Sandostatin Injection / Sandostatin LAR Depot

Prior Authorization Request

CVS Caremark administers the prescription benefit plan for the patient identified. This patient's benefit plan requires prior authorization for certain medications in order for the drug to be covered. To make an appropriate determination, providing the most accurate diagnosis for the use of the prescribed medication is necessary. **Please respond below and fax this form to CVS Caremark toll-free at 1-866-249-6155.** If you have questions regarding the prior authorization, please contact CVS Caremark at **1-866-814-5506.** For inquiries or questions related to the patient's eligibility, drug copay or medication delivery; please contact the Specialty Customer Care Team: CaremarkConnect® 1-800-237-2767.

The recipient of this fax may make a request to opt-out of receiving telemarketing fax transmissions from CVS Caremark. There are numerous ways you may opt-out: The recipient may call the toll-free number at 877-265-2711, at any time, 24 hours a day/7 days a week. The recipient may also send an opt-out request via email to do_not_call@cvscaremark.com. An opt out request is only valid if it (1) identifies the number to which the request relates, and (2) if the person/entity making the request does not, subsequent to the request, provide express invitation or permission to CVS Caremark to send facsimile advertisements to such person/entity at that particular number. CVS Caremark is required by law to honor an opt-out request within thirty days of receipt.

Patient's Name: _____ **Date**: _____
Patient's ID: _____ **Patient's Date of Birth:** _____
Physician's Name: _____
Specialty: _____ **NPI#:** _____
Physician Office Telephone: _____ **Physician Office Fax:** _____
Request Initiated For: _____

1. Which drug is being prescribed?
   - ❑ Sandostatin injection
   - ❑ Sandostatin LAR Depot
   - ❑ octreotide acetate injection (generic)
   - ❑ Other _____

2. What is the diagnosis?
   - ❑ Acromegaly
   - ❑ Vasoactive intestinal peptide (VIP)-secreting tumors (VIPomas) (management of symptoms related to hormone hypersecretion)
   - ❑ Primary gastrinoma, unresected
   - ❑ Neuroendocrine tumors of the gastrointestinal tract (carcinoid tumors), locoregional advanced or metastatic
   - ❑ Neuroendocrine tumors of the thymus (carcinoid tumors), unresectable or metastatic
   - ❑ Neuroendocrine tumors of the lung (carcinoid tumors), unresectable or metastatic
   - ❑ Neuroendocrine tumors of the pancreas
   - ❑ Carcinoid syndrome
   - ❑ Meningioma, unresectable recurrent or progressive
   - ❑ Pheochromocytoma, unresectable or metastatic
   - ❑ Paraganglioma, unresectable or metastatic
   - ❑ Thymoma or thymic carcinoma
   - ❑ Congenital hyperinsulinism in an infant/persistent hyperinsulinemic hypoglycemia of infancy (PHHI)
   - ❑ AIDS-associated secretory diarrhea, severe
   - ❑ Bowel obstruction in terminal cancer
   - ❑ Chemotherapy-induced diarrhea
   - ❑ Radiation-induced diarrhea
   - ❑ Enterocutaneous fistula (Volume depletion from enterocutaneous fistula)
   - ❑ Acute bleeding of gastroesophageal varices associated with cirrhosis
   - ❑ Islet cell tumors (e.g., insulinomas or glucagonomas)
   - ❑ Pancreatic fistulas
   - ❑ Pituitary adenoma
   - ❑ Short bowel syndrome
   - ❑ Zollinger-Ellison syndrome

Send completed form to: Case Review Unit, CVS Caremark Prior Authorization Fax: 1-866-249-6155

❑ Other _____

3. What is the ICD-10 code? _____

Complete the following questions if Sandostatin LAR is being prescribed for acromegaly.

4. The preferred products for your patient's health plan are Somatuline Depot and Somavert. Can the patient's treatment be switched to a preferred product? ***If Yes, please call 1-866-814-5506 to have the updated form faxed to your office OR you may complete the PA electronically (ePA). You may sign up online via CoverMyMeds at: www.covermymeds.com/epa/caremark/ or call 1-866-452-5017.***
   ❑ Yes - Somatuline Depot
   ❑ Yes - Somavert
   ❑ No - Continue request for Sandostatin LAR

5. Is this request for continuation of therapy with the requested product?
   ❑ Yes ❑ No *If No, skip to #7*

6. Is the patient currently receiving the requested product through samples or a manufacturer's patient assistance program? If Unknown, answer Yes. ❑ Yes ❑ No *If No, skip to Section A: Acromegaly.*

7. Does the patient have a documented inadequate response or intolerable adverse event to treatment with both of the preferred products (Somatuline Depot and Somavert)? ***ACTION REQUIRED: If Yes, attach supporting chart note(s).*** ❑ Yes ❑ No *If No, complete this form in its entirety and State Step Therapy section.*

Complete the following section based on the patient's diagnosis, if applicable.

