## Prior Authorization Review Panel

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**CHC-MCO Policy Submission**

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

| | |
|---|---|
| **Plan: PA Health & Wellness** | **Submission Date: 02/01/2020** |
| **Policy Number: PA.CP.PHAR.40** | **Effective Date: 01/01/2018**<br>**Revision Date: 01/15/2020** |
| **Policy Name: Octreotide Acetate (Sandostatin, Sandostatin LAR Depot)** | |

**Type of Submission – Check all that apply:**

- ☐ **New Policy**
- ✓ **Revised Policy***
- ☐ **Annual Review - No Revisions**
- ☐ **Statewide PDL -** *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

**Please provide any changes or clarifying information for the policy below:**

1Q 2020 annual review: specialist added for acromegaly indication for alignment with other somatostatin analogs; references reviewed and updated.

| | |
|---|---|
| **Name of Authorized Individual (Please type or print):**<br><br>**Francis G. Grillo, MD** | **Signature of Authorized Individual:** |

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

Reference Number: PA.CP.PHAR.40
Effective Date: 01/18
Last Review Date: 01/15/2020

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 (SC/IV) is indicated:

- Acromegaly
  - 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;
- Carcinoid tumors*
  - 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
- Vasoactive intestinal peptide tumors* (VIPomas)
  - For the treatment of the profuse watery diarrhea associated with vasoactive intestinal peptide (VIP)-secreting tumors

Sandostatin LAR Depot (IM) is indicated for treatment in patients who have responded to and tolerated Sandostatin Injection subcutaneous injection for:

- Acromegaly
- Carcinoid tumors*
  - Severe diarrhea/flushing episodes associated with metastatic carcinoid tumors
- Vasoactive intestinal peptide tumors* (VIPomas)
  - Profuse watery diarrhea associated with VIP-secreting tumors

**Neuroendocrine tumors*

Limitation(s) 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.

## 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. Prescribed by or in consultation with an endocrinologist;
3. Age ≥ 18 years or, if younger, epiphyseal growth plates have closed;
4. 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;
5. Request is for one or both of the following formulations *(both products may be used together)* (a or b):
   a. Sandostatin Injection: 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 a carcinoid tumor *(most commonly arising in the lungs and bronchi, small intestine, appendix, rectum, or thymus)* and one of the following (a or b):
   a. Request is for carcinoid syndrome (i.e., presence of diarrhea or flushing symptoms indicative of hormonal hypersecretion);
   b. Request is for advanced disease, with or without carcinoid syndrome;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Request is for any of the following *(both products may be used together)* (a, b, or c):*
   a. Sandostatin Injection: Dose does not exceed 1500 mcg per day in divided doses;
   b. Sandostatin LAR Depot (i and ii):
      i. Dose does not to exceed 30 mg every 4 weeks;
      ii. If request is for symptom management only, member has received Sandostatin Injection for at least two weeks with improvement in diarrhea or flushing episodes;
   c. Dose for Sandostatin Injection or Sandostatin LAR Depot is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence).*

**Prescribed regimen must be FDA-approved or recommended by NCCN*

**Approval duration: 6 months**

**C. Vasoactive Intestinal Peptide Tumor and other Pancreatic Neuroendocrine Tumors** (must meet all):

1. Diagnosis of a pancreatic neuroendocrine tumor including but not limited to VIPoma, gastrinoma, insulinoma or glucagonoma, and one of the following (a, b, c, or d):
   a. Request is for management of symptoms indicative of hormonal hypersecretion (e.g., diarrhea);
   b. Request is for treatment of a gastrinoma with or without symptoms;

c. For other pancreatic neuroendocrine tumors, request is for advanced disease, with or without symptoms;
d. If request is for an insulinoma, tumor is somatostatin receptor positive on imaging;

2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Request is for any of the following *(both products may be used together)* (a, b, or c):*
   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. If request is for symptom management only, member has received Sandostatin Injection for at least two weeks with improvement in symptoms prior to request for Sandostatin LAR Depot.
   c. Dose for Sandostatin Injection or Sandostatin LAR Depot is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence).*

**Prescribed regimen must be FDA-approved or recommended by NCCN*

**Approval duration: 6 months**

**D. Meningioma (off-label)** (must meet all):
1. Diagnosis of meningioma *(cancer of the central nervous system)*;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Disease is not amenable to surgery or radiation;
5. Octreotide scan is positive;
6. Dose for Sandostatin Injection and/or Sandostatin LAR Depot is within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence).**

**Prescribed regimen must be FDA-approved or recommended by NCCN*

**Approval duration: 6 months**

**E. 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 within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence).**

**Prescribed regimen must be FDA-approved or recommended by NCCN*

**Approval duration:** 6 months

**F. Other diagnoses/indications:** Refer to PA.CP.PMN.53

## II. 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 either 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**

