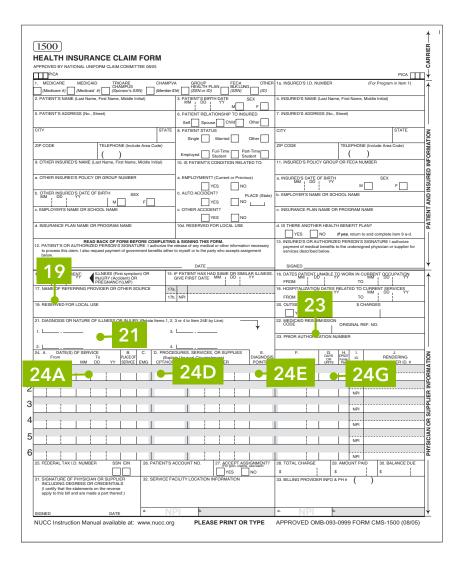
- Hypoglycemia or Hyperglycemia
  - Patients treated with SOMATULINE DEPOT may experience hypoglycemia or hyperglycemia.
    - Blood glucose levels should be monitored when SOMATULINE DEPOT treatment is initiated, or when the dose is altered, and antidiabetic treatment should be adjusted accordingly.





## 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



Enter the appropriate ICD-10-CM diagnosis code (eg, C7A.092, malignant carcinoid tumor

the 11-digit drug NDC number, the unit of measurement qualifier, and dosage.

CPT\*/HCPCS Code: Enter the appropriate CPT\*/HCPCS code. For Somatuline Depot Include the appropriate CPT® codes to report administration procedures (eg, 96372, therapeutic, prophylactic, or diagnostic injection, specify substance, or drug;

Report the appropriate number of units for the procedure and the appropriate number of milligrams for Somatuline Depot J1930

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





## 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**

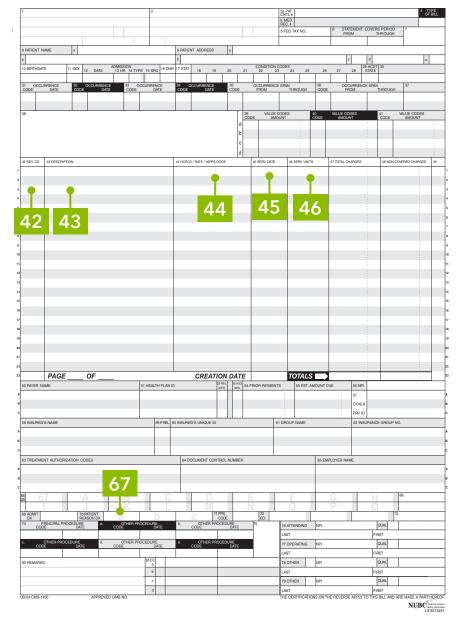
Private payers vary in the payment methods they use to reimburse the sites of service where Somatuline Depot is administered. Some private payers may require that physicians obtain Somatuline Depot through a specialty pharmacy. Specialty pharmacies may bill the payer through the medical or pharmacy benefit,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



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

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

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

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

service as appropriate and the appropriate number of milligrams for Somatuline Depot (120 mg, 90 mg, or 60 mg).

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





## **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 Ipsen medications

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



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



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-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 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<sup>b</sup> 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**

■ 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.

<sup>&</sup>lt;sup>b</sup>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 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.





<sup>&</sup>lt;sup>a</sup>Please see Patient Eligibility & Terms and Conditions on page 15.

## **IPSEN CARES®** Overview

## **Somatuline Depot Copay Assistance Program**

Eligible<sup>a</sup> commercially insured patients pay as little as

per prescription

- 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.





<sup>&</sup>lt;sup>a</sup>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, 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 provided to the patient in the Somatuline® Depot Copay Program. For cash-pay patients, the maximum 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 quardian 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.





## Somatuline Depot Copay Assistance Program **Frequently Asked Questions**

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

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.

### How will IPSEN CARES determine that the patient is eligible<sup>a</sup>?

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.

### How do patients know that they have been enrolled?

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?

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?

- 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?
- 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?
- 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.

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 <a href="https://www.ipsencares.com">www.ipsencares.com</a>





<sup>&</sup>lt;sup>a</sup>Please see Patient Eligibility & Terms and Conditions on page 15.

