UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

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<tr>
<th>Program Number</th>
<th>2016 P 1091-5</th>
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<tr>
<td>Program</td>
<td>Prior Authorization/Notification</td>
</tr>
<tr>
<td>Medication</td>
<td>Sandostatin® (octreotide acetate)</td>
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<td></td>
<td>Note: Only the subcutaneous formulation of octreotide requires notification. Sandostatin LAR is covered under the medical benefit and therefore addressed in the Sandostatin / Sandostatin LAR drug policy.</td>
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<tr>
<td>Effective Date</td>
<td>12/1/2016</td>
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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 VIP-secreting tumors.¹,²

The NCCN (National Comprehensive Cancer Network) recommends the use of octreotide acetate for the treatment of meningiomas. The NCCN also recommends octreotide acetate for the treatment of several types of neuroendocrine tumors including carcinoid tumors, neuroendocrine tumors of the pancreas, neuroendocrine tumors of the lung, adrenal gland, hormone-secreting poorly differentiated (high grade) / large or small cell neuroendocrine tumors, and thymic carcinomas. The NCCN Palliative Care Guidelines recommend octreotide for the treatment of malignant bowel obstruction.³

Clinical evidence supports the use of octreotide acetate for the treatment of chemotherapy and/or radiation-induced diarrhea,³-⁷ for refractory HIV/AIDS-related diarrhea that does not respond to first-line anti-diarrheal therapy,⁸-¹⁶ and as an adjunct to endoscopic therapy for bleeding gastroesophageal varices associated with liver disease.¹⁷-²²

**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. **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: 27-28
               
               i. Surgery
               
               ii. Radiotherapy
               
               iii. Dopamine agonist (e.g., bromocriptine, cabergoline) therapy
            
            -OR-
            
            (b) Not a candidate for **any** of the following: 27-28
               
               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.

B. **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.
C. Meningioma [off-label]

1. Initial Authorization
   a. Sandostatin will be approved based on all of the following criteria:
      
      (1) Diagnosis of meningioma

      -AND-

      (2) One of the following:

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

      -AND-

      (3) 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 Tumors [some off-label]²

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, thymus, adrenal glands, and vasoactive intestinal polypeptidomas (VIPomas)]
      (2) Hormone-secreting poorly differentiated (high grade) / large or small cell neuroendocrine tumor

      Authorization will be issued for 12 months.

2. Reauthorization

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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.**

E. **Thymoma or Thymic Carcinoma [off-label]**

1. **Initial Authorization**

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

      (1) Diagnosis of thymoma or thymic carcinoma

      **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 [off-label]**

1. **Initial Authorization**

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

      (1) Diagnosis of malignant bowel obstruction

      **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 [off-label]**

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

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

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 [off-label]

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 [off-label]

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.

3. **Additional Clinical Rules:** None.

4. **References:**


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<tr>
<th>Program</th>
<th>Prior Authorization/Notification - Sandostatin (octreotide acetate)</th>
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<tr>
<td></td>
<td><strong>Change Control</strong></td>
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<tr>
<td>7/2013</td>
<td>Clarified information presented in Table 1</td>
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<tr>
<td>11/2013</td>
<td>Removed detailed criteria for chemotherapy- and/or radiation-induced diarrhea and HIV/AIDS-related diarrhea. Revised reauthorization criteria to standard language throughout. Updated references.</td>
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<tr>
<td>11/2014</td>
<td>Annual review with no changes to coverage. Updated references.</td>
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<tr>
<td>11/2015</td>
<td>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.</td>
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<tr>
<td>9/2016</td>
<td>Annual review. Changed Member to Patient. Revised criteria for meningioma and neuroendocrine tumor.</td>
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