



**Somatuline<sup>®</sup> Depot**  
(lanreotide) Injection 60mg, 90mg and 120mg

# *REIMBURSEMENT RESOURCE GUIDE*

## INDICATIONS

SOMATULINE<sup>®</sup> DEPOT (lanreotide) Injection is a somatostatin analog indicated for:

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

Somatuline<sup>®</sup>  
Depot  
Acquisition

Somatuline<sup>®</sup>  
Depot  
Billing and Coding

IPSEN CARES<sup>®</sup>  
Reimbursement  
and Support

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

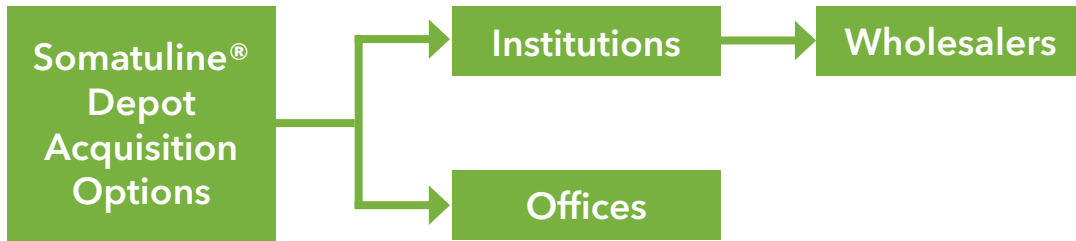
## Important Notice

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

For additional medical information about Somatuline<sup>®</sup> Depot, please call Ipsen Medical Affairs at 1-855-463-5127.

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

## SOMATULINE<sup>®</sup> DEPOT ACQUISITION



### If Somatuline<sup>®</sup> Depot Is Covered Under the Medical Benefit

#### Purchase Somatuline<sup>®</sup> Depot Directly (Buy and Bill)

- Requires an upfront financial investment
- Your office acquires Somatuline<sup>®</sup> Depot directly from a select group of 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<sup>®</sup> 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<sup>®</sup> provides helpful information on selecting the appropriate Specialty Pharmacy provider by calling 1-866-435-5677

### If Somatuline<sup>®</sup> Depot Is Covered Under the Pharmacy Benefit

#### Specialty Pharmacy

- Does not require an upfront financial investment
- Your office orders Somatuline<sup>®</sup> 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<sup>®</sup> provides helpful information on selecting the appropriate Specialty Pharmacy provider by calling 1-866-435-5677

Please see accompanying full Prescribing Information and Patient Information.

## Authorized Specialty Distributors

Specialty Distributor	Customer Service/Ordering	New Accounts	Product	Order Times
ASD Healthcare <sup>®</sup>	Phone: 1-800-746-6273 <a href="http://www.asdhealthcare.com/home">www.asdhealthcare.com/home</a>	1-800-385-2368	Somatuline <sup>®</sup> Depot	Mon - Thu: 7 am - 6:30 pm ET Fri: 7:00 am - 6:00 pm ET
Besse <sup>®</sup> Medical	Phone: 1-800-543-2111 <a href="http://www.besse.com">www.besse.com</a>	Phone: 1-800-543-2111 <a href="https://www.besse.com/business-application">https://www.besse.com/business-application</a>	Somatuline <sup>®</sup> Depot	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	Phone: 1-866-300-3838 Oncology: 1-877-453-3972 <a href="http://www.cardinalhealth.com/spd">www.cardinalhealth.com/spd</a>	Phone: 1-866-300-3838 Oncology: 1-877-453-3972 <a href="http://www.cardinalhealth.com/spd">www.cardinalhealth.com/spd</a>	Somatuline <sup>®</sup> Depot	Mon - Fri: 8:00 am - 7:00 pm ET
CuraScript SD <sup>®</sup>	Phone: 1-877-599-7748 <a href="http://www.curascriptsd.com/contact-us">www.curascriptsd.com/contact-us</a>	Phone: 1-877-599-7748 <a href="http://www.curascriptsd.com/new-accounts">www.curascriptsd.com/new-accounts</a>	Somatuline <sup>®</sup> Depot	Mon - Fri: 8:30 am - 7:00 pm ET
McKesson Specialty Health	Oncology: 1-800-482-6700 Other: 1-855-477-9800 <a href="https://mscs.mckesson.com/CustomerCenter/MckessonWebStore.html#PRELOGIN_VIEW">https://mscs.mckesson.com/CustomerCenter/MckessonWebStore.html#PRELOGIN_VIEW</a>	Oncology: 1-800-482-6700 Other: 1-855-477-9800	Somatuline <sup>®</sup> Depot	Mon - Fri: 8:00 am - 8:00 pm ET
Oncology Supply <sup>®</sup>	Phone: 1-800-633-7555 <a href="http://www.oncologysupply.com">www.oncologysupply.com</a>	Phone: 1-800-633-7555 <a href="http://www.oncologysupply.com/open-an-account">www.oncologysupply.com/open-an-account</a>	Somatuline <sup>®</sup> Depot	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<sup>®</sup> Depot given their reputation, capabilities, and customer satisfaction ratings. Our goal is to provide you with options to select the Specialty Distributors that will meet your needs. You are free to engage any of the above Specialty Distributors. You may also open an account with more than one of the above distributors if you wish.

