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.\(^17-22\)

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. **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.

C. 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

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. 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
E. **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.**

F. **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.**

G. **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.**

H. **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. **References:**


<table>
<thead>
<tr>
<th>Program</th>
<th>Prior Authorization - Sandostatin® (octreotide acetate)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Change Control</td>
<td></td>
</tr>
<tr>
<td>Date</td>
<td>Change</td>
</tr>
<tr>
<td>12/2012</td>
<td>New clinical policy</td>
</tr>
<tr>
<td>3/2015</td>
<td>Template updated</td>
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<tr>
<td></td>
<td>For acromegaly, removed radiotherapy and dopamine agonists as treatments that patients must not be a candidate for before approval.</td>
</tr>
<tr>
<td></td>
<td>Changed Chemotherapy Induced Diarrhea criteria section to now include radiation induced diarrhea.</td>
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<tr>
<td></td>
<td>Removed tincture of opium as an example of a standard therapy for diarrhea.</td>
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<tr>
<td></td>
<td>Added new section for off-label use of sandostatin for the treatment of carcinoid tumor based on NCCN recommendation.</td>
</tr>
<tr>
<td></td>
<td>Background and references updated.</td>
</tr>
<tr>
<td>9/2016</td>
<td>Updated clinical criteria to align with E&amp;I, including removing Sandostatin LAR from policy. Updated policy template.</td>
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