Clinical Policy: Octreotide Acetate (Sandostatin Injection, Sandostatin LAR Depot)

Reference Number: PA.CP.PHAR.40
Effective Date: 01/18
Last Review Date:

Coding Implications
Revision Log

Description
It is the policy of Pennsylvania Health and Wellness® clinical policy for the following octreotide acetate formulations: 1) Sandostatin® Injection and its generic, "octreotide acetate injection" and 2) Sandostatin® LAR Depot.

Policy/Criteria
It is the policy of Pennsylvania Health and Wellness that Sandostatin Injection, its generic (octreotide acetate injection), and Sandostatin LAR Depot are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Acromegaly (must meet all):

1. Age ≥ 18 years or, if younger, epiphyseal growth plates have closed;
2. Diagnosis of acromegaly with inadequate response to (i.e., unable to achieve normalization of growth hormone (GH) or insulin growth factor 1 (IGF-I) levels or unable to adequately control tumor mass), or when treatment is not appropriate with either of the following:
   a. Surgical resection;
   b. Pituitary irradiation;
3. Request is for one of the following formulations:
   a. Octreotide acetate injection (subcutaneous or intravenous use):
      i. Upward dose titration does not exceed 1,500 mcg/day in divided doses;
   b. Sandostatin LAR Depot [intramuscular (IM) use]:
      i. Member has been adherent to octreotide acetate injection for at least two weeks with a reduction in GH or IGF-I levels or an increased control of tumor mass immediately prior to the request for Sandostatin LAR Depot;
      ii. The starting dose of Sandostatin LAR Depot does not exceed 20 mg IM at 4-week intervals for 3 months (after 3 months dosage may be adjusted based on GH/IGF-1 levels and symptoms not to exceed 40 mg every 4 weeks).

Approval duration: 3 months

B. Carcinoid tumors (neuroendocrine tumors of the gastrointestinal tract, lung, and thymus) (must meet all):

1. Age ≥ 18 years;
2. Diagnosis of severe diarrhea and flushing episodes associated with metastatic carcinoid tumors;
3. Request is for one or both of the following formulations (Octreotide acetate injection may be used alone or with Sandostatin LAR Depot for exacerbation of symptoms):
   a. Octreotide acetate injection (subcutaneous or intravenous use):
      i. Upward dose titration does not exceed 1500 mcg/day in divided doses;
   b. Sandostatin LAR Depot (IM use):

i. Member has been adherent to octreotide acetate injection for two weeks with reduction in number or severity of diarrhea or flushing episodes immediately prior to the request for Sandostatin LAR Depot;
ii. The starting dose of Sandostatin LAR Depot does not exceed 20 mg IM at 4-week intervals for 2 months with continued administration of octreotide acetate injection for up to 4 weeks (after 2 months, dosage of Sandostatin LAR Depot is adjusted based on symptoms not to exceed 30 mg every 4 weeks).

Approval duration: 3 months

C. Vasoactive intestinal peptide tumors (neuroendocrine tumors – pancreatic or extrapancreatic - that secrete vasoactive intestinal polypeptide) (must meet all):
1. Age ≥ 18 years;
2. Diagnosis of profuse watery diarrhea associated with vasoactive intestinal peptide secreting tumor;
3. Request is for one or both of the following formulations (Octreotide acetate injection may be used alone or with Sandostatin LAR Depot for exacerbation of symptoms):
   a. Octreotide acetate injection (subcutaneous or intravenous use):
      i. Upward dose titration does not exceed 750 mcg/day in divided doses;
   b. Sandostatin LAR Depot (IM use):
      i. Member has been adherent to octreotide acetate injection for two weeks with a reduction in diarrhea immediately prior to the request for Sandostatin LAR Depot;
      ii. The starting dose of Sandostatin LAR Depot does not exceed 20 mg IM at 4-week intervals for 2 months with continued administration of octreotide acetate solution for up to 4 weeks (after 2 months, dosage of Sandostatin LAR Depot is adjusted based on symptoms not to exceed 30 mg every 4 weeks).

Approval duration: 3 months

D. Other diagnoses/indications: Refer to CP.PHAR.57 - Global Biopharm Policy
1. The following NCCN recommended uses, meeting NCCN categories 1, 2a, or 2b, are approved per the CP.PHAR.57 Global Biopharm Policy:
   a. Meningioma (central nervous system cancer);
   b. The following neuroendocrine tumors with therapeutic goals not covered under sections B and C above:
      i. Adrenal gland tumor;
      ii. Gastrinoma;
      iii. Tumor of the GI tract, lung, thymus;
   c. Thymoma and thymic carcinoma.