B. **Carcinoid tumor -Neuroendocrine Tumor of the Gastrointestinal Tract, Lung, and Thymus** (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, request is for any of the following *(both products may be used together)* (a, b, or c):*
    a. Sandostatin Injection: New dose does not exceed 1500 mcg per day in divided doses;
    b. Sandostatin LAR Depot: New dose does not to exceed 30 mg every 4 weeks.
    c. New dose for Sandostatin Injection or Sandostatin LAR Depot is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence).*

**Prescribed regimen must be FDA-approved or recommended by NCCN*

**Approval duration: 6 months**

**C. Vasoactive Intestinal Peptide Tumor and other Pancreatics Neuroendocrine Tumors** (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, request is for anyof the following *(both products may be used together)* (a, b, or c):*
    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;
    c. New dose for Sandostatin Injection or Sandostatin LAR Depot is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence).*

**Prescribed regimen must be FDA-approved or recommended by NCCN*

**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;
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 within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence).**

**Prescribed regimen must be FDA-approved or recommended by NCCN*

**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 within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence).**

**Prescribed regimen must be FDA-approved or recommended by NCCN*

**Approval duration: 6 months**

**F. 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

## III. Appendices/General Information

*Appendix A: Abbreviation/Acronym Key*
FDA: Food and Drug Administration
GH: growth hormone
IGF-1: insulin growth factor 1 (somatomedin C)
VIPoma: vasoactive intestinal peptide tumor

*Appendix B: Therapeutic Alternatives*
Not applicable

*Appendix C: Contraindications/Boxed Warnings*
Sandostatin LAR Depot: None reported
Sandostatin Injection:
- Contraindication(s): Sensitivity to this drug or any of its components.
- Boxed warning(s): None reported.

*Appendix D: General Information*
Acromegaly: 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.

## IV. Dosage and Administration

| Drug Name | Indication | Dosing Regimen | Maximum Dose |
|---|---|---|---|
| Octreotide acetate (Sandostatin Injection) (SC or IV) | Acromegaly | Up to 1500 mcg in 2 or more divided doses | 1500 mcg/day |
| | Carcinoid tumors | Up to 1500 mcg in 2 or more divided doses | 1500 mcg/day |
| | VIPomas | Up to 750 mcg in 2 or more divided doses | 750 mcg/day |
| Octreotide acetate (Sandostatin LAR Depot) (IM) | Acromegaly | 20-40 mg every 4 weeks | 40 mg/4 weeks |
| | Carcinoid tumors | 20-30 mg every 4 weeks | 30 mg/4 weeks |
| | VIPomas | 20-30 mg every 4 weeks | 30 mg/4 weeks |

## V. Product Availability

| Drug Name | Availability |
|---|---|
| Octreotide acetate (Sandostatin Injection) | Single-use ampule: 50 mcg/mL, 100 mcg/mL, 500 mcg/mL<br>Multi-dose vial: 200 mcg/mL, 1000 mcg/mL |
| Octreotide acetate (Sandostatin LAR Depot) | Single-use kit (vial): 10 mg, 20 mg, 30 mg |

## VI. References

1. Sandostatin Prescribing Information. East Hanover, NJ: Novartis Pharmaceuticals Corporation; April 2019. Available at http://www.pharma.us.novartis.com/product/pi/pdf/sandostatin_inj.pdf. Accessed November 6, 2019.
2. Sandostatin LAR Depot prescribing information. East Hanover, NJ: Novartis Pharmaceuticals Corporation; April 2019. Available at http://www.pharma.us.novartis.com/product/pi/pdf/sandostatin_lar.pdf. Accessed November 6, 2019.
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. Octreotide acetate and octreotide acetate (LAR). National Comprehensive Cancer Network Compendium. Available at nccn.org. Accessed November 6, 2019.
5. Octreotide acetate (LAR). In: National Comprehensive Cancer Network Compendium. Available at nccn.org. Accessed November 6, 2019.
6. Neuroendodrine and adrenal tumors (Version 1.2019). National Comprehensive Cancer Network Guidelines. Available at nccn.org. Accessed November 6, 2019.
7. Central nervous system cancers (Version 3.2019). National Comprehensive Cancer Network Guidelines. Available at nccn.org. Accessed November 6, 2019.

8. Thymomas and thymic carcinomas (Version 2.2019). National Comprehensive Cancer Network Guidelines. Available at nccn.org. Accessed November 6, 2019.
9. Katznelson L, Laws Jr. ER, Melmed S, et al. Acromegaly: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab. 2014;99:3933-3951.

**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 | |
| 1Q 2019 annual review; off-label NCCN recommended uses added for tumor control of neuroendocrine tumors with or without symptoms; positive octreotide scan added for insulinoma and meningioma per NCCN; references reviewed and updated. | 01/19 | |
| 1Q 2020 annual review: specialist added for acromegaly indication for alignment with other somatostatin analogs; references reviewed and updated. | 01/20 | |