**Please see accompanying full Prescribing Information and Patient Information.**

# SOMATULINE<sup>®</sup> DEPOT BILLING AND CODING

## Reimbursement Coding

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

### Healthcare Common Procedure Coding System (HCPCS) Level II Code

A permanent HCPCS code has been assigned to report use of Somatuline<sup>®</sup> Depot.

Somatuline <sup>®</sup> Depot HCPCS Code	Description
J1930	Injection, lanreotide, 1 mg

### National Drug Codes (NDCs)

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

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

**\*GEP-NET and carcinoid syndrome: dosing is 120 mg administered every 4 weeks by deep subcutaneous injection.**

Acromegaly: the starting dose is 90 mg once every 4 weeks. For patients with moderate or severe renal or hepatic impairment, initial dose is 60 mg once every 4 weeks.

### Current Procedural Terminology (CPT<sup>®</sup>) Drug Administration Codes

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

CPT <sup>®</sup> Code	Description
96372	Therapeutic, prophylactic, or diagnosis injection; subcutaneous or intramuscular

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

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

## Diagnosis Codes

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

### Diagnosis Codes for Acromegaly

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

### Diagnosis Codes for GEP-NETs\*

Note: This list is not exhaustive.

ICD-10-CM Code	Description
C7A.01	Malignant carcinoid tumors of the small intestine
C7A.010	Malignant carcinoid tumor of the duodenum
C7A.011	Malignant carcinoid tumor of the jejunum
C7A.012	Malignant carcinoid tumor of the ileum
C7A.019	Malignant carcinoid tumor of the small intestine, unspecified portion
C7A.020	Malignant carcinoid tumor of the appendix
C7A.021	Malignant carcinoid tumor of the cecum

\*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.

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

## Diagnosis Codes for GEP-NETs\* (Continued)

ICD-10-CM Code	Description
C7A.023	Malignant carcinoid tumor of the transverse colon
C7A.024	Malignant carcinoid tumor of the descending 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
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<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.

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

## **Additional Information: Consult With Individual Payers as Appropriate**

Always verify the patient's health insurance benefits prior to injecting Somatuline<sup>®</sup> Depot. Medicare Administrative Contractors (MACs) may develop coverage policies for Somatuline<sup>®</sup> 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](http://www.cms.gov).

CPT<sup>®</sup> is © 2017 American Medical Association (AMA). All rights reserved. No fee schedules, basic units, relative values, or related listings are included in CPT<sup>®</sup>. The AMA assumes no liability for the data contained herein.

Please see accompanying full Prescribing Information and Patient Information.



