



Policy Type: PA/SP

Pharmacy Coverage Policy: EOCCO142

### Description

Octreotide acetate (Sandostatin) works through suppressing LH response to GnRH, decreasing splanchnic blood flow, and inhibiting the release of serotonin, gastrin, vasoactive intestinal peptide, secretin, motilin, and pancreatic polypeptide.

### Length of Authorization

- Initial: Six months
- Renewal: 12 months

### Quantity Limits

Product Name	Dosage Form	Indication	Quantity Limit
octreotide acetate (generic, Sandostatin)	50 mcg/mL ampule	Acromegaly; Metastatic carcinoid tumor; Vasoactive intestinal peptide tumor (VIPoma)	90 ampules/30 days
	100 mcg/mL ampule		
	500 mcg/mL ampule		
Provider Administered Agents*			
octreotide acetate (Sandostatin LAR)	10 mg vial	Acromegaly; Metastatic carcinoid tumor; Vasoactive intestinal peptide tumor (VIPoma)	N/A
	20 mg vial		
	30 mg vial		

\*Medical drug that requires administration by a healthcare professional and is not available for self-administration by the member, considered one of the excluded classes under the prescription benefit.

### Initial Evaluation

- I. **Octreotide acetate (Sandostatin) and generic octreotide acetate** may be considered medically necessary when the following criteria below are met:
  - A. Member is 18 years of age or older; **AND**
  - B. If requesting brand octreotide acetate (Sandostatin): Treatment with generic octreotide has been ineffective, not tolerated, or is contraindicated; **AND**
  - C. A diagnosis of one of the following:
    1. **Acromegaly; AND**
      - i. Member has had inadequate response to, or cannot be treated with: surgical resection, pituitary irradiation, and bromocriptine mesylate at a maximally tolerated dose; **OR**
    2. **Metastatic carcinoid tumor; AND**
      - i. Use is intended for the symptomatic management of severe diarrhea and/or flushing episodes; **OR**
    3. **Vasoactive intestinal peptide tumors (VIPomas)** [pancreatic neuroendocrine (islet cell) tumor, insulinoma, glucagonoma, somatostatinoma, and gastrinoma]; **AND**

- i. Use is intended for the symptomatic management of profuse watery diarrhea
- II. Octreotide (Sandostatin, Sandostatin LAR) is considered investigational when used for all other conditions.

**Renewal Evaluation**

- I. Disease response with improvement in patient’s symptoms including reduction in symptomatic episodes (such as diarrhea, rapid gastric dumping, flushing), and/or stabilization of glucose levels, and/or decrease in size of tumor or tumor spread; **OR**
- II. For **acromegaly** ONLY:
  - A. Disease response as indicated by an improvement in signs and symptoms compared to baseline; **AND**
    - 1. Age-adjusted normalization of serum IGF-1; **OR**
    - 2. Reduction of growth hormone (GH) by random testing to < 1.0 mcg/L

**References**

- 1. Sandostatin [package insert]. East Hanover, NJ; Novartis Pharmaceuticals Corporation; April 2019.
- 2. Melmed, S. Treatment of acromegaly. In; UpToDate. Martin, KA (Ed), UpToDate, Waltham, MA, 2019

**Policy Implementation/Update:**

Date Created	October 2016
Date Effective	October 2016
Last Updated	October 2016
Last Reviewed	10/2017; 12/2019

Action and Summary of Changes	Date
Transitioned to policy format and updated the following: <ul style="list-style-type: none"> <li>• Added age requirement of 18 years or older</li> <li>• For octreotide (Sandostatin), added requirement for inadequate response to <u>generic</u> octreotide, unless not tolerated or contraindicated</li> <li>• Removed octreotide (Sandostatin LAR) from the policy as it is excluded from coverage under the pharmacy benefit</li> </ul>	12/2019
Criteria created	10/2016