Somatuline® Depot (lanreotide) Injection

# IPSEN CARES® Enrollment Form

Please print the form, fill it out completely, sign it, and **FAX TO 1-888-525-2416**

❑ All IPSEN CARES® Program Services ☐ HCP Injection Training ☐ Benefits Verification Only ☐ Nurse Home Health Administration ☐ Adherence Calls

## PATIENT

Patient Name (First & Last) _____
Patient Address _____
City _____ State _____ Zip _____
Caregiver/Alternate Contact Name _____
Relationship of Caregiver/Alternative Contact to Patient _____
Caregiver/Alternate Contact Phone # (___) _____
Date of Birth (MM/DD/YY) _____/_____/_____ ☐ Male ☐ Female
Email Address _____
Home Phone # (___) _____ Other Phone # (___) _____
Preferred Language _____

## INSURANCE

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

Is patient insured? ☐ Yes ☐ No
Does patient have secondary insurance? ☐ Yes ☐ No
Pharmacy Insurance Co. _____
Insurance Co. Phone # (___) _____ Subscriber Policy ID # _____
Policy/Employer/Group # _____
Medical Insurance Co. _____
Insurance Co. Phone # (___) _____
Subscriber Name _____ Policy ID # _____

## PRESCRIBER

Prescriber Name _____
DEA # _____ State License # _____
Tax ID # _____ NPI # _____
Medicaid Provider # (Required if Medicaid Patient) _____
Medicare PTAN # (Required if Medicare Patient) _____
Office/Institution _____
Specialty ☐ Oncologist ☐ Endocrinologist ☐ Other _____
Street Address _____
City _____ State _____ Zip _____
Office Contact and Title _____
Phone # (___) _____ Fax # (___) _____
Email Address _____
Preferred Method of Contact ☐ Phone ☐ Fax ☐ Email

## PRESCRIPTION

**Somatuline® Depot (lanreotide) Injection**

| Indication | Strength | Frequency |
|---|---|---|
| ☐ Acromegaly | ☐ 60 mg<br>☐ 90 mg<br>☐ 120 mg | ☐ 4 weeks<br>☐ 6 weeks (extended dosing interval)<br>☐ 8 weeks (extended dosing interval)<br>☐ Other _____ |
| ☐ Gastroenteropancreatic neuroendocrine tumor (GEP-NET) | ☐ 120 mg | ☐ 4 weeks<br>☐ Other _____ |
| ☐ Carcinoid Syndrome | ☐ 120 mg | ☐ 4 weeks<br>☐ Other _____ |

Quantity _____ Number of Refills _____

**Route: Deep Subcutaneous**

Site of Injection ☐ Upper outer buttocks, rotate between sides ☐ Other _____
Directions for Use _____

## PRESCRIBER /OFFICE MANAGER ATTESTATION:

(The Prescriber must sign if this form is to be used as a prescription to be triaged to a Specialty Pharmacy, request for Injection Training, request for Nurse Home Health Administration (HHA) or to enroll a patient for free goods as part of the Patient Assistance Program (PAP). The office manager of the Prescriber may sign if the request is limited to Benefit Verification or Copay Assistance Support.)

By signing below, I certify that a prescription signed by a licensed prescriber is on file or provided above for the above therapy and that the patient has provided the necessary authorization to release the above referenced information and medical and/or patient information relating to Somatuline® Depot therapy to Ipsen and its agents or contractors for the purpose of seeking reimbursement for Somatuline® Depot therapy, assisting in initiating or continuing Somatuline® Depot therapy, and/or evaluating the patient's eligibility for Ipsen's patient support programs administered by IPSEN CARES®.

These medications will not be offered for sale, trade, or barter. Additionally, no claim for reimbursement will be submitted concerning these medications to Medicare, Medicaid, or any third party, nor will any medications be returned for credit. If named patient does not return for therapy, product will be returned to Ipsen. I acknowledge that I have assisted the patient in enrolling in IPSEN CARES® exclusively for purposes of patient care and not in consideration for, expectation of, or actual receipt of remuneration of any sort.

**For Prescriber Only:** If I have requested nurse home health administration of Somatuline® Depot, I certify and acknowledge as to my understanding that nurse home health administration is for product injection only and does not replace regular treatment visits with me or other healthcare providers. I authorize Ipsen to be my agent and to forward the above prescription, by fax or other mode of delivery, to the pharmacy chosen by the above-named patient. For the state of New York, copies of all prescriptions should be on official New York state prescription forms. I certify that any medications received from Ipsen in connection with any IPSEN CARES® program will be used only for the patient named on this form.

Name _____ Title _____
Signature _____ Date _____

Please see full Prescribing Information and Patient Information.