# Sample CMS-1500 Claim Form for Somatuline<sup>®</sup> Depot 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 (Medicare #)  MEDICAID (Medicaid #)  TRICARE (Tricare #)  CHAMPVA (Champus #)  GROUP HEALTH PLAN (Group Health Plan #)  FECA (FECA #)  OTHER (Other #)

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), CITY, STATE, ZIP CODE, TELEPHONE (Area Code)

6. PATIENT RELATIONSHIP TO INSURED (Self, Spouse, Child, Other)

7. INSURED'S ADDRESS (No., Street), CITY, STATE, ZIP CODE, TELEPHONE (Area Code)

8. PATIENT STATUS (Single, Married, Other) EMPLOYMENT (Employed, Full-Time Student, Part-Time Student)

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, 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. RESERVED FOR LOCAL USE

15. IF PATIENT HAS HAD SAME OR SIMILAR ILLNESS (GIVE FIRST DATE)

16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION (FROM TO)

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE (17a. NAME, 17b. NPI)

18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES (FROM TO)

19. RESERVED FOR LOCAL USE

20. OUTSIDE CHARGES

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY (Diagnose Items 1, 2, 3 or 4 to Item 24E by Line)

22. MEDICARE RESUBMISSION CODE

23. PRIOR AUTHORIZATION NUMBER

24. A. DATE(S) OF SERVICE (From To), B. PLACE OF SERVICE (EMG), C. PROCEDURE(S), SERVICES, OR SUPPLIES (CPT/HCPCS), D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances), E. DIAGNOSIS POINT, F. CPT/HCPCS, G. REPORT UNIT, H. ICD-9-CM, I. RENDERING I.D. #

25. FEDERAL TAX I.D. NUMBER, SSN, EIN

26. PATIENT'S ACCOUNT NO.

27. ACCEPT ASSIGNMENT? (YES/NO)

28. TOTAL CHARGE (\$)

29. AMOUNT PAID (\$)

30. BALANCE DUE (\$)

31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREE 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 (a. NPI, b. NPI)

33. BILLING PROVIDER INFO & PH # (a. NPI, b. NPI)

SIGNED \_\_\_\_\_ DATE \_\_\_\_\_

NUCC Instruction Manual available at: [www.nucc.org](http://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, (e.g., 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#, the unit of measurement qualifier, and dosage.  
**Example:** N41504112003MG120.00 (Note: some payers may request the NDC number be listed in box 19).  
In the nonshaded area, list the date of service.

**24D**  
CPT<sup>®</sup>/HCPCS code: Enter the appropriate CPT<sup>®</sup>/HCPCS code. For Somatuline<sup>®</sup> Depot use J1930, Injection, lanreotide, 1 mg. Include the appropriate CPT<sup>®</sup> codes to report administration procedures, (e.g., 96372, therapeutic, prophylactic, or diagnostic injection, specify substance, or drug; subcutaneous or intramuscular).

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

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

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

Please see accompanying full **Prescribing Information** and **Patient Information**.

# Sample CMS-1450 (UB-04) Claim Form for Somatuline<sup>®</sup> Depot Hospital Outpatient Administration

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.

1 PATIENT NAME	2 PATIENT ADDRESS	3a PAT. CNTL. #	3b MED. REC. #	4 TYPE OF BILL
5 BIRTH DATE	6 SEX	7 DATE OF ADMISSION	8 STATEMENT COVERS PERIOD FROM	9 STATE
10 OCCURRENCE DATE	11 OCCURRENCE DATE	12 OCCURRENCE DATE	13 OCCURRENCE DATE	14 OCCURRENCE DATE
15 VALUE CODES	16 VALUE CODES	17 VALUE CODES	18 VALUE CODES	19 VALUE CODES
20 REV. CD.	21 DESCRIPTION	22 HCPCS / RATE / HPPS CODE	23 SERV. DATE	24 SERV. UNITS
25 TOTAL CHARGES	26 NON COVERED CHARGES	27	28	29
30 PAYER NAME	31 HEALTH PLAN ID	32 PRIOR PAYMENTS	33 EST. AMOUNT DUE	34 NP1
35 INSURED'S NAME	36 INSURED'S UNIQUE ID	37 GROUP NAME	38 INSURANCE GROUP NO.	39
40 TREATMENT AUTHORIZATION CODES	41 DOCUMENT CONTROL NUMBER	42 EMPLOYER NAME	43	44
45 ADMIT DATE	46 PATIENT REASON DX	47 PPS CODE	48 ATTENDING NP1	49 QUAL
50 OTHER PROCEDURE DATE	51 OTHER PROCEDURE DATE	52 OTHER PROCEDURE DATE	53 OTHER NP1	54 QUAL
55 OTHER PROCEDURE DATE	56 OTHER PROCEDURE DATE	57 OTHER PROCEDURE DATE	58 OTHER NP1	59 QUAL
60 REMARKS	61	62	63	64

