

# Specialty Guideline Management

## octreotide products

### Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

| Brand Name            | Generic Name                                 |
|-----------------------|--|
| Sandostatin           | octreotide acetate injection                 |
| Bynfezia Pen          | octreotide acetate injection                 |
| Mycapssa              | octreotide delayed-release capsule           |
| Sandostatin LAR Depot | octreotide acetate for injectable suspension |

### Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

#### FDA-approved Indications<sup>1-3,37,38,40</sup>

- Sandostatin/Bynfezia Pen/ octreotide acetate injection:
  - Indicated to reduce blood levels of growth hormone (GH) and insulin growth factor-1 (IGF-1; 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.
  - 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.
  - Indicated for the treatment of the profuse watery diarrhea associated with vasoactive intestinal peptide (VIP)-secreting tumors.

- Sandostatin LAR/octreotide acetate for injectable suspension: Sandostatin LAR Depot and octreotide acetate for injectable suspension are indicated in patients who have responded to and tolerated Sandostatin Injection/octreotide acetate injection for:
  - Long-term maintenance therapy in acromegalic patients who have had an inadequate response to surgery and/or radiotherapy, or for whom surgery and/or radiotherapy is not an option. The goal of treatment in acromegaly is to reduce GH and IGF-1 levels to normal.
  - Long-term treatment of the severe diarrhea and flushing episodes associated with metastatic carcinoid tumors.
  - Long-term treatment of the profuse watery diarrhea associated with vasoactive intestinal peptide (VIP)-secreting tumors.

#### **Limitations of Use:**

In patients with carcinoid syndrome and VIPomas, the effect of Sandostatin Injection and Sandostatin LAR Depot on tumor size, rate of growth and development of metastases, has not been determined.

- Mycapssa is indicated for long-term maintenance treatment in acromegaly patients who have responded to and tolerated treatment with octreotide or lanreotide.

## Compendial Uses (applies to injectable products)

- Neuroendocrine tumors (NETs):<sup>4,39</sup>
  - Tumors of the gastrointestinal (GI) tract, lung, and thymus (carcinoid tumors)
  - Tumors of the pancreas (islet cell tumors)
  - Gastroenteropancreatic neuroendocrine tumors (GEP-NETs)
- Pheochromocytoma and paraganglioma<sup>4</sup>
- Thymomas and thymic carcinomas<sup>4,34</sup>
- Congenital hyperinsulinism (CHI)/persistent hyperinsulinemic hypoglycemia of infancy (PHHI)(octreotide and Sandostatin only)
- Acquired immune deficiency syndrome (AIDS)-associated diarrhea<sup>12,13,31</sup>
- Inoperable bowel obstruction<sup>14-16,32</sup>
- Cancer-related diarrhea<sup>11</sup>
- Enterocutaneous fistula<sup>17-19,26</sup>
- Gastroesophageal varices<sup>20-25</sup>
- Pancreatic fistulas<sup>27-29,35,36</sup>
- Pituitary adenoma<sup>9,30</sup>
- Short bowel syndrome<sup>12,31,33</sup>
- Zollinger-Ellison syndrome<sup>7</sup>
- Meningiomas<sup>4</sup>

All other indications are considered experimental/investigational and not medically necessary.

# Documentation

Submission of the following information is necessary to initiate the prior authorization review:

- For acromegaly:
  - For initial approval: Laboratory report indicating high pretreatment insulin-like growth factor-1 (IGF-1) level and chart notes indicating an inadequate or partial response to surgery or radiotherapy or a clinical reason for not having surgery or radiotherapy.
  - For continuation: Laboratory report indicating normal current IGF-1 levels or chart notes indicating that the member's IGF-1 level has decreased or normalized since initiation of therapy.
- Cancer-related diarrhea: Chart notes indicating grade 3 or 4 diarrhea.

## Coverage Criteria

### Acromegaly<sup>1-3,5,6,37,38,40</sup>

Authorization of 12 months may be granted for the treatment of acromegaly when all of the following criteria are met:

- Member has a high pretreatment IGF-1 level for age and/or gender based on the laboratory reference range.
- Member had an inadequate or partial response to surgery or radiotherapy OR there is a clinical reason why the member has not had surgery or radiotherapy.
- For Mycapssa requests, member has previously responded to and tolerated treatment with octreotide or lanreotide.

