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

Reference Number: LA.PHAR.40
Effective Date: 10.05.23
Last Review Date: 05.24.24
Line of Business: Medicaid

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

****Please note: This policy is for medical benefit****

Description

Octreotide acetate (Sandostatin® Injection, Sandostatin® LAR Depot, Mycapssa®) is a somatostatin analog.

FDA Approved Indication(s)

Sandostatin Injection is indicated for:

- 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 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

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

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
Provider must submit documentation (including such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of Louisiana Healthcare Connections that Sandostatin Injection, Mycapssa, 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 as evidenced by one of the following (a or b):
   a. Pre-treatment IGF-I level above the upper limit of normal based on age and gender for the reporting laboratory;
   b. Serum GH level ≥ 1 µg/mL after a 2-hour oral glucose tolerance test;
2. Prescribed by or in consultation with an endocrinologist;
3. Age ≥ 18 years or, if younger, epiphyseal growth plates have closed;
4. One of the following (a or b):
   a. 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)
   b. Member is not a candidate for surgical resection or pituitary irradiation;
5. For Sandostatin injection, member must use generic octreotide acetate, unless contraindicated or clinically significant adverse effects are experienced;
6. For Sandostatin LAR requests, member has received Sandostatin Injection for at least two weeks with improvement in GH or IGF-I levels, or tumor mass control;
7. For Mycapssa requests, member has responded to and tolerated treatment with octreotide or lanreotide;
8. Dose does not exceed any of the following *(Sandostatin Injection can be used with Sandostatin LAR Depot)* (a, b, or c):
   a. Sandostatin Injection: 1,500 mcg per day in divided doses;
   b. Sandostatin LAR Depot: 40 mg every 4 weeks;
   c. Mycapssa: 80 mg (4 capsules) per day;

Approval duration: 6 months

B. Carcinoid Tumor (Neuroendocrine Tumor of the Gastrointestinal Tract, Lung and Thymus) (must meet all):

1. Request is for Sandostatin Injection or Sandostatin LAR Depot;
2. 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;
3. Prescribed by or in consultation with an oncologist;
4. Age ≥ 18 years;
5. For Sandostatin injection, member must use generic octreotide acetate, unless contraindicated or clinically significant adverse effects are experienced;

6. For Sandostatin LAR Depot requests, if request is for symptom management only, member has received Sandostatin Injection for at least two weeks with improvement in diarrhea or flushing episodes;
7. Request meets one of the following *(Sandostatin Injection can be used with Sandostatin LAR Depot)* (a or b):*
   a. Dose does not exceed any of the following (i or ii):
      i. Sandostatin Injection: 1,500 mcg per day in divided doses;
      ii. Sandostatin LAR Depot: 30 mg every 4 weeks;
   b. Dose 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. Pancreatic Neuroendocrine Tumor (including VIPoma) and Adrenal Tumor (must meet all):
1. Request is for Sandostatin Injection or Sandostatin LAR Depot;
2. Diagnosis of one of the following (a or b):
   a. Pancreatic neuroendocrine tumor including but not limited to VIPoma, gastrinoma, insulinoma or glucagonoma, and one of the following (i, ii, iii, or iv):
      i. Request is for management of symptoms indicative of hormonal hypersecretion (e.g., diarrhea);
      ii. Request is for treatment of a gastrinoma with or without symptoms;
      iii. For other pancreatic neuroendocrine tumors, request is for advanced disease, with or without symptoms;
      iv. If request is for an insulinoma, tumor is somatostatin receptor positive on imaging;
   b. Advanced adrenal pheochromocytoma/paraganglioma;
3. Prescribed by or in consultation with an oncologist;
4. Age ≥ 18 years;
5. For Sandostatin injection, member must use generic octreotide acetate, unless contraindicated or clinically significant adverse effects are experienced;
6. For Sandostatin LAR Depot requests, if request is for symptom management only, member has received Sandostatin Injection for at least two weeks with improvement in symptoms;
7. Request meets one of the following (*Sandostatin Injection can be used with Sandostatin LAR Depot)* (a or b):*
   a. Dose does not exceed any of the following (i or ii):
      i. Sandostatin Injection: 750 mcg per day in divided doses;
      ii. Sandostatin LAR Depot: 30 mg every 4 weeks;
   b. Dose 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. Request is for Sandostatin Injection or Sandostatin LAR Depot;
2. Diagnosis of meningioma *(cancer of the central nervous system);*

