Reference number
1734-A

SPECIALTY GUIDELINE MANAGEMENT

SANDOSTATIN (octreotide acetate injection)
BYNFEZIA PEN (octreotide acetate injection)
MYCAPSSA (octreotide delayed-release capsule)
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/Bynfezia Pen:
      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.

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

B. Compendial Uses *(applies to injectable products)*
   1. Neuroendocrine tumors (NETs):
      a. Tumors of the gastrointestinal (GI) tract, lung, and thymus (carcinoid tumors)
      b. Tumors of the pancreas
   2. Pheochromocytoma and paraganglioma
   3. Thymomas and thymic carcinomas
   4. Congenital hyperinsulinism (CHI)/persistent hyperinsulinemic hypoglycemia of infancy (PHHI)[5] (octreotide and Sandostatin only)
   5. Acquired immune deficiency syndrome (AIDS)-associated diarrhea
   6. Inoperable bowel obstruction
   7. Chemotherapy- and radiation-induced diarrhea

8. Enterocutaneous fistula
9. Gastroesophageal varices
10. Islet cell tumors
11. Pancreatic fistulas
12. Pituitary adenoma
13. Short bowel syndrome
14. Zollinger-Ellison syndrome

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

II. DOCUMENTATION

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

A. For acromegaly:
   1. 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.
   2. 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

B. Chemotherapy- and radiation-induced diarrhea: Chart notes indicating grade 3 or 4 diarrhea with current chemotherapy or radiation.

III. CRITERIA FOR INITIAL APPROVAL

A. Acromegaly

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

1. Member has a high pretreatment 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.
3. For Mycapssa requests, member has previously responded to and tolerated treatment with octreotide or lanreotide.

B. Neuroendocrine tumors (NETs) (injectable products only)

1. Tumors of the gastrointestinal (GI) tract (carcinoid tumor)
   Authorization of 12 months may be granted for treatment of locoregional advanced or metastatic NETs of the GI tract or unresected primary gastrinoma.
2. Tumors of the thymus (carcinoid tumor)
   Authorization of 12 months may be granted for treatment of unresectable or metastatic NETs of the thymus.
3. Tumors of the lung (carcinoid tumor)
   Authorization of 12 months may be granted for treatment of unresectable or metastatic NETs of the lung.
4. Tumors of the pancreas
   Authorization of 12 months may be granted for treatment of NETs of the pancreas.

C. Carcinoid syndrome (injectable products only)

Authorization of 12 months may be granted for treatment of carcinoid syndrome when it is used in any of the following clinical settings:

1. As a single agent
2. In combination with telotristat for persistent diarrhea due to poorly controlled carcinoid syndrome
3. In combination with other systemic therapy options for persistent symptoms such as flushing or diarrhea, or for progressive disease

D. Vasoactive intestinal peptide tumors (VIPomas) (injectable products only)
Authorization of 12 months may be granted for management of symptoms related to hormone hypersecretion of VIPomas.

E. Pheochromocytoma and paraganglioma (injectable products only)
Authorization of 12 months may be granted for treatment of locally unresectable or metastatic pheochromocytoma and paraganglioma.

F. Thymomas and thymic carcinomas (injectable products only)
Authorization of 12 months may be granted for treatment of thymomas and thymic carcinomas when the requested drug is used as a second-line therapy with or without prednisone in any of the following clinical settings:

1. Unresectable disease following first-line chemotherapy for potentially resectable locally advanced disease, solitary metastasis, or ipsilateral pleural metastasis
2. Extrathoracic metastatic disease

G. 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.

H. AIDS-associated diarrhea (injectable products only)
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.

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

J. Chemotherapy- and radiation-induced diarrhea (injectable products only)
Authorization of 12 months may be granted for treatment of chemotherapy- or radiation-induced diarrhea when all of the following criteria are met:

1. Member is receiving treatment with chemotherapy or radiation
2. Member has grade 3 or greater diarrhea according to National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE).

K. Enterocutaneous fistula (injectable products only)
Authorization of 12 months may be granted for management of volume depletion from enterocutaneous fistula.

L. Gastroesophageal varices (injectable products only)
Authorization of 6 months may be granted for treatment of acute bleeding of gastroesophageal varices associated with cirrhosis.

M. Islet cell tumors (injectable products only)

Authorization of 12 months may be granted for stabilization of blood glucose levels in patients with functioning islet cell tumors (e.g., insulinomas or glucagonomas).

N. Pancreatic fistulas (injectable products only)
Authorization of 6 months may be granted for prevention and treatment of pancreatic fistulas following pancreatic surgery.

O. Pituitary adenoma (injectable products only)
Authorization of 12 months may be granted for treatment of pituitary adenoma.

P. Short bowel syndrome (injectable products only)
Authorization of 12 months may be grated for treatment of short bowel syndrome when the daily intravenous fluid requirement is greater than 3 liters.

Q. Zollinger-Ellison syndrome (injectable products only)
Authorization of 12 months may be grated for treatment of Zollinger-Ellison syndrome.

IV. CONTINUATION OF THERAPY

A. 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.

B. Carcinoid syndrome, VIPomas, AIDS-associated diarrhea, bowel obstruction, chemotherapy/radiation-induced diarrhea, islet cell tumors, and Zollinger-Ellison syndrome (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.

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

V. REFERENCES

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