IPSENCARES®
Coverage, Access, Reimbursement & Education Support

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

Guide to Writing a Supporting Statement for a Medicare Part D Exception Request

A supporting statement for a Medicare Part D exception request explains the prescriber's rationale and clinical decision-making for choosing a specific treatment option.

There are 2 types of exception requests[1]:

Tier exception

A request to obtain a non-preferred drug at a lower cost-sharing level

Formulary exception

A request to obtain a non-formulary drug or to have a utilization management requirement waived (eg, step therapy, prior authorization)

Use of this information **does not** guarantee that a health plan will provide coverage for Somatuline Depot and is not intended to be a substitute for, or to influence, your independent medical judgment.

The following pages share tips for writing an effective supporting statement and a template you can use to write your statement for individual patients.

Call 1-866-435-5677 Monday – Friday, 8:00 AM – 8:00 PM ET, for additional information, or visit us online at IPSENCARES.com

Reference: 1. Exceptions. Centers for Medicare & Medicaid Services. September 10, 2024. Accessed June 18, 2025. https://www.cms.gov/medicare/appeals-grievances/prescription-drug/exceptions

Please see Important Safety Information on pages 4 and 5 and full Prescribing Information and Patient Information.

Tips for Writing an Effective Supporting Statement for Medicare Part D Patients

Before you begin a supporting statement, have the following information ready:

- Patient's full name and date of birth
- Patient's insurance policy/ID number
- Case ID number
- Brief medical history, including diagnosis, ICD-10 code, comorbidities, and allergies
- Patient's current and prior therapeutic regimens (include start/stop dates and the reason[s] for discontinuation)
- Background on the patient's current condition and symptoms
- Clinical support for your recommendation

Consider these additional points when writing your statement for Somatuline Depot:

- **Review the health plan's coverage criteria** for Somatuline Depot and provide details for the criteria that your patient meets. If applicable, provide your rationale for excluding your patient from criteria they do not meet
- **Clearly state** why Somatuline Depot is medically necessary for the patient and that the preferred drug(s) (for tier exceptions) or covered option(s) (for formulary exceptions) would not be as effective and/or would have adverse effects[1]
- **Provide clinical justification** to support your decision to prescribe Somatuline Depot and attach relevant clinical data, such as chart notes, and laboratory test results[2]
- **Describe** any other patient characteristics and/or clinical considerations relevant to Somatuline Depot therapy
  - Attach clinical documentation that supports your recommendation[2]

Be mindful of following preferred health plan processes.

- Read the process for submitting the statement to ensure that you are meeting the requirements of the health plan and state guidelines, including how to submit the request (eg, fax, phone, email, health plan website)
- Track the status of your request and follow up with the health plan if needed

IPSEN CARES® can help provide logistical information about submitting statements

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ICD-10, International Classification of Diseases, 10th Revision.

References: 1. Exceptions. Centers for Medicare & Medicaid Services. September 10, 2024. Accessed June 18, 2025. https://www.cms.gov/medicare/appeals-grievances/prescription-drug/exceptions **2.** Somatuline Depot (lanreotide) Prescribing Information. Cambridge, MA: Ipsen Biopharmaceuticals, Inc.

