Questions? Call IPSEN CARES™ at 1-866-435-5677

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 ❑ 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 ❑ 90 mg ❑ 120 mg	❑ 4 weeks ❑ 6 weeks (extended dosing interval) ❑ 8 weeks (extended dosing interval) ❑ Other_____
❑ Gastroenteropancreatic neuroendocrine tumor (GEP-NET)	❑ 120 mg	❑ 4 weeks ❑ Other_____

Quantity _____ Number of Refills _____

Route: Deep Subcutaneous

Site of Injection ❑ Upper outer buttocks, rotate between sides ❑ Other _____

Directions for Use _____

PRESCRIBER ATTESTATION:

By signing below, I certify that the above therapy is medically necessary and that I have received 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™.

If I have requested home health administration of Somatuline® Depot, I certify and acknowledge as to my understanding that 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. When free starter therapy is sent to my office, I certify that the product will be used for the above patient, and neither the patient nor any third party will be charged for such product. If named patient does not return for therapy, product will be returned to Ipsen.

_____ _____

Prescriber Signature Date

Please See the Following Pages for Indications and Important Safety Information and the Accompanying Full Prescribing Information.

ACROMEGALY SECTION (If Applicable)

Somatuline® Depot (lanreotide) Injection is a somatostatin analog indicated for:

Acromegaly – Long-term treatment of adult patients with acromegaly who had an inadequate response to or cannot be treated with surgery and/or radiotherapy.

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 SECTION (If Applicable)

Somatuline® Depot (lanreotide) Injection is a somatostatin analog indicated for:

Gastroenteropancreatic neuroendocrine tumors (GEP-NETs) – Treatment of adult patients with unresectable, well- or moderately differentiated, locally advanced or metastatic GEP-NETs to improve progression-free survival.

Diagnosis ❑ GEP-NETs (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 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:

- Acromegaly – Long-term treatment of adult patients with acromegaly who had an inadequate response to or cannot be treated with surgery and/or radiotherapy.
- Gastroenteropancreatic neuroendocrine tumors (GEP-NETs) – Treatment of adult patients with unresectable, well- or moderately differentiated, locally advanced or metastatic GEP-NETs to improve progression-free survival.

Important Safety Information

Contraindications

Somatuline 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 may reduce gallbladder motility and lead to gallstone formation. Periodic monitoring may be needed.
- Hypoglycemia or Hyperglycemia: Pharmacological studies show that Somatuline, like somatostatin and other somatostatin analogs, inhibits the secretion of insulin and glucagon. Blood glucose levels should be monitored when Somatuline treatment is initiated, or when the dose is altered, and antidiabetic treatment should be adjusted accordingly.
- Thyroid Function: Slight decreases in thyroid function have been seen in acromegalic patients during treatment, though clinical hypothyroidism is rare (<1%). Thyroid function tests are recommended where clinically indicated.
- Cardiac Abnormalities: Somatuline may decrease heart rate. In cardiac studies with acromegalic patients, the most common cardiac adverse reactions were sinus bradycardia, bradycardia, and hypertension.

  In 81 patients with baseline heart rates of ≥ 60 beats per minute (bpm) treated with Somatuline® Depot in the GEP-NETs clinical trial, the incidence of heart rate < 60 bpm was 23% (19/81) with Somatuline vs 16% (15/94) with placebo; 10 patients (12%) had documented heart rates < 60 bpm on more than one visit. The incidence of documented episodes of heart rate < 50 bpm or bradycardia reported as an adverse event was 1% in each treatment group. Initiate appropriate medical management in patients who develop symptomatic bradycardia.

  In patients without underlying cardiac disease, Somatuline 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.
- Drug Interactions: The pharmacological gastrointestinal effects of Somatuline may reduce the intestinal absorption of concomitant drugs. Concomitant administration of Somatuline® Depot may decrease the relative bioavailability of cyclosporine and may necessitate the adjustment of cyclosporine dose to maintain therapeutic levels.

Adverse Reactions

In acromegaly, the most common adverse reactions (incidence > 5%) in clinical trials were diarrhea (37%), cholelithiasis (20%), abdominal pain (19%), nausea (11%), injection-site reactions (9%), constipation (8%), flatulence (7%), headache (7%), arthralgia (7%), vomiting (7%), and loose stools (6%).

In the GEP-NET pivotal trial, the most common adverse reactions (incidence >10% and more common than placebo) in patients treated with Somatuline® Depot vs placebo were abdominal pain (34% vs 24%), musculoskeletal pain (19% vs 13%), vomiting (19% vs 9%), headache (16% vs 11%), injection site reaction (15% vs 7%), hyperglycemia (14% vs 5%), hypertension (14% vs 5%), and cholelithiasis (14% vs 7%).