**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<sup>®</sup> 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 (e.g., 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<sup>®</sup>/HCPCS Code:** Enter the appropriate CPT<sup>®</sup>/HCPCS code.  
 For Somatuline<sup>®</sup> Depot use J1930, Injection, lanreotide, 1 mg.  
 For the administration use the CPT<sup>®</sup> code representing the administration route, (e.g., 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 a MMDDYY format.

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

**67**  
**ICD-10-CM Code:** Enter the complete ICD-10-CM diagnosis code, (e.g., 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.

Please see accompanying full Prescribing Information and Patient Information.

## Product Information

NDC*	Description	Dispensing/Sale Pack Quantity
15054-1060-03	60 mg/0.2 mL sterile, prefilled syringe	1
15054-1090-03	90 mg/0.3 mL sterile, prefilled syringe	1
15054-1120-03	120 mg/0.5 mL sterile, prefilled syringe	1

\*Please note that for billing purposes, the NDC number requires 11 digits. Therefore, a zero must be entered into the 10th position (e.g., "15054-1120-03"). This is consistent with Red Book and First DataBank listings.

### HCPCS Code for Somatuline<sup>®</sup> Depot

J1930, Injection, lanreotide, 1 mg.

### Somatuline<sup>®</sup> Depot Pack Dimensions

Approximate Dimensions - Unit

Depth: 3.5", Height: 0.8", Width: 12"

### Storage and Handling Information

Store Somatuline<sup>®</sup> 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 Requirement

Somatuline<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> Depot should never be exposed to dry ice. Ipsen will ship Somatuline<sup>®</sup> 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<sup>®</sup> 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.

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

## Payer Coverage

Contacting the payer directly is the best way to determine how the physician may obtain reimbursement for Somatuline<sup>®</sup> 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<sup>®</sup> or your Ipsen Field Reimbursement Manager for more information regarding coding coverage and reimbursement, including local medical policies.

### Medicare

Medicare may cover Somatuline<sup>®</sup> Depot (lanreotide) 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<sup>®</sup> Depot are billed to Medicare Administrative Contractors (MACs).

Local Medicare Administrative Contractors manage Medicare Part A/B Benefits. MACs may make specific coverage decisions for Somatuline<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> Depot.<sup>1</sup> Medicaid coverage and payment for Somatuline<sup>®</sup> Depot varies from state to state. Providers should check with the state program or may contact IPSEN CARES<sup>®</sup> for more specific coverage information.

### Private Payers

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

<sup>1</sup> Fingertip Formulary Customized Report. January 2016.

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

# IPSEN CARES<sup>®</sup> REIMBURSEMENT AND SUPPORT

## Personal Support at Your Patients' Fingertips

The IPSEN CARES<sup>®</sup> team is fully dedicated to:

- Facilitating eligible patients' access to the Ipsen medications that are important to their care
- Providing information and support for the interactions between your office, your patients, and your patients' insurance company

IPSEN CARES<sup>®</sup> provides a single point of contact for you, your staff, and your patients.

Ipsen is proud of our patient support program, IPSEN CARES<sup>®</sup>, which is available for your patients and your practice.



