Somatuline® Depot (lanreotide) Injection 60 mg 90 mg 120 mg

Patient Assistance Program Application

To be completed by patient and physician's office.

Fax Completed Form To:
1-888-525-2416

The Somatuline Depot 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 Somatuline Depot PAP provides Somatuline® Depot (lanreotide) Injection product only, and does not cover the cost of previously purchased product or medical services.

Instructions: Both the patient and the healthcare provider have to complete the application.

PATIENT REQUIREMENTS

- Complete and sign the Patient Information section, including the Financial Information section.
- If you are seeking financial assistance from the PAP, please fax a copy of proof of total household income. Accepted forms include most recently filed Federal Tax Forms (i.e., Form 1040) including supporting documents (W-2), social security income (SSA 1099), or the completed Income Statement form included at the end of this application.

HEALTHCARE PROVIDER REQUIREMENTS

- Complete and sign the Healthcare Provider Information section.
- Verify that the patient is being prescribed and administered Somatuline Depot.
- Ensure the entire application is complete and signed before sending it to the fax number provided above.

It is important that you and your healthcare provider complete all requested information and sign where indicated. Since incomplete or incorrect applications will delay the application process, please ensure all information provided is correct.

We recommend that you fax the completed form in order to expedite the process. Once the application is received, we will evaluate the patient's eligibility to participate in the Somatuline Depot PAP. Healthcare providers will be notified upon completion of eligibility review. Please note that program rules are subject to change without notice. For further assistance, please call 1-866-435-5677 from 8:00 AM to 8:00 PM ET, Monday through Friday.

Please see Somatuline Depot Important Safety Information on the following pages and accompanying Patient Information and full Prescribing Information.

Sincerely,

The IPSEN Coverage, Access, Reimbursement & Education Support (CARES) program

IPSEN CARES®
Coverage. Access. Reimbursement & Education Support

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

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PATIENT INFORMATION: THIS SECTION TO BE COMPLETED BY THE PATIENT

First Name _____ MI _____ Last Name _____
Date of birth (MM/DD/YYYY) _____/_____/_____
Mailing Address _____ Apt # _____
City _____ State _____ Zip _____
Social Security Number _____ Gender ☐ Male ☐ Female
Daytime Phone Number (____)_____ Evening Phone Number (____) _____
Email Address _____ Are you a US resident? ☐ Yes ☐ No
Prescribing Physician _____ Treating Facility _____

PROOF OF ANNUAL HOUSEHOLD INCOME (REQUIRED)

My estimated annual household income currently is $ _____
(Please include dollar amount of monthly income from)

$_____ Social Security Disability Income (SSDI) (beginning _____ / _____)
$_____ Supplemental Security Income(SSI)
$_____ Aid from the Department of Public Welfare
$_____ Unemployment Benefits (from _____ / to _____ / _____)
$_____ Workers Compensation Benefits (from _____ / to _____ / _____)
$_____ Dividends, interest, or investment accounts
$_____ Employment (myself and/or my spouse)
$_____ Other (includes assistance from family, friends, charity, or church. Please specify the amount of financial assistance you receive - may include percentage of rent, food, etc.)

Number of People in Household _____

Insurance Type	Status	Status	Please indicate Primary (P) or Secondary (S)
Commercial	☐ Approved ☐ Denied ☐ Waiting for Decision	_____/_____/_____	
Medicaid	☐ Approved ☐ Denied ☐ Waiting for Decision	_____/_____/_____	
Medicare	☐ Approved ☐ Denied ☐ Waiting for Decision	_____/_____/_____	
TriCare	☐ Approved ☐ Denied ☐ Waiting for Decision	_____/_____/_____	
Healthcare Exchange	☐ Approved ☐ Denied ☐ Waiting for Decision	_____/_____/_____	
Other	☐ Approved ☐ Denied ☐ Waiting for Decision	_____/_____/_____	
☐ Uninsured	Patient is not eligible for any public health insurance, which includes Medicare and Medicaid, or has been denied coverage by a third-party payer.		

Please see accompanying full Prescribing Information and Patient Information.

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PATIENT INFORMATION (CONTINUED): THIS SECTION TO BE COMPLETED BY THE PATIENT

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

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

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

Patient Signature_____ Date_____

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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 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.**

Please see accompanying full Prescribing Information and Patient Information.

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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.

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.

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Please see accompanying full Prescribing Information and Patient Information.

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HEALTHCARE PROVIDER INFORMATION: THIS SECTION MUST BE COMPLETED BY THE PRESCRIBING PHYSICIAN'S OFFICE

Prescriber Name _____ Street Address _____
City _____ State _____ Zip _____
DEA# _____ State license # _____
Medicaid provider # _____ Office contact and title _____
Medicare PTAN # _____ Phone (____) _____ Fax (____) _____
Office/Institution _____ Email Address _____
Specialty _____ Preferred method of contact ☐ Phone ☐ Fax ☐ Email
Tax ID # _____ NPI# _____

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 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 for the above therapy and that the patient named on this form 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. 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 patient named on this form. 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 named patient.

These medications will not be offered for sale, trade, or barter. Additionally, no claim for reimbursement will be submitted concerning these medications to any payor, including Medicare, Medicaid, or any other federal or state health insurance program, nor will any medications be returned for credit. If the 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.

Prescriber Signature _____ Date _____

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