UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 1091-13
Program	Prior Authorization/Notification
Medication	Sandostatin® (octreotide acetate) Note: Only the subcutaneous formulation of octreotide requires notification. Sandostatin LAR is covered under the medical benefit and therefore addressed in the Somatostatin Analogs drug policy.
P&T Approval Date	8/2008, 12/2009, 11/2010, 11/2011, 11/2012, 7/2013, 11/2013, 11/2014, 11/2015, 9/2016, 9/2017, 9/2018, 9/2019, 9/2020, 10/2021, 1/2022, 1/2023, 1/2024
Effective Date	4/1/2024

1. **Background:**
Sandostatin (octreotide acetate) is indicated to reduce blood levels of growth hormone and IGF-I (somatomedin C) in acromegaly patients who have had inadequate response to or cannot be treated with surgical resection, pituitary irradiation and bromocriptine mesylate at maximally tolerated doses. It is also indicated for the symptomatic treatment of patients with metastatic carcinoid tumors where it suppresses or inhibits the severe diarrhea and flushing episodes associated with the disease and for the treatment of profuse watery diarrhea associated with vasoactive intestinal peptide (VIP)-secreting tumors.

The National Comprehensive Cancer Network (NCCN)) recommends the use of octreotide acetate for the treatment of thyomas and thymic carcinomas as well as meningiomas. The NCCN also recommends octreotide acetate for the treatment of several types of neuroendocrine and adrenal tumors, including neuroendocrine tumors of the gastrointestinal tract, lung and thymus, neuroendocrine tumors of the pancreas, , and pheochromocytoma/paraganglioma. The NCCN Palliative Care Guidelines recommend octreotide for the treatment of chemotherapy and/or radiation-induced diarrhea and malignant bowel obstruction.

Clinical evidence supports the use of octreotide acetate for the treatment of refractory HIV/AIDS-related diarrhea that does not respond to first-line anti-diarrheal therapy and as an adjunct to endoscopic therapy for bleeding gastroesophageal varices associated with liver disease.

Coverage Information:
Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

2. Coverage Criteria[a]:

A. Patients less than 19 years of age

1. **Initial Authorization**

   a. **Sandostatin** will be approved based on **both** of the following criteria:

      (1) Patient is less than 19 years of age
      (2) Treatment is for an oncology indication

   Authorization will be issued for 12 months.

B. Acromegaly

1. **Initial Authorization**

   a. **Sandostatin** will be approved based on **both** of the following criteria:

      (1) Diagnosis of acromegaly

      -AND-

      (2) **One** of the following:

         (a) Inadequate response to **one** of the following:

            i. Surgery
            ii. Radiotherapy
            iii. Dopamine agonist (e.g., bromocriptine, cabergoline) therapy

         -OR-

         (b) Not a candidate for **any** of the following:

            i. Surgery
            ii. Radiotherapy
            iii. Dopamine agonist (e.g., bromocriptine, cabergoline) therapy

   Authorization will be issued for 12 months.

2. **Reauthorization**

   a. **Sandostatin** will be approved based on the following criterion:

      (1) Documentation of positive clinical response to Sandostatin therapy

   Authorization will be issued for 12 months.

C. Meningioma

1. **Initial Authorization**

   a. **Sandostatin** will be approved based on **all** of the following criteria:

      (1) Diagnosis of meningioma

      -AND-

      (2) Disease is surgically inaccessible

      -AND-

      (3) **One** of the following:

         (a) Disease is recurrent
         (b) Disease is progressive

      -AND-

      (4) Additional radiation is not possible

      Authorization will be issued for 12 months.

2. **Reauthorization**

   a. **Sandostatin** will be approved based upon the following criterion:

      (1) Patient does not show evidence of progressive disease while on Sandostatin therapy

      Authorization will be issued for 12 months.

D. Neuroendocrine and Adrenal Tumors

1. **Initial Authorization**

   a. **Sandostatin** will be approved based on diagnosis of **one** of the following:

      (1) Neuroendocrine tumors [e.g., carcinoid tumors, Islet cell tumors, gastrinomas, glucagonomas, insulinomas, lung tumors, somatostatinomas, tumors of the pancreas, GI tract, lung, thymus, adrenal glands, and vasoactive intestinal polypeptidomas (VIPomas)]

      -OR-

      (2) **All** of the following:

(a) Diagnosis of Pheochromocytoma or Paraganglioma

-AND-

(b) Disease is locally unresectable or distant metastases

-AND-

(c) Disease is somatostatin receptor positive

-AND-

(d) Presence of symptomatic disease

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Sandostatin** will be approved based upon **one** of the following criteria:

(1) Patient does not show evidence of progressive disease while on Sandostatin therapy

-OR-

(2) Documentation of positive clinical response (e.g., suppression of severe diarrhea, flushing, etc.) to Sandostatin therapy

Authorization will be issued for 12 months.