Use in Special Populations

In the treatment of acromegaly, for patients with moderate and severe renal impairment or moderate and severe hepatic impairment, initial dose is 60 mg every 4 weeks.

You may report suspected adverse reactions to FDA at 1-800-FDA-1088 or to Ipsen Biopharmaceuticals, Inc. at 1-888-980-2889.

Please See the Accompanying Full Prescribing Information.

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

Somatuline® Depot
(lanreotide) Injection

Patient Authorization

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
11800 Weston Parkway
Cary, NC 27513

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; (6) evaluate my eligibility for home health administration if requested by my physician; (7) evaluate the effectiveness of Ipsen's patient support programs and conduct market analysis, including aggregating my PHI with other data for such analysis; (8) facilitate my participation in the Somatuline® Depot Copay Assistance program and other Somatuline® Depot patient programs that I have elected to receive information about, as indicated below; and (9) solicit my opinions about IPSEN CARES™ services.

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 may revoke (cancel) this authorization at any time by mailing a letter requesting such revocation to IPSEN CARES™, 11800 Weston Parkway, Cary, NC 27513, or by calling 1-866-435-5677. Canceling this authorization will end my consent to further disclosure of my PHI and my receipt of the services, but will not affect my healthcare providers' use and disclosure of PHI in reliance on this authorization before they receive notice of my cancellation. This authorization expires one year after the date I sign it below. I understand that I will receive a copy of the signed authorization. I understand that I may refuse to sign this authorization and if I do not sign it, my enrollment in and eligibility for health plan benefits and treatment (including the receipt of Somatuline® Depot) and payment for treatment will not be affected, but I will not have access to the IPSEN CARES™ program and other services described above.

Patient Name _____ Parent/Legal Guardian _____

Name _____ Relationship to Patient _____

Signature _____ Date _____

Additional Product and Support Information

❑ In addition to participating in the IPSEN CARES™ program described above, I would like to receive information from Ipsen, which may include marketing and educational material about Somatuline® Depot and relevant disease state 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 of the parent/caregiver) to provide these services and that 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 after signature. I may revoke this authorization by calling 1-866-435-5677 or by 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 _____

IPSEN CARES™
Coverage, Access, Reimbursement & Education Support

What is Somatuline® Depot (lanreotide) Injection?

Somatuline® Depot is a prescription medicine used for:

- Long-term treatment of adults with acromegaly when surgery or radiotherapy has not worked well enough or the patient is not able to have surgery or radiotherapy.
- Treatment of adults with 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.

It is not known if Somatuline® Depot is safe and effective in children.

Important Safety Information

Who should not take Somatuline® Depot?

Do not take Somatuline® Depot if you are allergic to lanreotide.

What are the possible side effects of Somatuline® Depot?

Somatuline® Depot may cause serious side effects, including:

- **Gallstones**. Tell your healthcare professional if you get any of these symptoms:
  - 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
  - nausea
- **Changes in your blood sugar** (high blood sugar or low blood sugar). If you have diabetes, test your blood sugar as your healthcare professional tells you to. Your healthcare professional may change your dose of diabetes medicine.
- **Slow heart rate**
- **High blood pressure**

The most common side effects of Somatuline® Depot in people with acromegaly include diarrhea, stomach area (abdominal) pain, nausea, and pain, itching, or a lump at the injection site.

The most common side effects of Somatuline® Depot in people with GEP-NETs include stomach area (abdominal) pain, muscle and joint aches, vomiting, headache, and pain, itching, or a lump at the injection site.

Somatuline® Depot may cause dizziness. If this happens, do not drive a car or operate machinery.

What should I tell my healthcare professional before receiving Somatuline® Depot?

- Tell your healthcare professional if you have diabetes or gallbladder, thyroid, heart, kidney, or liver problems.
- Tell your healthcare professional if you are pregnant or plan to become pregnant as Somatuline® Depot may harm your unborn baby. Tell your healthcare professional if you are breastfeeding or plan to breastfeed. It is not known if Somatuline® Depot passes into your breast milk. You and your healthcare professional should decide if you will take Somatuline® Depot or breastfeed. You should not do both.
- **Tell your healthcare professional 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.
- Especially tell your healthcare professional if you take insulin or other diabetes medicines, a cyclosporine (Gengraf®, Neoral®, or Sandimmune®), a medicine called bromocriptine (Parlodel®, Cycloset®), or medicines that lower your heart rate, such as beta blockers.

Tell your healthcare professional 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 healthcare professional.

You may report side effects to FDA at 1-800-FDA-1088 or Ipsen Biopharmaceuticals, Inc. at 1-888-980-2889.

Please See the Accompanying Patient Information and Full Prescribing Information.

Somatuline® Depot
(lanreotide) Injection

IPSEN
Innovation for patient care