## **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
	Patient Address	- Caregiver/Legal Gui	ardian (First & Last Name)
	City State Zip	-	
_	☐ Male ☐ Female Date of Birth (MM/DD/YY)//	Caregiver/Legal Gua	ardian Phone #
STEP	Email	Relationship to Pat	ient
S	Would you like to enroll in the Ipsen adherence text messaging progran Information? I give permission to Ipsen to contact me by SMS/text me data rates may apply. ☐ Yes ☐ No		
	Would you like to receive marketing information from Ipsen as describ II give permission to Ipsen to contact me with information via major advertisements, disease state awareness materials and educational Automatic dialing may be used. Carrier, text, and data rates may apply of purchasing any goods or services. $\begin{tabular}{ c c c c c c c c c c c c c c c c c c c$	mail, phone or SMS/tex material about SOMAT	t message, all of which may include telemarketin ULINE® DEPOT and programs that support patien
	INSURANCE INFORMATION Complete or attach front and back copy of p.	atient's primary and secon	dary insurance cards for pharmacy and medical benefits.
	Is patient insured?  Yes  No	Does patient have s	econdary insurance?    Yes    No
7	Primary Insurance Co.	_ Secondary Insurance	:e Co
ᇤ	Insurance Co. Phone #	Insurance Co. Phon	e#
ST	Subscriber Policy ID #	_ Subscriber Policy ID	) #
			oup#
1h	Policy/Employer/Group #  Is Physician a Participating Provider? (check one)   Participating  Is Physician a Participating Provider? (check one)   Participating  ATIENT AUTHORIZATION AND ADDITIONAL PRODUCT AND SUPPORT  Sove read and understand the IPSEN CARES Patient Authorization and Acc	Policy/Employer/Gr Non-Participating	
l h	Policy/Employer/Group # Is Physician a Participating Provider? (check one)   Participating ATIENT AUTHORIZATION AND ADDITIONAL PRODUCT AND SUPPORT	Policy/Employer/Gr Non-Participating	
l h	Policy/Employer/Group #	Policy/Employer/Gr Non-Participating INFORMATION ditional Product and Su	pport Information on Page S, in Step 8 and agree to  Date
l h	Policy/Employer/Group #	Policy/Employer/Gr Non-Participating  INFORMATION  ditional Product and Su  Street Address	pport Information on Page S, in Step 8 and agree to  Date
l h	Policy/Employer/Group #	Policy/Employer/Gr Non-Participating  INFORMATION  ditional Product and Su  Street Address	pport Information on Page 5, in Step 8 and agree to Date
I h	Policy/Employer/Group #	Policy/Employer/Gr Non-Participating INFORMATION diltional Product and Su  Street Address City	pport Information on Page 5, in Step 8 and agree to  Date
Ih si	Policy/Employer/Group #  Is Physician a Participating Provider? (check one)   Participating  XTENT AUTHORIZATION AND ADDITIONAL PRODUCT AND SUPPORT  over read on understand the PESIC AMES Patient Authorization and Acceptance of Patient or Caregiver/Legal Guardian  PRESCRIBER INFORMATION  PRESCRIBER INFORMATION  DEA #	Policy/Employer/Gr Non-Participating  INFORMATION diltional Product and Su  Street Address  City  Office Contact and	pport information on Page 5, in Step 8 and agree to  Date
Ih si	Policy/Employer/Group #  Is Physician a Participating Provider? (check one)   Participating  NIENT AUTHORIZATION AND ADDITIONAL PRODUCT AND SUPPORT  owe read and understand the IPSEN CARES Potent Authorization and Ac- terms.  grature of Patient or Caregiver/Legal Guardian    PRESCRIBER INFORMATION  PRESCRIBER INFORMATION  DEA # State License #  Tax (D # NP! #	Policy/Employer/Gr Non-Participating INFORMATION ditional Product and Su  Street Address	pport information on Page 5, in Step 8 and agree to  Date
l h	Policy/Employer/Group #  Is Physician a Participating Provider? (check one)   Participating  XTERT AUTHORIZATION AND ADDITIONAL PRODUCT AND SUPPORT  sowe read and understand the IPSEN CARES Patient Authorization and Ac-  terms.  PRESCRIBER INFORMATION  PRESCRIBER INFORMATION  Prescriber Name   State License #    Tax ID #   NPI #    Medicaid Provider # (Required if Medicaid Patient)    Medicaire PTAN # (Required if Medicare Patient)	Policy/Employer/Gr Non-Participating INFORMATION ditional Product and Su  Street Address	pport information on Page 5, in Step 8 and agree to  Date
Ih si	Policy/Employer/Group #  Is Physician a Participating Provider? (check one)   Participating  XTERT AUTHORIZATION AND ADDITIONAL PRODUCT AND SUPPORT  sowe read and understand the IPSEN CARES Patient Authorization and Ac-  terms.  PRESCRIBER INFORMATION  PRESCRIBER INFORMATION  Prescriber Name   State License #    Tax ID #   NPI #    Medicaid Provider # (Required if Medicaid Patient)    Medicaire PTAN # (Required if Medicare Patient)	Policy/Employer/Gr Non-Participating  INFORMATION  ditional Product and Su  Street Address  City  Office Contact and Phone #  Email  Preferred Method o	poport Information on Page 5, in Step 8 and agree to  Oate
Ih si	Policy/Employer/Group #  Is Physician a Participating Provider? (check one)   Participating  INTENT AUTHORIZATION AND ADDITIONAL PRODUCT AND SUPPORT  NOW read and understand the IPSEN CARES Patient Authorization and As  terms.  PRESCRIBER INFORMATION  PRESCRIBER INFORMATION  PRESCRIBER INFORMATION  Prescriber Name    DEA # State License # Taxub # New York Patient or New York Patient Office Institution    Office Institution   Office Institution	Policy/Employer/Gr Non-Participating  INFORMATION  ditional Product and Su  Street Address  City  Office Contact and Phone #  Email  Preferred Method o	poport Information on Page 5, in Step 8 and agree to  Oate
Ih si	Policy/Employer/Group #	Policy/Employer/Gr Non-Participating INFORMATION ditional Product and Su Street Address City Office Contact and Phone # Email Preferred Method o Best time to contact Would you like to re nurse for your staff	pport Information on Page 5, in Step 8 and agree to

