

## SPECIALTY GUIDELINE MANAGEMENT

### SANDOSTATIN INJECTION (octreotide) SANDOSTATIN LAR DEPOT INJECTION (octreotide) octreotide acetate injection

#### POLICY

#### I. 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.

##### A. FDA-Approved Indications

1. Octreotide acetate/Sandostatin:
  - a. Acromegaly: Sandostatin is indicated to reduce blood levels of growth hormone and 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.
  - b. Carcinoid Tumors: Sandostatin is 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.
  - c. Vasoactive Intestinal Peptide Tumors (VIPomas): Sandostatin is indicated for the treatment of the profuse watery diarrhea associated with VIP-secreting tumors.
2. Sandostatin LAR: Sandostatin LAR depot is indicated in patients in whom initial treatment with Sandostatin injection has been shown to be effective and tolerated.
  - a. Acromegaly: Sandostatin LAR depot is indicated 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
  - b. Carcinoid Tumors: Sandostatin LAR depot is indicated for long-term treatment of the severe diarrhea and flushing episodes associated with metastatic carcinoid tumors
  - c. Vasoactive Intestinal Peptide Tumors (VIPomas): Sandostatin LAR depot is indicated for long-term treatment of the profuse watery diarrhea associated with VIP-secreting tumors

##### B. Compendial Uses

1. Neuroendocrine tumors (NETs):
  - a. Adrenal gland tumors
  - b. Tumors of the gastrointestinal tract (carcinoid tumors)
  - c. Tumor of the thymus (carcinoid tumors)
  - d. Tumors of the lung (carcinoid tumors)
  - e. Tumors of the pancreas
  - f. Poorly differentiated (high-grade)/large or small cell tumors (excluding lung)
2. Meningiomas
3. Thymomas and Thymic carcinomas
4. Congenital hyperinsulinism (CHI)/persistent hyperinsulinemic hypoglycemia of infancy (PHHI) (octreotide and Sandostatin only)

All other indications are considered experimental/investigational and are not a covered benefit.

**II. REQUIRED DOCUMENTATION**

The following information is necessary to initiate the prior authorization review: Insulin-like growth factor 1 (IGF-1) level (for acromegaly only).

**III. CRITERIA FOR INITIAL APPROVAL****A. Acromegaly**

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

1. Member has clinical evidence of acromegaly (see Appendix A)
2. Member has a high pre-treatment IGF-1 level for age and/or gender (see Appendix B)
3. Member had an inadequate or partial response to surgery or radiotherapy or there is a clinical reason why the member has not had surgery (see Appendix C) or radiotherapy

**B. Neuroendocrine tumors (NETs)**

1. Tumors of the gastrointestinal tract (carcinoid tumor)

Authorization of 12 months may be granted for treatment of NETs of the GI tract when either of the following criteria is met:

- a. Member has distant metastases or unresectable disease
- b. The primary site of the tumor is gastric, the tumor is 2 centimeters or less in size, and member has hypersecretion of gastrin (eg, Zollinger-Ellison syndrome)

2. Tumors of the thymus (carcinoid tumor)

Authorization of 12 months may be granted for treatment of NETs of the thymus when the member has distant metastases or unresectable disease.

3. Tumors of the lung (carcinoid tumor)

Authorization of 12 months may be granted for treatment of NETs of the lung when the member has advanced disease with multiple lung nodules, distant metastases or unresectable disease.

4. Tumors of the pancreas

Authorization of 12 months may be granted for treatment of NETs of the pancreas when both of the following criteria are met [a and b]:

- a. The tumor type is one of the following:
  - i. ACTH-secreting pancreatic NET
  - ii. Cholecystokininoma (CCKoma)
  - iii. Gastrinoma
  - iv. Glucagonoma
  - v. Insulinoma
  - vi. Non-functioning pancreatic tumor
  - vii. Pancreatic polypeptidoma (PPoma)
  - viii. Parathyroid hormone-related protein (PTHrp)-secreting pancreatic NET
  - ix. Somatostatinoma
  - x. VIPoma
- b. Somatostatin receptor status is positive or member experiences symptoms of hormone hypersecretion (eg, hypoglycemia, peptic ulcers, diarrhea, flushing)

5. Tumors of the adrenal gland

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

- a. Member has a diagnosis of non-adrenocorticotrophic hormone (non-ACTH) dependent Cushing's syndrome
- b. The cortisol production is symmetric
- c. Tumors are less than 4 centimeters

- d. Somatostatin receptor status is positive
- 6. Poorly differentiated (high-grade)/large or small cell tumors (excluding lung)  
Authorization of 12 months may be granted for treatment of poorly differentiated (high-grade)/large or small cell NETs when all of the following criteria are met:
  - a. Member has metastatic or unresectable disease
  - b. Somatostatin receptor status is positive
  - c. Member experiences hormone-related symptoms

**C. Meningiomas**

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

- 1. Disease is recurrent or progressive
- 2. Disease is unresectable
- 3. Disease is refractory to radiation therapy
- 4. Somatostatin receptor status is positive

**D. Thymomas and thymic carcinomas**

Authorization of 12 months may be granted for treatment of locally advanced, advanced, or recurrent thymomas and thymic carcinomas when the disease has progressed on at least one prior chemotherapy regimen.

**E. 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.

**IV. CONTINUATION OF THERAPY**

**A. Acromegaly**

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

- 1. Member has clinical evidence of acromegaly (see Appendix A)
- 2. Member's IGF-1 level has decreased or normalized since initiation of therapy

**B. All other indications**

Members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

**V. DOSAGE AND ADMINISTRATION**

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines. The following dosing limits apply:

**A. Octreotide/Sandostatin:**

- 1. Acromegaly: 1500mcg per day
- 2. NETs of the GI tract, thymus, and lung (carcinoid tumors): 1500mcg per day
- 3. VIPomas: 750mcg per day

**B. Sandostatin LAR:**

- 1. Acromegaly: 40mg per 28 days
- 2. NETs of the GI tract, thymus, and lung (carcinoid tumors): 30mg per 28 days
- 3. VIPomas: 30mg per 28 days

**VI. APPENDICES**

- A. Appendix A: Clinical evidence of acromegaly (not all-inclusive)
  - 1. Frontal bossing
  - 2. Coarse facial features
  - 3. Thick lips
  - 4. Protruding jaw with widely spaced teeth
  - 5. Large hands and feet
  
- B. Appendix B: Normal IGF-1 levels for age and gender  
The normal range varies based on the laboratory performing the analysis. One must obtain lab-specific values to make this determination.
  
- C. Appendix C: Clinical reasons for not having surgery
  - 1. The member has medically unstable conditions (poor surgical candidate)
  - 2. The member is at high risk for complications of anesthesia because of airway difficulties
  - 3. The member has major systemic manifestations of acromegaly including cardiomyopathy, severe hypertension and uncontrolled diabetes
  - 4. The member refuses surgery or prefers the medical option over surgery
  - 5. There is a lack of an available skilled surgeon
  - 6. Tumor cannot be localized

**VII. REFERENCES**

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