II. Continued Approval

A. Acromegaly (must meet all)**:**

1. Currently receiving medication via It is the policy of Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies;
2. If has taken octreotide for ≥ 12 months, improvement in biochemical control (i.e., any decrease in random GH or age- and sex-adjusted IGF-1 serum concentrations since baseline*) or in tumor mass control.

**Any improvement short of full biochemical control may result in beneficial clinical outcomes; combination therapy may be necessary to achieve additional biochemical control.*

Approval duration: 12 months

B. Carcinoid tumors (neuroendocrine tumors of the gastrointestinal tract, lung, and thymus) (must meet all)**:**
1. Currently receiving medication via It is the policy of Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies;
2. Member continues to respond positively to therapy in terms of improved control of diarrhea or flushing episodes.

Approval duration: 12 months

C. Vasoactive intestinal peptide tumors (neuroendocrine tumors – pancreatic or extrapancreatic - that secrete vasoactive intestinal polypeptide) (must meet all)**:**
1. Currently receiving medication via It is the policy of Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies;
2. Member continues to respond positively to therapy in terms of improved control of diarrhea.

Approval duration: 12 months

D. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via It is the policy of Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies; or
2. Refer to CP.PHAR.57 - Global Biopharm Policy**.**

Background

Description/Mechanism of Action:

Octreotide is the acetate salt of a long-acting cyclic octapeptide with pharmacologic properties mimicking those of the natural hormone somatostatin. It is a more potent inhibitor of growth hormone, glucagon, and insulin than somatostatin. Like somatostatin, it also suppresses LH response to GnRH, decreases splanchnic blood flow, and inhibits release of serotonin, gastrin, vasoactive intestinal peptide, secretin, motilin, and pancreatic polypeptide.

GH excess occurring in growing children/adolescents before epiphyseal growth plate closure (known as pituitary gigantism) is not included in the present policy given unique etiologic and management considerations.

Formulations:
Intramuscular injection:
Sandostatin LAR Depot: 10 mg, 20 mg, 30 mg
Subcutaneous (deep/intrafat) or intravenous injection:
Sandostatin injection: 50 mcg/mL, 100 mcg/mL, 200 mcg/mL, 500 mcg/mL, 1000 mcg/mL
Octreotide acetate injection: 50 mcg/mL, 100 mcg/mL, 200 mcg/mL, 500 mcg/mL, 1000 mcg/mL

FDA Approved Indications:
Sandostatin injection (subcutaneous or intravenous use) and Sandostatin LAR Depot (intramuscular use) are somatostatin analogues with the following indications:

- Acromegaly
  - To reduce blood levels of growth hormone and IGF-I (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. The goal is to achieve normalization of growth hormone and IGF-I (somatomedin C) levels.
- Carcinoid Tumors
  - For symptomatic treatment of patients with metastatic carcinoid tumors where it suppresses or inhibits the severe diarrhea and flushing episodes associated with the disease.
- Vasoactive Intestinal Peptide Tumors (VIPomas)
  - For treatment of the profuse watery diarrhea associated with 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.

Appendices
Appendix A: Abbreviation Key
GH: growth hormone
GnRH: gonadotropin- releasing hormone
IGF-1: insulin growth factor 1 (somatomedin C)
IM: intramuscular
LH: luteinizing hormone
VIPomas: vasoactive intestinal peptide tumors

Coding Implications
Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J2353	Injection, octreotide, depot form for intramuscular injection, 1 mg
J2354	Injection, octreotide, nondepot form for subcutaneous or intravenous injection, 25 mcg

Reviews, Revisions, and Approvals	Date	Approval Date

References

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2. Sandostatin LAR Depot prescribing information. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2016. Available at http://www.pharma.us.novartis.com/product/pi/pdf/sandostatin_lar.pdf. Accessed March 16, 2017.
3. Melmed S, Colao A, Barkan A, et al. Guidelines for acromegaly management: an update. J Clin Endocrinol Metab. May 2009; 94(5): 1509-1517.
4. Neuroendodrine tumors (Version 1.2017). In: National Comprehensive Cancer Network Guidelines. Available at nccn.org. Accessed March 20, 2017.
5. Goldfinger SE. VIPoma: clinical manifestations, diagnosis, and management. In: UpToDate, Waltham, MA: Wolters Kluwer Health; 2017. Available at uptodate.com. Accessed March 30, 2016.
6. Octreotide acetate. In: National Comprehensive Cancer Network Compendium. Available at nccn.org. Accessed March 20, 2017.
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