ease print the form, fill it out completely, sign it, and far EN CARES must receive pages 1 and 2 in order for the form to be	k to: 1-888-525-2416. complete. Somatuline Dep
PLEASE BE SURE TO REVIEW ORIGINAL IPSEN CARES EN	IROLLMENT FORM
PATIENT AUTHORIZATION IPSEN CARES® PR	
coverage, to [psen Biopharmaceuticals, Inc., in administer the Ipsen Coverage, Access, Reinbaprogram on its behalf (collectively, "Ipsen") in (2) establish my benefit eligibility and potenti- (3) communicate with my healthcare provider provide support services including patient ed (bepot; (5) help get Somatuline" Depot shippe my eligibility for home health administration i participation in Somatuline" Depot patient pr about, as indicated below. I agree that, using! contact me for reasons related to the IPSEN C. leave messages for me that may disclose that	se personal health information ("PHI") about yn medical condition, prescription, and insurance is affiliates, and its agents that have been hired to ursement & Education Support (IPSEN CARES") order for Ipsen to (1) enroll me in IPSEN CARES") al out-of-pocket costs for Somatuline® Depot; is and health plans about my treatment plan; (4) ucation and financial assistance for Somatuline® d to me or my healthcare providers; (6) evaluate frequested by my physician; and (7) facilitate my ograms that I have elected to receive information the contact information I provide, Ipsen may ARES® program and support services and may I am on Somatuline® Depot therapy, I consent to representative in order for the program to obtain
privacy laws and Ipsen may re-disclose it; how and disclosing it only for the purposes describ	osed to Ipsen, it is no longer protected by federal rever, Ipsen has agreed to protect my PHI by using red above or as required by law. I understand that ation from Ipsen in exchange for my PHI and/or ne.
requesting such revocation to IPSEN CARES®, not change any actions taken before I withdra end further uses and disclosures of PHI by the those uses and disclosures have been made in that I may refuse to sign this form and, if I do s CARES® programs, but it will not affect my elig seek payment for this treatment or affect my!	SEN CARES® at 1-866-435-5677 or mailing a letter 11800 Weston Parkway, Cary, NC 27513, but it will wathorization. Withdrawal of authorization will parties identified in this form except to the extent reliance upon my authorization. I understand o, I will not be able to participate in IPSEN ibility to obtain medical treatment, my ability to sourance enrollment or eligibility for insurance rs from the date signed unless a shorter time is ation before that time. I understand that I will
Patient Name (First & Last)	Legal Guardian (First & Last Name)
Patient Date of Birth (mm/dd/yy)//	
Phone #Signature of Patient or Legal Guardian	Relationship to Patient Date





## **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.

JLI	se print the form, fill it out completely, sign it, and fax to: 1-888-525-2416 EN CARES must receive pages 1, 2, and 3 in order for the form to be complete.  Somatuline De [larreceide] Insertor deng	epot ®m ©
nay or a guar	Patient Assistance Program (PAP) is designed to provide Somatuline' Depot (lanreotide) at no cost to eligible patients. Patien y be eligible to receive free drug if they are experiencing financial hardship, have no insurance coverage, and received a prescri- an on-label use of Somatuline Depot, as supported by Information provided in the Program application. Eligiblity does not trantee approval for participation in the program. The PAP provides Somatuline Depot product only, and does not cover the criviously purchased product or medical services.	iption
	PATIENT INFORMATION	
	First NameMILast Name	
	Date of Birth (MM/DD/YYYY)/ Gender	
	Mailing AddressApt#	
	CityStateZip	
	Phone # Are you a US resident? ☐ Yes ☐ No	
	Ne you a ostesidente. 🗆 les 🗆 no	
	Email Address	
_	Prescribing PhysicianTreating Facility	
STEP :		
S	INSURANCE INFORMATION	
	Complete or attach front and back copy 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 bu limited to Medicare or Medicaid, or has been denied coverage by their health insurance.	it not
	PROOF OF INCOME:	
STEP 2	My estimated annual household income currently is \$ Number of people in household	
	* Examples of income can include, but not limited, to Social Security Disability Income, Supplemental Security Income, Aid from the Department of Pub Unemployment Benefits, Workers Compensation Benefits, Dividends, interest or investment account, Employment (myself and or my spouse), Other	lic Welf





## 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







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 <u>SOMATULINEDEPOT.com</u>

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

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