E. Thymoma or Thymic Carcinoma

1. **Initial Authorization**

a. **Sandostatin** will be approved based on **all** of the following criteria:

(1) Diagnosis of thymoma or thymic carcinoma

-AND-

(2) **One** of the following:

(a) Used as a second-line therapy for **one** of the following:

i. Unresectable disease following first-line chemotherapy for potentially resectable locally advanced disease, solitary metastasis, or ipsilateral pleural metastasis.

-OR-

ii. Extrathoracic metastatic disease.

-OR-

(b) **Both** of the following:

i. Used as first line therapy for one of the following:

- Unresectable locally advanced disease in combination with radiation therapy
- Potentially resectable locally advanced disease
- Potentially resectable solitary metastasis or ipsilateral pleural metastasis
- Consideration following surgery for solitary metastasis or ipsilateral pleural metastasis
- Extrathoracic metastatic disease
- Postoperative treatment for thymoma after R2 resection

-AND-

ii. Patient is unable to tolerate first-line combination regimens

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Sandostatin** will be approved based upon the following criterion:

(1) Patient does not show evidence of progressive disease while on Sandostatin therapy

Authorization will be issued for 12 months.

F. Malignant Bowel Obstruction

1. **Initial Authorization**

a. **Sandostatin** will be approved based on **both** of the following criterion:

(1) Diagnosis of malignant bowel obstruction

-AND-

(2) Gut function cannot be maintained

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Sandostatin** will be approved based upon the following criterion:

(1) Documentation of positive clinical response to Sandostatin therapy

Authorization will be issued for 12 months.

G. Chemotherapy- and/or Radiation-Induced Diarrhea

1. **Initial Authorization**

a. **Sandostatin** will be approved based on **both** of the following criterion:

(1) Diagnosis of diarrhea due to concurrent cancer chemotherapy and/or radiation

-AND-

(2) **One** of the following:

(a) Presence of Grade 3 or 4 severe diarrhea

-OR-

(b) Patients in palliative or end of life care

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Sandostatin** will be approved based on the following criterion:

(1) Documentation of positive clinical response to Sandostatin therapy

Authorization will be issued for 12 months.

H. HIV/AIDS-Related Diarrhea

1. **Initial Authorization**

a. **Sandostatin** will be approved based on the following criterion:

(1) Diagnosis of HIV/AIDS-related diarrhea

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Sandostatin** will be approved based on the following criterion:

(1) Documentation of positive clinical response to Sandostatin therapy

Authorization will be issued for 12 months.

I. Bleeding Gastroesophageal Varices

1. **Initial Authorization**

a. **Sandostatin** will be approved based on the following criterion:

(1) Diagnosis of bleeding gastroesophageal varices associated with liver disease

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Sandostatin** will be approved based upon the following criterion:

(1) Documentation of positive clinical response to Sandostatin therapy

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

4. References:

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Program	Prior Authorization/Notification – Sandostatin (octreotide acetate)
Change Control	
7/2013	Clarified information presented in Table 1
11/2013	Removed detailed criteria for chemotherapy- and/or radiation-induced diarrhea and HIV/AIDS-related diarrhea. Revised reauthorization criteria to standard language throughout. Updated references.
9/2014	Administrative change – Tried/Failed exemption for State of New Jersey removed.
11/2014	Annual review with no changes to coverage. Updated references.
11/2015	Annual review. Updated background section. Updated to align with Indication Section of FDA label. Added age criteria for those less than 19 years of age with an oncology indication. Increased authorization and reauthorization period from 6 months to 12 months. Edited reauthorization wording for oncology indication. References updated.
9/2016	Annual review. Changed Member to Patient. Revised criteria for meningioma and neuroendocrine tumor.
9/2017	Annual review. Updated criteria for meningioma and neuroendocrine tumors. Updated references.
9/2018	Annual review. Revised coverage criteria based on NCCN guidelines. Updated references.
9/2019	Annual review. Revised coverage criteria based on NCCN guidelines. Updated background and references.
9/2020	Annual review. Revised coverage for meningioma based on NCCN guidelines. Updated references.
10/2021	Annual review. Revised coverage criteria for thymoma based on NCCN guidelines. Updated references.
1/2022	Revised coverage criteria for thymoma to include postoperative treatment for thymic carcinoma in accordance with NCCN guidelines.
1/2023	Annual review. Removed thymic carcinoma after R1/R2 resection from thymoma criteria based on NCCN guidelines. Added state mandate and updated references.
1/2024	Annual review with no changes to coverage criteria. Updated background and references.