Section A: Acromegaly

8. Is the patient currently on therapy with the requested medication? *If Yes, skip to #12* ❑ Yes ❑ No

9. How does the patient's pretreatment IGF-1 (insulin-like growth factor 1) level compare to the laboratory's reference normal range based on age and/or gender? ***ACTION REQUIRED: Attach a laboratory report or chart note(s) with pretreatment IGF-level and reference normal range.***
   ❑ IGF-1 level is **higher** than the laboratory's normal range
   ❑ IGF-1 level is **lower** than the laboratory's normal range
   ❑ IGF-1 level **falls within** the laboratory's normal range

10. Has the patient had an inadequate or partial response to surgery or radiotherapy? ***ACTION REQUIRED: If Yes, attach supporting chart note(s) indicating an inadequate or partial response to surgery or radiotherapy and no further questions.*** ❑ Yes ❑ No

11. Is there a clinical reason why the patient has not had surgery or radiotherapy? ***ACTION REQUIRED: If Yes, attach supporting chart note(s) indicating a clinical reason for not having surgery or radiotherapy.***
    ❑ Yes ❑ No *No further questions*

12. How has the patient's IGF-1 (insulin-like growth factor 1) level changed since initiation of therapy? ***ACTION REQUIRED: If 'decreased or normalized,' attach laboratory report indicating normal current IGF-1 levels or chart notes indicating that the patient's IGF-1 level has decreased or normalized since initiation of therapy.***
    ❑ Increased
    ❑ Decreased or normalized
    ❑ No change

Section B: Vasoactive Intestinal Peptide (VIP)-Secreting Tumors (VIPomas)

13. Is the patient currently on therapy with the requested medication? ❑ Yes ❑ No *If No, no further questions.*

14. Is the patient experiencing clinical benefit as evidenced by improvement or stabilization in clinical signs and symptoms since initiation of therapy? ❑ Yes ❑ No

Section C: Carcinoid Syndrome

15. Is the patient currently on therapy with the requested medication? *If Yes, skip to #17* ❑ Yes ❑ No

16. Is the requested medication being prescribed in any of the following clinical settings? ***Indicate below and no further questions.***
    ❑ As a single agent
    ❑ In combination with telotristat for persistent diarrhea due to poorly controlled carcinoid syndrome
    ❑ In combination with other systemic therapy options for persistent symptoms such as flushing or diarrhea, or for progressive disease
    ❑ Other _____

17. Is the patient experiencing clinical benefit as evidenced by improvement or stabilization in clinical signs and symptoms since starting therapy? ❑ Yes ❑ No

Section D: Thymomas and Thymic Carcinomas

18. Is the requested drug prescribed as a second-line therapy with or without prednisone? ❑ Yes ❑ No

19. Which of the following clinical settings is the requested medication being used in?
    ❑ Unresectable disease following first-line chemotherapy for potentially resectable locally advanced disease, solitary metastasis, or ipsilateral pleural metastasis
    ❑ Extrathoracic metastatic disease
    ❑ Other _____

Section E: AIDS-Associated Diarrhea

20. Is the patient currently on therapy with the requested medication? *If Yes, skip to #23* ❑ Yes ❑ No

21. Has the patient tried anti-microbial (e.g., ciprofloxacin or metronidazole) or anti-motility agents (e.g., loperamide or diphenoxylate and atropine)? ❑ Yes ❑ No

22. Have the anti-microbial or anti-motility agents become ineffective? ❑ Yes ❑ No *No further questions*

23. Is the patient experiencing clinical benefit as evidenced by improvement or stabilization in clinical signs and symptoms since initiation of therapy? ❑ Yes ❑ No

Section F: Bowel Obstruction in Terminal Cancer

24. Is the patient currently on therapy with the requested medication? *If Yes, skip to #27* ❑ Yes ❑ No

25. Is the requested medication being prescribed to manage gastrointestinal symptoms (e.g., nausea, pain, vomiting) from bowel obstruction? ❑ Yes ❑ No