### Neuroendocrine Tumors (NETs) (injectable products only)<sup>1-4,7,8,37,39,40</sup>

- Authorization of 12 months may be granted for treatment of NETs of the gastrointestinal (GI) tract, lung, and thymus (carcinoid tumors).
- Authorization of 12 months may be granted for treatment of NETs of the pancreas (islet cell tumors), including gastrinomas, glucagonomas, and insulinomas.
- Authorization of 12 months may be granted for treatment of gastroenteropancreatic neuroendocrine tumors (GEP-NETs).

### Carcinoid Syndrome (injectable products only)<sup>1-4,7,37,40</sup>

Authorization of 12 months may be granted for treatment of carcinoid syndrome.

## **Vasoactive Intestinal Peptide Tumors (VIPomas) (injectable products only)<sup>1-4,7,37,40</sup>**

Authorization of 12 months may be granted for management of symptoms related to hormone hypersecretion of VIPomas.

## **Pheochromocytoma and Paraganglioma (injectable products only)<sup>4</sup>**

Authorization of 12 months may be granted for treatment of pheochromocytoma and paraganglioma.

## **Thymomas and Thymic Carcinomas (injectable products only)<sup>4,10,34</sup>**

Authorization of 12 months may be granted for treatment of thymomas and thymic carcinomas.

## **Congenital Hyperinsulinism (CHI)/Persistent Hyperinsulinemic Hypoglycemia of Infancy (octreotide and Sandostatin only)**

Authorization of 6 months may be granted for treatment of CHI and persistent hyperinsulinemic hypoglycemia in an infant.

## **AIDS-Associated Diarrhea (injectable products only)<sup>13</sup>**

Authorization of 12 months may be granted for treatment of AIDS-associated severe secretory diarrhea when anti-microbial (e.g., ciprofloxacin or metronidazole) or anti-motility agents (e.g., loperamide or diphenoxylate and atropine) have become ineffective.

## **Inoperable Bowel Obstruction in Cancer (injectable products only)<sup>11,14-16,32</sup>**

Authorization of 12 months may be granted for management of GI symptoms (e.g., nausea, pain, vomiting) of inoperable bowel obstruction in members with cancer.

## **Cancer-Related Diarrhea (injectable products only)<sup>11</sup>**

Authorization of 12 months may be granted for treatment of cancer-related diarrhea when the member has grade 3 or greater diarrhea according to National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE).

## **Enterocutaneous Fistula (injectable products only)<sup>17-19,26</sup>**

Authorization of 12 months may be granted for management of volume depletion from enterocutaneous fistula.

|                     |
|---------------------|
| Reference number(s) |
| 1734-A              |

## Gastroesophageal Varices (injectable products only)<sup>20-25</sup>

Authorization of 6 months may be granted for treatment of acute bleeding of gastroesophageal varices associated with cirrhosis.

## Pancreatic Fistulas (injectable products only)<sup>27-29,35,36</sup>

Authorization of 6 months may be granted for prevention and treatment of pancreatic fistulas following pancreatic surgery.

## Pituitary Adenoma (injectable products only)<sup>9,30</sup>

Authorization of 12 months may be granted for treatment of pituitary adenoma.

## Short Bowel Syndrome (injectable products only)<sup>12,31,33</sup>

Authorization of 12 months may be granted for treatment of short bowel syndrome when the daily intravenous fluid requirement is greater than 3 liters.

## Zollinger-Ellison Syndrome (injectable products only)<sup>7</sup>

Authorization of 12 months may be granted for treatment of Zollinger-Ellison syndrome.

## Meningiomas (injectable products only)<sup>4</sup>

Authorization of 12 months may be granted for treatment of meningiomas when used in combination with everolimus for surgically inaccessible recurrent or progressive disease.

# Continuation of Therapy

## Acromegaly

Authorization of 12 months may be granted for continuation of therapy for acromegaly when the member's IGF-1 level has decreased or normalized since initiation of therapy.

## NETs, Carcinoid Syndrome, Vipomas, Pheochromocytoma/Paraganglioma, Thymomas/Thymic Carcinomas, AIDS-Associated Diarrhea, Bowel Obstruction, Cancer-Related Diarrhea, Zollinger-Ellison Syndrome, and Meningiomas (injectable products only)

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization when the member is experiencing clinical benefit as evidenced by improvement or stabilization in clinical signs and symptoms since initiation of therapy.

## All Other Indications

All members (including new members) requesting authorization for continuation of therapy must meet all requirements in the coverage criteria.

## References

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