## ACROMEGALY SECTION (If Applicable)

**SOMATULINE® 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

Have you documented that your patient has experienced an inadequate response to or cannot be treated with surgery and/or radiotherapy? ☐ Yes ☐ No

Diagnosis ❑ Acromegaly (ICD-10-CM Code) _____ Description _____

CPT Code _____ Description _____

Date of Diagnosis _____/_____/_____ Therapy Start Date _____/_____/_____

Have other products been used to treat this patient? ☐ Yes ☐ No Product _____ Date of Last Injection _____/_____/_____

Allergies ☐ No Known Drug Allergies ☐ List Allergies _____

List Medications _____

## GEP-NET AND CARCINOID SYNDROME SECTION (If Applicable)

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

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

Diagnosis ☐ GEP-NETs (ICD-10-CM Code) _____ Description _____

☐ Carcinod Syndrome (ICD-10-CM Code) _____ Description _____

CPT Code _____ Description _____

Date of Diagnosis _____/_____/_____ Therapy Start Date _____/_____/_____

Have other products been used to treat this patient? ☐ Yes ☐ No Product _____ Date of Last Injection _____/_____/_____

Allergies ☐ No Known Drug Allergies ☐ List Allergies _____

List Medications _____

## PATIENT SUPPORT

Would you like us to provide starter therapy if patient is eligible? ☐ Yes ☐ No

Would you like to request injection training and nursing support from an IPSEN CARES® nurse for your staff? ☐ Yes ☐ No

If yes, requested location for training is ☐ Prescriber's Office ☐ Other MD Office/Clinic _____

Would you like to request nurse home health administration of Somatuline® Depot for your patient by an IPSEN CARES® nurse if the patient is eligible? ☐ Yes ☐ No

## SPECIALTY PHARMACY

Preferred Specialty Pharmacy _____

Was Rx sent to a Specialty Pharmacy already? ☐ Yes ☐ No If yes, please provide the name of the Specialty Pharmacy _____

## INDICATIONS

SOMATULINE® 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.

## IMPORTANT SAFETY INFORMATION

### Contraindications

- SOMATULINE DEPOT is contraindicated in patients with hypersensitivity to lanreotide. Allergic reactions (including angioedema and anaphylaxis) have been reported following administration of lanreotide.

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

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## IMPORTANT SAFETY INFORMATION, CONTINUED

### 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.
- **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.**

Please see full Prescribing Information and Patient Information.

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Please Fill Out Form Completely and Fax Back to 1-888-525-2416

Somatuline® Depot
(lanreotide) Injection

Please print the form, sign it, and fax it to IPSEN CARES® at the number above, or send the form to:
**IPSEN CARES® Program**
**Ipsen Biopharmaceuticals, Inc.**
**11800 Weston Parkway**
**Cary, NC 27513**

# Patient Authorization

## Patient Authorization and Signature - IPSEN CARES® Program

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

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

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

Patient Name _____ Parent/Legal Guardian _____
Name _____ Relationship to Patient _____
Signature _____ Date _____
Patient Date of Birth _____ Patient Phone Number _____

## Additional Product and Support Information

☐ I agree to be contacted by autodialed text messages ("texts") at the mobile phone number I provided for the purpose of helping me stay on therapy. I may opt out of individual communications of the program entirely at any time by calling 866-435-5677 or replying "STOP" by text to the number I receive texts from. Ipsen will not sell or rent my information and will only use my information in accordance with this authorization and my consent. Consent to being contacted by text messages is not a condition of participation in the IPSEN CARES® programs or the purchase of any products. I understand that my cellular service carrier's data and text messaging rates may apply. Privacy policy at www.ipsencares.com.

☐ In addition to participating in the IPSEN CARES® program above, I would also like to receive information from Ipsen, which may include marketing and educational material about Somatuline® Depot and programs that support patients. I understand that I do not have to sign this section of the form in order to participate in the IPSEN CARES® program and that I may revoke my authorization to receive additional product information at any time. By signing below, I agree that Ipsen and its agents may use and disclose my personal information (including name, address, phone number, and/or email) to provide these services and Ipsen may also contact me to solicit my opinions regarding Somatuline® Depot and Ipsen's products and services. I understand that my cell phone carrier's standard rates may apply for calls to my cell phone. This authorization is valid for one year from the date I sign the form. I may revoke this authorization, by calling 866.435.5677 or sending a request in writing to: IPSEN CARES®, 11800 Weston Parkway, Cary, NC 27513.