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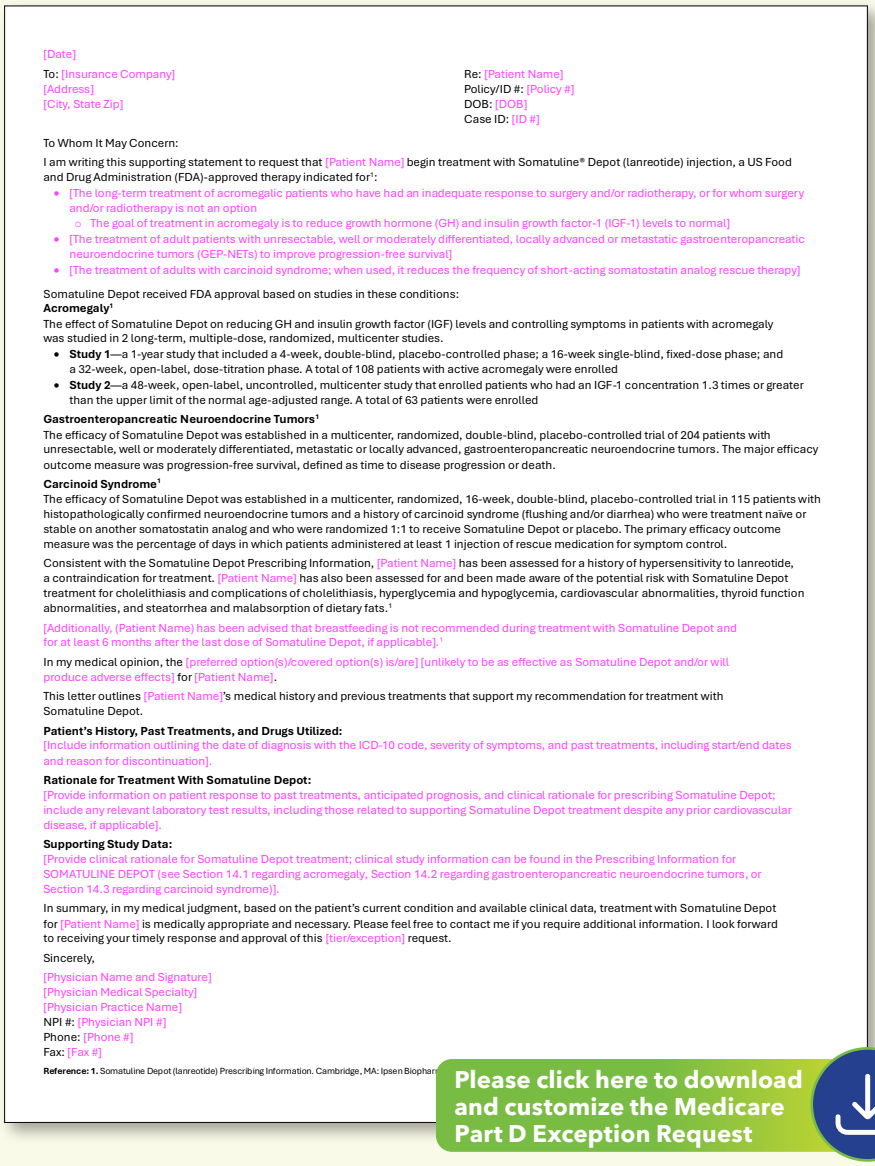
Sample Medicare Part D Supporting Statement for Somatuline Depot

The image below shows the format for a sample supporting statement for Somatuline Depot that uses a downloadable template. Take a look to get a sense of what a statement format may look like, and then you may download the template to customize it based on your medical opinion and your individual patient's needs.



[Date]

To: [Insurance Company]
[Address]
[City, State Zip]

Re: [Patient Name]
Policy/ID #: [Policy #]
DOB: [DOB]
Case ID: [ID #]

To Whom It May Concern:

I am writing this supporting statement to request that [Patient Name] begin treatment with Somatuline® Depot (lanreotide) injection, a US Food and Drug Administration (FDA)-approved therapy indicated for[1]:

- [The long-term treatment of acromegalic patients 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]
- [The treatment of adults with carcinoid syndrome; when used, it reduces the frequency of short-acting somatostatin analog rescue therapy]

Somatuline Depot received FDA approval based on studies in these conditions:

Acromegaly[1]

The effect of Somatuline Depot on reducing GH and insulin growth factor (IGF) levels and controlling symptoms in patients with acromegaly was studied in 2 long-term, multiple-dose, randomized, multicenter studies.

- **Study 1**—a 1-year study that included a 4-week, double-blind, placebo-controlled phase; a 16-week single-blind, fixed-dose phase; and a 32-week, open-label, dose-titration phase. A total of 108 patients with active acromegaly were enrolled
- **Study 2**—a 48-week, open-label, uncontrolled, multicenter study that enrolled patients who had an IGF-1 concentration 1.3 times or greater than the upper limit of the normal age-adjusted range. A total of 63 patients were enrolled

Gastroenteropancreatic Neuroendocrine Tumors[1]

The efficacy of Somatuline Depot was established in a multicenter, randomized, double-blind, placebo-controlled trial of 204 patients with unresectable, well or moderately differentiated, metastatic or locally advanced, gastroenteropancreatic neuroendocrine tumors. The major efficacy outcome measure was progression-free survival, defined as time to disease progression or death.

Carcinoid Syndrome[1]

The efficacy of Somatuline Depot was established in a multicenter, randomized, 16-week, double-blind, placebo-controlled trial in 115 patients with histopathologically confirmed neuroendocrine tumors and a history of carcinoid syndrome (flushing and/or diarrhea) who were treatment naïve or stable on another somatostatin analog and who were randomized 1:1 to receive Somatuline Depot or placebo. The primary efficacy outcome measure was the percentage of days in which patients administered at least 1 injection of rescue medication for symptom control.