**PHONE OR FAX**  
1-866-435-5677  
Fax: 1-888-525-2416



**HOURS**  
Monday through Friday  
8:00 AM to 8:00 PM ET



**WEBSITE**  
[www.ipsencares.com](http://www.ipsencares.com)

<h3>Reimbursement Assistance</h3> <ul style="list-style-type: none"> <li>▪ <b>Benefits Verification</b> - verifies patients' coverage, restrictions (if applicable), and copayment/coinsurance amounts.</li> <li>▪ <b>Prior Authorization (PA)</b> - provides information on documentation required by payers on PA specifics and recommendations for next steps based on payer policy.</li> <li>▪ <b>Appeals Information</b> - 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.</li> </ul>	<h3>Financial Support</h3> <ul style="list-style-type: none"> <li>▪ <b>Copayment Assistance</b> - offers copayment assistance to eligible* patients. This includes referring to the Somatuline<sup>®</sup> Depot Commercial Copay Program or referring to an independent non-profit organization if available.</li> <li>▪ <b>Patient Assistance Program (PAP)</b> - determines patients' eligibility for PAP and dispenses free product to eligible patients.</li> </ul>
<h3>Product Distribution</h3> <ul style="list-style-type: none"> <li>▪ <b>Specialty Distributor Network</b> - provides contact information to various distributors that can supply Somatuline<sup>®</sup> Depot directly to your facility.</li> <li>▪ <b>Specialty Pharmacy Network</b> - determines which in-network pharmacy is best for a patient based on insurance requirements and triage referrals. Follow-up phone calls are placed 24 hours after referral is triaged to confirm receipt and shipment date.</li> </ul>	<h3>Patient Support</h3> <ul style="list-style-type: none"> <li>▪ <b>Communication</b> - conducts calls to both health-care provider and patient with status updates about patient's IPSEN CARES<sup>®</sup> enrollment, benefits verification results, coverage status, dispense date, etc.</li> </ul>

\*For patient eligibility and terms, please see next page.

**IPSEN CARES<sup>®</sup>**  
Coverage, Access, Reimbursement & Education Support

IPSEN CARES<sup>®</sup> can provide information to patients and healthcare professionals relating to medical and pharmacy coverage and policies for Somatuline<sup>®</sup> Depot at 1-866-435-5677, [www.ipsencares.com](http://www.ipsencares.com)

Please see accompanying full Prescribing Information and Patient Information.

## Savings Off Your Private Insurance Copay or Coinsurance Costs for Somatuline<sup>®</sup> Depot

### Somatuline<sup>®</sup> Depot Copay Savings Program

**Most eligible privately insured patients pay no more than \$5.00 per prescription, with a benefit of up to \$20,000 during the program year**



**Eligible patients may receive up to a \$20,000 savings during the program year\***

Program exhausts after 12 months, 13 injections, or a maximum copay benefit of \$20,000, whichever comes first. Patients must enroll annually to receive a continued benefit. Please see eligibility terms and conditions below.

### Four Simple Steps for Enrolled Patients to Receive Their Somatuline<sup>®</sup> Depot Savings

1. Patient receives treatment with Somatuline<sup>®</sup> Depot. Physician follows standard procedure for collection of patient copay.
2. Provider submits claim to patient's insurance company and to the program. (Instructions to submit claims to the program will be sent to the Provider's office.)
3. The IPSEN CARES<sup>®</sup> program will process each claim and notify the patient and provider on the claim status.
4. The program will send the patient's funds for approved claims directly to physician offices on behalf of the patients.

More details regarding enrollment are available by calling IPSEN CARES<sup>®</sup>. If your office does not accept medical claims processing or your patients purchase Somatuline<sup>®</sup> Depot through a Specialty Pharmacy provider, your patient may qualify for a copay card and will receive a savings check with pharmacy receipt. If your office does not want to participate in the program, the patient can submit their Explanation of Benefits (EOB) to IPSEN CARES<sup>®</sup> at 1-844-745-2352.

### Eligible Patients Can Now Save Up to \$20,000 During the Program Year on Out-of-Pocket Prescription Costs for Somatuline<sup>®</sup> Depot

**Patient Eligibility & Terms and Conditions:** Patients who are eligible to participate (i.e., prescriptions or coverage could be paid in part or in full) in any state or federally funded programs, including, but not limited to, Medicare or Medicaid, VA, DOD, or TRICARE (collectively, "Government Programs") are not eligible for copay assistance through IPSEN CARES<sup>®</sup>. 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 free starter therapy through the IPSEN CARES<sup>®</sup> program are not eligible for the copay assistance program while they are waiting for insurance prescription coverage to begin. Patients receiving assistance through another assistance program or foundation, free trial, or other similar offer or program, also are not eligible for the copay assistance program during current enrollment year.

