SPECIALTY GUIDELINE MANAGEMENT

SANDOSTATIN (octreotide acetate injection)
SANDOSTATIN LAR DEPOT (octreotide acetate for injectable suspension)

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. 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. 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. Indicated for the treatment of the profuse watery diarrhea associated with vasoactive intestinal peptide (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. 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. Indicated for long-term treatment of the severe diarrhea and flushing episodes associated with metastatic carcinoid tumors.
      c. Indicated for long-term treatment of the profuse watery diarrhea associated with vasoactive intestinal peptide (VIP)-secreting tumors.

B. Compendial Uses
   1. Neuroendocrine tumors (NETs):
      a. Adrenal gland tumors
      b. Tumors of the gastrointestinal (GI) tract, lung, and thymus (carcinoid tumors)
      c. Tumors of the pancreas
   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. CRITERIA FOR INITIAL APPROVAL

A. Acromegaly
   Authorization of 24 months may be granted for the treatment of acromegaly when all of the following criteria are met:
1. Member has a high pretreatment insulin-like growth factor-1 (IGF-1) level for age and/or gender based on the laboratory reference range.
2. 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

B. Neuroendocrine tumors (NETs)/carcinoid syndrome
1. Tumors of the gastrointestinal (GI) tract (carcinoid tumor)
   Authorization of 24 months may be granted for treatment of metastatic or unresectable NETs of the GI tract.
2. Tumors of the thymus (carcinoid tumor)
   Authorization of 24 months may be granted for treatment of metastatic or unresectable NETs of the thymus.
3. Tumors of the lung (carcinoid tumor)
   Authorization of 24 months may be granted for treatment of metastatic or unresectable NETs of the lung.
4. Tumors of the pancreas
   Authorization of 24 months may be granted for treatment of NETs of the pancreas.
5. Tumors of the adrenal gland
   Authorization of 24 months may be granted for treatment of NETs of the adrenal gland.

C. Meningiomas
   Authorization of 24 months may be granted to members for treatment of unresectable meningioma.

D. Thymomas and thymic carcinomas
   Authorization of 24 months may be granted for treatment of thymomas and thymic carcinomas.

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.

III. CONTINUATION OF THERAPY

A. Acromegaly
   Authorization of 24 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.

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

IV. REFERENCES