Patient Name _____ Parent/Legal Guardian _____
Name _____ Relationship to Patient _____
Signature _____ Date _____

**Please See Next Page for Important Safety Information and full Prescribing Information and Patient Information. Questions? Call IPSEN CARES® at 1-866-435-5677**

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## What is SOMATULINE® DEPOT (lanreotide) Injection?

SOMATULINE DEPOT is a prescription medicine used in adults for:

- the long-term treatment of people with acromegaly when surgery or radiotherapy have not worked well enough or a patient is unable to have surgery or radiotherapy;
- the treatment of a type of cancer known as neuroendocrine tumors, from the gastrointestinal tract or the pancreas (GEP-NETs) that has spread or cannot be removed by surgery; and
- the treatment of carcinoid syndrome to reduce the need for the use of short-acting somatostatin medicine.

It is not known if SOMATULINE DEPOT is safe and effective in children.

## IMPORTANT SAFETY INFORMATION

- **Do not take SOMATULINE DEPOT** if you are allergic to lanreotide.
- **SOMATULINE DEPOT may cause serious side effects**, including:
  - **Gallstones**
  - **Changes to your blood sugar (high or low blood sugar),**
  - **Slow heart rate, and**
  - **High blood pressure, and**
  - **Changes in your thyroid function in acromegaly patients.**

  **Tell your healthcare provider (HCP) if you have any of the following symptoms:**
  - **Symptoms of gallstones** may include sudden pain in your upper right stomach area (abdomen), sudden pain in your right shoulder or between your shoulder blades, yellowing of your skin and whites of your eyes, fever with chills, and nausea.
  - **Symptoms of high blood sugar** may include increased thirst, increased appetite, nausea, weakness or tiredness, urinating more than normal, and fruity smelling breath.
  - **Symptoms of low blood sugar** may include dizziness or lightheadedness, sweating, confusion, headache, blurred vision, slurred speech, shakiness, fast heartbeat, irritability or mood changes, and hunger.
  - **Symptoms of slow heart rate** may include dizziness or lightheadedness, fainting or near-fainting, chest pain, shortness of breath, confusion or memory problems, and weakness or extreme tiredness.
  - SOMATULINE DEPOT can cause the thyroid gland to not make enough thyroid hormone in people with acromegaly. Symptoms of low thyroid levels may include fatigue, weight gain, puffy face, being cold all the time, constipation, dry skin, thinning or dry hair, decreased sweating, and depression.
- **The most common side effects of SOMATULINE DEPOT in people with:**
  - **Acromegaly:** diarrhea; stomach (abdominal) pain; nausea; pain, itching, or a lump at the injection site
  - **GEP-NETs:** stomach area (abdominal) pain; muscle and joint aches; vomiting; headache; pain, itching or a lump at the injection site
  - **Carcinoid syndrome:** headache, dizziness, muscle spasm; side effects were generally similar to those commonly seen with GEP-NETs
- SOMATULINE DEPOT may cause dizziness. If this happens, do not drive a car or operate machinery.
- Tell your HCP right away if you have signs of an allergic reaction after receiving SOMATULINE DEPOT, including swelling of your face, lips or tongue; breathing problems; fainting, dizziness or feeling lightheaded (low blood pressure); itching; skin flushing or redness; rash; or hives.
- **Before taking SOMATULINE DEPOT, tell your HCP about all your medical conditions including if you:** have diabetes; have gallbladder, heart, thyroid, kidney or liver problems; are pregnant or plan to become pregnant; or are breastfeeding or plan to breastfeed. It is not known if SOMATULINE DEPOT will harm your unborn baby or pass into breast milk. You should not breastfeed if you receive SOMATULINE DEPOT and for 6 months after your last dose. SOMATULINE DEPOT may affect your ability to become pregnant.
- **Tell your HCP about all the medicines you take,** including prescription and over-the-counter medicines, vitamins, and herbal supplements. SOMATULINE DEPOT and other medicines may affect each other, causing side effects. SOMATULINE DEPOT may affect the way other medicines work, and other medicines may affect how SOMATULINE DEPOT works. Your dose of SOMATULINE DEPOT or your other medications may need to be changed. If you have diabetes, your HCP may change your dose of diabetes medication when you first start receiving SOMATULINE DEPOT or if your dose of SOMATULINE DEPOT is changed.
- **Especially tell your HCP if you take:**
  - Insulin or other diabetes medicines,
  - A cyclosporine (Gengraf, Neoral, or Sandimmune), or
  - Medicines that lower your heart rate, such as beta blockers.

  Know the medicines you take. Keep a list of them to show your HCP when you get a new medicine.

**Tell your HCP if you have any side effect that bothers you or that does not go away.** These are not all the possible side effects of SOMATULINE DEPOT. For more information, ask your HCP.

**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.**

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