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 co-pay benefit provided to the patient in the Somatuline<sup>®</sup> Depot Copay Program for the 2018 calendar year. 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. "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<sup>®</sup> 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 the copay benefit.

Patient pays the first \$5 and any amount greater than the maximum copay savings amount per prescription. Patient or guardian is responsible for reporting receipt of copay savings benefit to any insurer, health plan, or other third party who pays for or reimburses any part of the prescription filled through the program, as may be required. Additionally, patients may not submit any benefit provided by this program for reimbursement through a Flexible Spending Account, Health Savings Account, or Health Reimbursement Account. Ipsen reserves the right to rescind, revoke, or amend these offers without notice at any time. Ipsen and/or TrialCard, Incorporated, are not responsible for any transactions processed under this program where Medicaid, Medicare, or Medigap payment in part or full has been applied. Cash-paying patients are eligible to participate. Data related to your 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 you. 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. Offer expires December 31, 2018.

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



## Frequently Asked Questions

- Q** Will this program replace the Somatuline<sup>®</sup> Depot Copay Assistance program?
- A** No, this program will run in parallel with the copay program. A patient's eligibility will be determined if he/she is eligible for the medical or pharmacy benefit offer. The patient can only participate in one program at a time.
- Q** How will IPSEN CARES<sup>®</sup> determine the program for which the patient is eligible?
- A** IPSEN CARES<sup>®</sup> will perform a benefits verification to determine if the patient requires assistance with pharmacy or medical benefit. The benefits verification will determine the patient's eligibility, and the appropriate offer will be given to the provider. If the patient qualifies for both benefits, IPSEN CARES<sup>®</sup> will allow the patient and his/her physician to determine which program they will use.
- Q** Can the patient switch between the two programs?
- A** Yes, the patients may switch if their benefit need changes but are subject to an aggregate annual maximum savings of \$20,000.
- Q** How does a patient enroll in the program?
- A** Enrollment for both the medical and pharmacy benefit programs is accomplished via IPSEN CARES<sup>®</sup>. The patient will need to call 1-866-435-5677 to enroll, or the patient may choose to self-enroll via the Somatuline<sup>®</sup> Depot Copay Assistance Program Enrollment form found on [www.ipsencares.com](http://www.ipsencares.com).
- Q** Are cash-pay patients still allowed to use the program?
- A** Yes, cash-pay patients may still qualify for the pharmacy benefit program. Eligible cash paying patients will receive up to \$1,666.66 of support per prescription, up to \$20,000 program annual maximum.
- Q** How do patients know that they have been enrolled?
- A** Patients can choose to self-enroll in the program or their physician may enroll them by calling IPSEN CARES<sup>®</sup>. Once enrolled, an IPSEN CARES<sup>®</sup> representative will notify patients that they have been enrolled. In addition, patients and their physician will be mailed letters welcoming them into the program.
- Q** How does the physician receive funds for the medical benefit program?
- A** The physician's office will receive funds in the same manner as other medical insurance benefit plans.
- Q** How is Somatuline<sup>®</sup> Depot reimbursed by payers?
- A** The reimbursement methods used by payers are not the same and may have variability between plans even within the same insurance company. Each payer may have a unique contract or payment policy in place with the healthcare facility. Similarly, patients will have a unique choice of benefits with different levels of coverage for Somatuline<sup>®</sup> Depot. When Somatuline<sup>®</sup> Depot is covered through the medical benefit, the claim will be subject to medical benefits reimbursement, deductible, and copays. When Somatuline<sup>®</sup> Depot is covered through the pharmacy benefit, the reimbursement is processed by the Specialty Pharmacy delivering Somatuline<sup>®</sup> Depot. Most payers will have deductible, copay, and coinsurance requirements that must be met by patients.
- Q** How does Medicare pay for Somatuline<sup>®</sup> Depot?
- A** Patients receiving Somatuline<sup>®</sup> Depot in a physician office setting with the drug injected by a healthcare professional will likely be covered under Medicare Part B (medical benefit). If the patient has supplemental insurance covering coinsurance and deductibles, the coinsurance and deductible left after Medicare payment can then be billed to the supplemental insurance company. IPSEN CARES<sup>®</sup> has trained specialists available to answer questions related to Medicare reimbursement and to help patients navigate different Medicare plan options for coverage.
- Q** What can be done to verify Somatuline<sup>®</sup> Depot is covered by patient's insurance prior to administration?
- A** Payers vary in benefit design for patients enrolled in insurance coverage. Ipsen strongly recommends that healthcare professionals and patients utilize IPSEN CARES<sup>®</sup> to help navigate the coverage and reimbursement process with payers, as well as answering any coding and billing specific questions. IPSEN CARES<sup>®</sup> is available to provide this information and service to healthcare professionals and patients at 1-866-435-5677.

