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

Reference Number: PA.CP.PHAR.40
Effective Date: 01/18
Last Review Date: 07/18

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.

FDA Approved Indication(s)
Sandostatin Injection is indicated:

- To reduce blood levels of growth hormone (GH) and insulin-like growth factor (IGF-I (somatomedin C) in acromegaly patients who have had inadequate response or cannot be treated with surgical resection, pituitary irradiation, and bromocriptine mesylate at maximally tolerated doses;
- 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;
- For the treatment of the profuse watery diarrhea associated with vasoactive intestinal peptide (VIP)-secreting tumors (VIPomas).

Sandostatin LAR Depot is indicated:

- For treatment in patients who have responded to and tolerated Sandostatin Injection subcutaneous injection for:
  - Acromegaly;
  - Severe diarrhea/flushing episodes associated with metastatic carcinoid tumors;
  - Profuse watery diarrhea associated with VIP-secreting tumors.

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. Diagnosis of acromegaly;
2. Age ≥ 18 years or, if younger, epiphyseal growth plates have closed;
3. Inadequate response to surgical resection or pituitary irradiation (i.e., unable to achieve normalization of GH and/or IGF-I levels or unable to adequately control tumor mass), or member is not a candidate for such treatment;
4. Request is for one or both of the following formulations (a and b):
   a. Sandostatin Injection:
      i. Dose does not exceed 1,500 mcg/day in divided doses;
   b. Sandostatin LAR Depot (i and ii):

i. Dose does not exceed 40 mg every 4 weeks.
ii. Member has received Sandostatin Injection for at least two weeks with improvement in GH or IGF-I levels, or tumor mass control.

Approval duration: 6 months

B. Carcinoid tumors (neuroendocrine tumors of the gastrointestinal tract, lung, and thymus) (must meet all):
1. Diagnosis of diarrhea or flushing episodes associated with a metastatic carcinoid tumor;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Request is for one or both of the following formulations (a and b):
   a. Sandostatin Injection:
      i. Dose does not exceed 1500 mcg/day in divided doses;
   b. Sandostatin LAR Depot (i and ii):
      i. Dose does not to exceed 30 mg every 4 weeks;
      ii. Member has received Sandostatin Injection for at least two weeks with improvement in diarrhea or flushing episodes.

Approval duration: 6 months

C. Vasoactive intestinal peptide tumors (neuroendocrine tumors – pancreatic or extrapancreatic - that secrete vasoactive intestinal polypeptide) (must meet all):
1. Diagnosis of diarrhea associated with a VIPoma;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Request is for one or both of the following:
   a. Sandostatin injection:
      i. Dose does not exceed 750 mcg/day in divided doses;
   b. Sandostatin LAR Depot (i and ii):
      i. Dose does not exceed 30 mg every 4 weeks;
      ii. Member has received Sandostatin Injection for at least two weeks with improvement in diarrhea prior to request for Sandostatin LAR Depot.

Approval duration: 6 months

D. Meningioma (off-label) (must meet all):
1. Diagnosis of meningioma (central nervous system cancer);
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Treatment for surgically inaccessible recurrent or progressive meningiomas when radiation is not possible;
5. Dose for Sandostatin Injection and/or Sandostatin LAR Depot is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence).*

Approval duration: 6 months

II. Thymoma and Thymic Carcinoma (off-label) (must meet all):

1. Diagnosis of thymoma or thymic carcinoma;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Second-line therapy (first-line therapies include CAP [cisplatin, doxorubicin, cyclophosphamide], ADOC [cisplatin, doxorubicin, vincristine, cyclophosphamide], PE [cisplatin, etoposide], VIP [etoposide, ifosfamide, cisplatin], carboplatin/placlitaxel;
5. Dose for Sandostatin Injection and/or Sandostatin LAR Depot is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence).*

Approval duration: 6 months

III. Other diagnoses/indications: Refer to CP.PHAR.57 - Global Biopharm Policy
Refer to PA.CP.PMN.53

IV. Continued Approval

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

1. Currently receiving medication via Pennyslvania Health and Wellness benefit, or member has previously met initial approval criteria; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy (e.g., improvement in GH or IGF-1 serum concentrations, or in tumor mass control, since initiation of therapy);
3. If request is for a dose increase, request is for one or both of the following (a and b):
    a. Sandostatin Injection: New dose does not exceed 1,500 mcg/day in divided doses;
    b. Sandostatin LAR Depot: New dose does not exceed 40 mg every 4 weeks.

Approval duration: 6 months

1. B. Carcinoid tumors (neuroendocrine tumors of the gastrointestinal tract, lung, and thymus) (must meet all)**:**Currently receiving medication via Pennyslvania Health and Wellness benefit, or member has previously met initial approval criteria; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
5. If request is for a dose increase, request is for one or both of the following (a and b):
    a. Sandostatin Injection: New dose does not exceed 1500 mcg/day in divided doses;
    Sandostatin LAR Depot: New dose does not to exceed 30 mg every 4 weeks

Approval duration: 6 months

C. Vasoactive intestinal peptide tumors (neuroendocrine tumors – pancreatic or extrapancreatic - that secrete vasoactive intestinal polypeptide) (must meet all)**:**

1. Currently receiving medication via Pennyslvania Health and Wellness benefit, or member has previously met initial approval criteria; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2.
3. Member is responding positively to therapy;
4. If request is for a dose increase, request is for one or both of the following:
   a. Sandostatin injection: New dose does not exceed 750 mcg/day in divided doses;
   b. Sandostatin LAR Depot: New dose does not exceed 30 mg every 4 weeks;

Approval duration: 6 months

D. Meningioma (off-label) (must meet all):

1. Currently receiving medication via Pennyslvania Health and Wellness benefit, or member has previously met initial approval criteria; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;

1. Member is responding positively to therapy;
2. If request is for a dose increase, new dose for Sandostatin Injection and/or Sandostatin LAR Depot is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence).*

Approval duration: 6 months

E. **Thymoma and Thymic Carcinoma (off-label)** (must meet all):

1. Currently receiving medication via Pennyslvania Health and Wellness benefit, or member has previously met initial approval criteria; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;

2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose for Sandostatin Injection and/or Sandostatin LAR Depot is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence).*

Approval duration: 6 months

Approval duration: 6 months

A. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Pennyslvania Health and Wellness benefit, or member has previously met initial approval criteria; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to PA.CP.PMN.53

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

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
Specialist added for oncology indications. Requests for non-oncology off-label indications and any oncology off-label indications not outlined above are directed to PA.CP.PMN.53. Positive therapeutic response examples (diarrhea, flushing, disease progression, unacceptable toxicity) are removed as they are not amenable to objective measurement. References updated. Updated approval duration to 6 months.	02/18	

References

1. Sandostatin Prescribing Information. East Hanover, NJ: Novartis Pharmaceuticals Corporation; March 2012. Available at http://www.pharma.us.novartis.com/product/pi/pdf/sandostatin_inj.pdf. Accessed November 2017.
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 November 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 November 2017.
5. Central nervous system cancers (Version 1.2017). In: National Comprehensive Cancer Network Guidelines. Available at nccn.org. Accessed November 2017.
6. Thymomas and thymic carcinomas (Version 1.2017). In: National Comprehensive Cancer Network Guidelines. Available at nccn.org. Accessed November 2017.
7. Octreotide acetate. In: National Comprehensive Cancer Network Compendium. Available at nccn.org. Accessed November 2017.
8. Octreotide acetate (LAR). In: National Comprehensive Cancer Network Compendium. Available at nccn.org. Accessed November 2017.