



[May [XX], 2015

Dear Healthcare Provider and Administrative Personnel,

As you may already know, on December 16, 2014, the Food and Drug Administration (FDA) approved Somatuline® Depot (lanreotide) Injection 120 mg 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. Somatuline® Depot is a somatostatin analog that is administered via deep subcutaneous injection.

Prior to this approval, Somatuline® Depot was only indicated for the treatment of acromegaly and the majority of patients received the product through their pharmacy benefit from a specialty pharmacy.

Somatuline® Depot with Safe'n'Sound® syringe technology:

- Ready-to-use, prefilled, low-volume syringe (0.5 mL)
- Retractable needle guard to help avoid needle stick injuries
- Manufactured without latex or natural dry rubber

As the majority of Commercial, Medicare and Medicaid insurers will allow for Somatuline® Depot to be physician administered (the buy and bill reimbursement model to which you are accustomed), it will be important that you check your current provider agreements. Somatuline® Depot should be administered by a healthcare professional.

Due to variances in contractual agreements between healthcare providers and payers, you are encouraged to contact payers to confirm your contracted rate for Somatuline® Depot J1930. You may need to request an amendment to your current contract in an effort to update your reimbursement to reflect current pricing.

**Important Update for Somatuline® Depot:**

Medicare has updated the Part B Drug Average Sales Price fee schedule effective April 2015. Please see below for correct product coding information.

NDC	Description	HPCS Code
15054-1120-03	Somatuline® Depot (lanreotide) 120 mg/0.5 mL sterile, prefilled syringe	J1930 lanreotide injection

This letter serves as formal documentation from Ipsen announcing this change. In the event that some payers request supporting documentation of this change, you may use the letter accordingly.

**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.

Please see next page for additional Important Safety Information.

## Additional Important Safety Information (cont'd)

### Warnings and Precautions (cont'd):

- **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.
- **Cardiac Abnormalities:** SOMATULINE may decrease heart rate. In 81 patients with baseline heart rates of  $\geq 60$  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 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%).

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 accompanying full Prescribing Information for Somatuline Depot.

Sincerely,

«OAS full name»

«OAS email»

SOMATULINE DEPOT is a registered trademark of IPSEN PHARMA S.A.S.  
Safe'n'Sound is a registered trademark of NEMERA LA VERPILLIERE SAS.  
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[May], 2015

Dear Payor,

In January 2015, Ipsen issued a communication to your plan notifying that the Food and Drug Administration (FDA) approved Somatuline® Depot (lanreotide) Injection 120 mg for the treatment of patients with unresectable, well- or moderately-differentiated, locally advanced or metastatic gastroenteropancreatic neuroendocrine tumors (GEP-NETs) to improve progression-free survival. As a result of this new indication, I intend to utilize Somatuline® Depot for patients with GEP-NETS as indicated and request that your billing and claims department are prepared to administer these claims.

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15054-1120-03	Somatuline® Depot (lanreotide) 120 mg/0.5 mL sterile, prefilled syringe	J1930 lanreotide injection

Please let me know if I can supply any additional information not included in this letter to help ensure that my impending claims for Somatuline® Depot are properly paid.

#### **Indication**

SOMATULINE® DEPOT (lanreotide) Injection 120 mg is 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.

#### **Important Safety Information**

##### **Contraindications:**

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##### **Warnings and Precautions:**

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**Additional Important Safety Information (cont'd)**

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**Please see accompanying full Prescribing Information for Somatuline Depot.**

Sincerely,

[Healthcare Provider name]

[Name of practice]

[Address]

SOMATULINE DEPOT is a registered trademark of IPSEN PHARMA S.A.S.  
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