**\*For additional patient eligibility and terms, see previous page.**

---

For additional information about the Somatuline<sup>®</sup> Depot Savings Program, call:

**1-866-435-5677**

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

For additional information, visit us online at [www.ipsencares.com](http://www.ipsencares.com)

---

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

## 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.
- **Hypoglycemia or Hyperglycemia**
  - Pharmacological studies show that SOMATULINE DEPOT, like somatostatin and other somatostatin analogs, inhibits the secretion of insulin and glucagon. Patients treated with SOMATULINE DEPOT may experience hypoglycemia or hyperglycemia.
  - Blood glucose levels should be monitored when SOMATULINE DEPOT treatment is initiated, or when the dose is altered, and antidiabetic treatment should be adjusted accordingly.
- **Cardiovascular Abnormalities**
  - SOMATULINE DEPOT may decrease heart rate.
  - In cardiac studies with acromegalic patients, the most common cardiac adverse reactions were sinus bradycardia, bradycardia, and hypertension.
  - In patients in the GEP-NET pivotal trial, 23% of SOMATULINE DEPOT-treated patients had a heart rate of less than 60 bpm compared to 16% of placebo-treated patients. The incidence of bradycardia was similar in the treatment groups. Initiate appropriate medical management in patients with symptomatic bradycardia.
  - In patients without underlying cardiac disease, SOMATULINE DEPOT may lead to a decrease in heart rate without necessarily reaching the threshold of bradycardia. In patients suffering from cardiac disorders prior to treatment, sinus bradycardia may occur. Care should be taken when initiating treatment in patients with bradycardia.

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



## IMPORTANT SAFETY INFORMATION (CONTINUED)

### Warnings and Precautions (Continued)

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

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

### Special Populations

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

**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](http://www.fda.gov/medwatch).

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

## Field Reimbursement Managers Are Available to Educate Healthcare Professionals

- Increase healthcare professional's knowledge about reimbursement of Ipsen products
- Provide information to help address complex reimbursement issues for healthcare professionals
- Explain IPSEN CARES<sup>®</sup> services and support offerings for patients and healthcare professionals

Please see accompanying full Prescribing Information and Patient Information.

IPSEN CARES<sup>®</sup> can provide information to patients and healthcare professionals relating to medical and pharmacy coverage and policies for Somatuline<sup>®</sup> Depot at 1-866-435-5677.



**Somatuline<sup>®</sup> Depot**  
(lanreotide) Injection 60mg, 90mg and 120mg

*REIMBURSEMENT*

*RESOURCE GUIDE*

Somatuline<sup>®</sup>  
Depot  
Acquisition

Somatuline<sup>®</sup>  
Depot  
Billing and Coding

IPSEN CARES<sup>®</sup>  
Reimbursement  
and Support

**IPSEN CARES<sup>®</sup>**  
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  
[www.ipsencares.com](http://www.ipsencares.com)

Please see accompanying full Prescribing Information and Patient Information.