3. Prescribed by or in consultation with an oncologist;
4. Age ≥ 18 years;
5. For Sandostatin injection, member must use generic octreotide acetate, unless contraindicated or clinically significant adverse effects are experienced;
6. Disease is not amenable to surgery or radiation;
7. Octreotide scan is positive;
8. Dose 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. Request is for Sandostatin Injection or Sandostatin LAR Depot;
2. Diagnosis of thymoma or thymic carcinoma;
3. Prescribed by or in consultation with an oncologist;
4. Age ≥ 18 years;
5. For Sandostatin injection, member must use generic octreotide acetate, unless contraindicated or clinically significant adverse effects are experienced;
6. Octreotide scan or dotatate PET/CT is positive;
7. Dose 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. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy LA.PMN.53

II. Continued Therapy

A. Acromegaly (must meet all)**:**
   a. Currently receiving medication via Louisiana Healthcare Connections benefit or member has previously met initial approval criteria;
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, new dose does not exceed any of the following *(Sandostatin injection can be used with Sandostatin LAR Depot)* (a, b, or c):
   a. Sandostatin Injection: 1,500 mcg per day in divided doses;
   b. Sandostatin LAR Depot: 40 mg every 4 weeks;
   c. Mycapssa: 80 mg (4 capsules) per day.

Approval duration: 6 months

B. Carcinoid Tumor and Pancreatic/Adrenal Neuroendocrine Tumor (must meet all)**:**
1. Currently receiving medication via Louisiana Healthcare Connections benefit, or documentation supports that member is currently receiving Sandostatin Injection or Sandostatin LAR Depot for a covered indication and has received this medication for at least 30 days;
2. Request is for Sandostatin Injection or Sandostatin LAR Depot;
3. Member is responding positively to therapy;
4. If request is for a dose increase, request meets one of the following *(Sandostatin Injection can be used with Sandostatin LAR Depot)* (a or b):*
   a. New dose does not exceed one of the following (i or ii):
      i. Sandostatin Injection (1 or 2):
         1) Carcinoid tumors: 1,500 mcg per day in divided doses;
         2) VIPomas: 750 mcg per day in divided doses;
      ii. Sandostatin LAR Depot: 30 mg every 4 weeks;
   b. Dose 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. Meningioma, Thymoma and Thymic Carcinoma (off-label) (must meet all):
1. Currently receiving medication via Louisiana Healthcare Connections benefit, or documentation supports that member is currently receiving Sandostatin Injection or Sandostatin LAR Depot for a covered indication and has received this medication for at least 30 days;
2. Request is for Sandostatin Injection or Sandostatin LAR Depot;
3. Member is responding positively to therapy;
4. If request is for a dose increase, new dose 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

D. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy LA.PMN.53

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy LA.PMN.53

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration
GH: growth hormone
IGF-I: insulin growth factor I (somatomedin C)
NCCN: National Comprehensive Cancer Network
VIPoma: vasoactive intestinal peptide tumor

Appendix B: Therapeutic Alternatives
Not applicable

Appendix C: Contraindications/Boxed Warnings
- Contraindication(s):
  - Sandostatin Injection and Mycapssa: hypersensitivity to this drug or any of its components
  - Sandostatin LAR Depot: none reported
- 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.