26. Does the patient have inoperable bowel obstruction? ❑ Yes ❑ No *No further questions*

27. Is the patient experiencing clinical benefit as evidenced by improvement or stabilization in clinical signs and symptoms since initiation of therapy? ❑ Yes ❑ No

Section G: Chemotherapy- and Radiation-Induced Diarrhea

28. Is the patient currently on therapy with the requested medication? *If Yes, skip to #31* ❑ Yes ❑ No

29. Is the patient receiving treatment with chemotherapy or radiation? ❑ Yes ❑ No

30. Does the patient have grade 3 or greater diarrhea according to National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE)? ***ACTION REQUIRED: If Yes, attach supporting chart note(s) indicating grade 3 or 4 diarrhea with current chemotherapy or radiation.***
    ❑ Yes ❑ No *No further questions*

31. Is the patient experiencing clinical benefit as evidenced by improvement or stabilization in clinical signs and symptoms since initiation of therapy? ❑ Yes ❑ No

Section H: Islet Cell Tumors

32. Is the patient currently on therapy with the requested medication? *If Yes, skip to #35* ❑ Yes ❑ No

33. Does the patient have functioning islet cell tumors (e.g., insulinomas or glucagonomas)? ❑ Yes ❑ No

34. Is the requested medication being prescribed to stabilize blood glucose levels?
❑ Yes ❑ No *No further questions*

35. Is the patient experiencing clinical benefit as evidenced by improvement or stabilization in clinical signs and symptoms since initiation of therapy? ❑ Yes ❑ No

Section I: Pancreatic Fistulas

36. Is the requested medication being prescribed for prevention or treatment of pancreatic fistulas following pancreatic surgery? ❑ Yes ❑ No

Section J: Short Bowel Syndrome

37. What is the patient's daily intravenous fluid requirement in liters? _____ liters

Section K: Zollinger-Ellison Syndrome

38. Is the patient currently on therapy with the requested medication? ❑ Yes ❑ No *If No, no further questions.*

39. Is the patient experiencing clinical benefit as evidenced by improvement or stabilization in clinical signs and symptoms since initiation of therapy? ❑ Yes ❑ No

State Step Therapy

1. Is the requested drug being used for an FDA-approved indication or an indication supported in the compendia of current literature (examples: AHFS, Lexicomp, Clinical Pharmacology, Micromedex, current accepted guidelines)?
❑ Yes ❑ No

2. Does the prescribed quantity fall within the manufacturer's published dosing guidelines or within dosing guidelines found in the compendia of current literature (examples: package insert, AHFS, Lexicomp, Clinical Pharmacology, Micromedex, current accepted guidelines)? ❑ Yes ❑ No

3. Does the patient reside in Maryland? ❑ Yes ❑ No *If No, skip to #7*

4. Is the alternate drug (Somatuline Depot and Somavert) FDA-approved for the medical condition being treated?
❑ Yes ❑ No *If No, please specify:* _____

5. Has the prescriber provided proof, documented in the patient's chart notes, indicating that the requested drug was ordered for the patient in the past 180 days? ❑ Yes ❑ No *If No, skip to #7*

6. Has the prescriber provided proof, documented in the patient chart notes, that in their opinion the requested drug is effective for the patient's condition? ❑ Yes ❑ No *No further questions*

7. Are any of the following conditions met for the alternate drug (Somatuline Depot and Somavert)?
❑ The alternate drug is contraindicated
❑ The alternate drug is likely to cause an adverse reaction, physical or mental harm
❑ The alternate drug is expected to be ineffective
❑ The alternate drug was previously tried or a drug in the same class or with the same action was previously tried and was stopped due to ineffectiveness or an adverse event
❑ The alternate drug is not in the patient's best interest
❑ None of the above
If Yes, please specify: _____

8. Is the patient stable or currently receiving a positive therapeutic outcome with the requested drug and a change in the prescription drug is expected to be ineffective or cause harm to the patient? ❑ Yes ❑ No

I attest that this information is accurate and true, and that documentation supporting this information is available for review if requested by CVS Caremark or the benefit plan sponsor.

X_____
Prescriber or Authorized Signature **Date (mm/dd/yy)**

Send completed form to: Case Review Unit, CVS Caremark Prior Authorization Fax: 1-866-249-6155

 Sandostatin Inj/LAR State Step, ACSF SGM - 6/2020.