Consistent with the Somatuline Depot Prescribing Information, [Patient Name] has been assessed for a history of hypersensitivity to lanreotide, a contraindication for treatment. [Patient Name] has also been assessed for and been made aware of the potential risk with Somatuline Depot treatment for cholelithiasis and complications of cholelithiasis, hyperglycemia and hypoglycemia, cardiovascular abnormalities, thyroid function abnormalities, and steatorrhea and malabsorption of dietary fats.[1]

[Additionally, (Patient Name) has been advised that breastfeeding is not recommended during treatment with Somatuline Depot and for at least 6 months after the last dose of Somatuline Depot, if applicable].[1]

In my medical opinion, the [preferred option(s)/covered option(s) is/are] [unlikely to be as effective as Somatuline Depot and/or will produce adverse effects] for [Patient Name].

This letter outlines [Patient Name]'s medical history and previous treatments that support my recommendation for treatment with Somatuline Depot.

Patient's History, Past Treatments, and Drugs Utilized:
[Include information outlining the date of diagnosis with the ICD-10 code, severity of symptoms, and past treatments, including start/end dates and reason for discontinuation].

Rationale for Treatment With Somatuline Depot:
[Provide information on patient response to past treatments, anticipated prognosis, and clinical rationale for prescribing Somatuline Depot; include any relevant laboratory test results, including those related to supporting Somatuline Depot treatment despite any prior cardiovascular disease, if applicable].

Supporting Study Data:
[Provide clinical rationale for Somatuline Depot treatment; clinical study information can be found in the Prescribing Information for SOMATULINE DEPOT (see Section 14.1 regarding acromegaly, Section 14.2 regarding gastroenteropancreatic neuroendocrine tumors, or Section 14.3 regarding carcinoid syndrome)].

In summary, in my medical judgment, based on the patient's current condition and available clinical data, treatment with Somatuline Depot for [Patient Name] is medically appropriate and necessary. Please feel free to contact me if you require additional information. I look forward to receiving your timely response and approval of this [tier/exception] request.

Sincerely,

[Physician Name and Signature]
[Physician Medical Specialty]
[Physician Practice Name]
NPI #: [Physician NPI #]
Phone: [Phone #]
Fax: [Fax #]

Reference: 1. Somatuline Depot (lanreotide) Prescribing Information. Cambridge, MA: Ipsen Biopharm

Please click here to download and customize the Medicare Part D Exception Request

This template is for informational purposes only, providing an outline of the types of information that may be required or helpful when responding to a request from a patient's health plan. Use of this information does not constitute medical or legal advice and does not guarantee reimbursement for coverage. It is not intended to be a substitute for, or an influence on, the independent clinical decision of the prescribing healthcare professional. IPSEN makes no representations or warranties about the template or its fitness for any specific use. IPSEN is not responsible for any changes made to the template document. All billing and coding decisions are the responsibility of the relevant physician.

Please see Important Safety Information on pages 4 and 5 and full Prescribing Information and Patient Information.

Indication and Important Safety Information for SOMATULINE DEPOT

INDICATIONS

SOMATULINE® DEPOT (lanreotide) 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.
- 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.

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.
  - If complications of cholelithiasis are suspected, discontinue SOMATULINE DEPOT and treat appropriately.
- **Hypoglycemia or Hyperglycemia**
  - 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 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.

Please see Important Safety Information on pages 4 and 5 and full Prescribing Information and Patient Information.

Indication and Important Safety Information for SOMATULINE DEPOT (cont'd)

Warnings and Precautions (cont'd)

- **Steatorrhea and Malabsorption of Dietary Fats**
  - New onset steatorrhea, stool discoloration and loose stools have been reported in patients receiving somatostatin analogs, including SOMATULINE DEPOT. Somatostatin analogs reversibly inhibit secretion of pancreatic enzymes and bile acids, which may result in malabsorption of dietary fats and subsequent symptoms of steatorrhea, loose stools, abdominal bloating, and weight loss.
  - If new occurrence or worsening of these symptoms are reported in patients receiving SOMATULINE DEPOT, evaluate patients for potential pancreatic exocrine insufficiency and manage accordingly.

Most Common Adverse Reactions

- **Acromegaly:** Adverse reactions in >5% of patients who received SOMATULINE DEPOT were diarrhea (37%), cholelithiasis (20%), abdominal pain (19%), nausea (11%), injection-site reactions (9%), constipation (8%), flatulence (7%), vomiting (7%), arthralgia (7%), headache (7%), and loose stools (6%).
- **GEP-NETs:** Adverse reactions in >10% of patients who received SOMATULINE DEPOT 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 in ≥5% of patients who received SOMATULINE DEPOT and 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/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program.

Please see full Prescribing Information and Patient Information.

[Date]

To: [Insurance Company]
[Address]
[City, State Zip]

Re: [Patient Name]
Policy/ID #: [Policy #]
DOB: [DOB]
Case ID: [ID #]

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