V. Dosage and Administration

Drug Name	Indication	Dosing Regimen	Maximum Dose
octreotide acetate (Sandostatin Injection) (SC or IV)	Acromegaly	Up to 1,500 mcg in 2 or more divided doses	1,500 mcg/day
	Carcinoid tumors	Up to 1,500 mcg in 2 or more divided doses	1,500 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
Mycapssa (octreotide acetate)	Acromegaly	Initial: 20 mg PO BID. Titrate based on IGF-1 levels and patient's signs and symptoms. Increase dose in 20 mg increments to a maximum of 40 mg PO QD	80 mg/day

VI. Product Availability

Drug Name	Availability
octreotide acetate (Sandostatin Injection)	Single-use ampules: 50 mcg/mL, 100 mcg/mL, 500 mcg/mL Multi-dose vials: 200 mcg/mL, 1,000 mcg/mL
octreotide acetate (Sandostatin LAR Depot)	Single-use kit (vials): 10 mg, 20 mg, 30 mg

Drug Name	Availability
Mycapssa (octreotide acetate)	Delayed-release capsule: 20 mg

VII. References

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2. Sandostatin LAR Depot prescribing information. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2023. Available at http://www.pharma.us.novartis.com/product/pi/pdf/sandostatin_lar.pdf. Accessed October 16, 2023.
3. Mycapssa Prescribing Information. Scotland, UK: MW Encap LTD; March 2022. Available at: www.mycapssa.com. Accessed October 16, 2023.

Acromegaly

4. Katznelson L, Laws Jr. ER, Melmed S, et al. Acromegaly: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab. 2014;99:3933-3951.
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7. Guistina A, Barkhoudarian G, Beckers A, et al. Multidisciplinary management of acromegaly: A consensus. Rev Endocr Metab Disord. 2020; 21(4): 667-678.
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Oncology

9. Octreotide acetate [Sandostatin, Bynfezia]. National Comprehensive Cancer Network Compendium. Available at nccn.org. Accessed November 22, 2023.
10. Octreotide acetate (LAR) [Sandostatin LAR Depot]. National Comprehensive Cancer Network Compendium. Available at nccn.org. Accessed November 22, 2023.
11. National Comprehensive Cancer Network Guidelines. Neuroendocrine and Adrenal Tumors Version 1.2023. Available at https://www.nccn.org/professionals/physician_gls/pdf/neuroendocrine.pdf. Accessed November 22, 2023.
12. National Comprehensive Cancer Network Guidelines. Central Nervous System Cancers Version 1.2023. Available at https://www.nccn.org/professionals/physician_gls/pdf/cns.pdf. Accessed November 22, 2023.
13. National Comprehensive Cancer Network Guidelines. Thymomas and Thymic Carcinomas Version 1.2023. Available at https://www.nccn.org/professionals/physician_gls/pdf/thymic.pdf. Accessed November 22, 2023.

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	LDH Approval Date
Converted corporate to local policy.	08.20	01.08.21
1Q 2021 annual review: advanced adrenal pheochromocytoma /paraganglioma added per NCCN; references reviewed and updated.	01.21	04.30.21
1Q 2022 annual review: no significant changes; references reviewed and updated.	04.22	05.03.22
For acromegaly, added confirmatory diagnostic requirements (IGF-I or GH) per PS/ES practice guidelines. Template changes applied to other diagnoses/indications and continued therapy section. Review: for Bynfezia and Sandostatin added must use generic octreotide language; for all oncologic indications clarified that request is for Sandostatin Injection, Bynfezia Pen, or Sandostatin LAR Depot; reorganized dose limits for all indications; moved the following onto separate criteria line: for Sandostatin LAR depot requests, if request is for symptom management and Mycapssa requests, member has responded to and tolerated treatment with octreotide or lanreotide; references reviewed and updated. Added verbiage this policy is for medical benefit only.	06.02.23	
For thymoma and thymic carcinoma, removed criterion, “prescribed as second-line therapy” and added octreotide scan or dotatate PET/CT is positive per NCCN; removed references to Bynfezia from policy due to product discontinuation; references reviewed and updated.	05.24.24	

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. LHCC makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved.

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