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

Reference Number: LA.PHAR.40
Effective Date:
Last Review Date: 01/2021~~08/2020~~ Coding Implications
Line of Business: Medicaid Revision Log

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

Description
Octreotide acetate (Sandostatin® Injection, Sandostatin® LAR Depot, Bynfezia Pen™ ~~,Mycapssa®~~) is a somatostatin analogue.

FDA Approved Indication(s)
Sandostatin Injection ~~(SC/IV)~~ and Bynfezia pen ~~(SC)~~ are 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 (IM) is indicated for treatment in patients who have responded to and tolerated Sandostatin Injection subcutaneous injection for:

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

~~Mycapssa 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, Bynfezia Pen, and Sandostatin LAR Depot on tumor size, rate of growth and development of metastases, has not been determined.

In patients with acromegaly, the effect of BYNFEZIA Pen on improvement in clinical signs and symptoms, reduction in tumor size and rate of growth, has not been determined.

Policy/Criteria
Prior authorization is required. *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, Bynfezia Pen~~,~~ ~~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;
  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 of the following formulations *(Sandostatin injection can be used with Sandostatin LAR Depot)* (a, b, or c):
     a. Sandostatin Injection and Bynfezia Pen: Dose does not exceed 1,500 mcg per 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;
     ~~c. Mycapssa (i and ii):~~
        ~~i. Dose does not exceed 80 mg (4 capsules) per day;~~
        ~~ii. Member has responded to and tolerated treatment with octreotide or lanreotide.~~

  Approval duration:
  Medicaid– 6 months

- **B.** Carcinoid Tumor - Neuroendocrine Tumor 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 *(Sandostatin injection can be used with Sandostatin LAR Depot)* (a, b, or c):*

a. Sandostatin Injection and Bynfezia Pen: 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, Bynfezia Pen, 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:
Medicaid– 6 months

C. ~~Vasoactive Intestinal Peptide Tumor and other Pancreatic Neuroendocrine Tumors~~ **Pancreatic Neuroendocrine Tumor (including VIPoma) and Adrenal Tumor** (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;~~

1.Diagnosis of one of the following (a or b):

e. 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;

f. Advanced adrenal pheochromocytoma/paraganglioma;

2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Request is for any of the following (*Sandostatin injection can be used with Sandostatin LAR Depot)* (a, b, or c):*
   a. Sandostatin injection and Bynfezia Pen:
      i. Dose does not exceed 750 mcg per 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, Bynfezia Pen 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:
Medicaid– 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, Bynfezia Pen 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:
Medicaid– 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/paclitaxel;
5. Dose for Sandostatin Injection, Bynfezia Pen 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:
Medicaid– 6 months

F. Other diagnoses/indications
1. Refer to the off-label use policy ~~for the relevant line of business~~ if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): LA.PMN.53 for Medicaid.

II. Continued Therapy

A. Acromegaly (must meet all):

1. Currently receiving medication via Louisiana Healthcare Connections benefit or member has previously met all 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, request is for one of the following *(Sandostatin injection can be used with Sandostatin LAR Depot)* (a, b, or c):
   a. Sandostatin Injection and Bynfezia Pen: New dose does not exceed 1,500 mcg per day in divided doses;
   b. Sandostatin LAR Depot: New dose does not exceed 40 mg every 4 weeks;
   ~~c. Mycapssa: dose does not exceed 80 mg (4 capsules) per day.~~

Approval duration:
Medicaid– 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, Bynfezia, or Sandostatin LAR Depot for a covered indication and has received this medication for at least 30 days;**
2. **Member is responding positively to therapy;**
3. **If request is for a dose increase, request meets one of the following *(Sandostatin Injection can be used with Sandostatin LAR Depot)* (a, b, or c):~~*~~**
   a. **Sandostatin Injection and Bynfezia Pen (i or ii):**
      i. **Carcinoid tumors: New dose does not exceed 1,500 mcg per day in divided doses;**
      ii. **VIPomas: New dose does not exceed 750 mcg per day in divided doses;**
   b. **Sandostatin LAR Depot: New dose does not exceed 30 mg every 4 weeks;**
   c. **New dose for Sandostatin Injection, Bynfezia Pen, 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:
Medicaid – 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, Bynfezia, or Sandostatin LAR Depot for a covered indication and has received this medication for at least 30 days;**
2. **Member is responding positively to therapy;**
3. **If request is for a dose increase, new dose for Sandostatin Injection, Bynfezia Pen, 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:

Medicaid – 6 months

D. Carcinoid Tumor – Neuroendocrine Tumor of the Gastrointestinal Tract, Lung and Thymus (must meet all):
4. Currently receiving medication via Louisiana Healthcare Connections benefit, or documentation supports that member is currently receiving Sandostatin or Sandostatin LAR for carcinoid tumor and has received this medication for at least 30 days;
5. Member is responding positively to therapy;
6. If request is for a dose increase, request is for any of the following *(Sandostatin injection can be used with Sandostatin LAR Depot)* (a, b, or c):*
   a. Sandostatin Injection and Bynfezia Pen: 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, Bynfezia Pen, 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:
Medicaid – 6 months

E. Vasoactive Intestinal Peptide Tumor and other Pancreatic Neuroendocrine Tumors (must meet all):
1. Currently receiving medication via Louisiana Healthcare Connections benefit, or documentation supports that member is currently receiving Sandostatin and/or Sandostatin LAR for a VIPoma and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request is for any of the following *(Sandostatin injection can be used with Sandostatin LAR Depot)* (a, b, or c):*
   a. Sandostatin injection and Bynfezia Pen: 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, Bynfezia Pen, 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:
Medicaid – 6 months

F. Meningioma (off-label) (must meet all):
4. Currently receiving medication via Louisiana Healthcare Connections benefit or member has previously met all initial approval criteria;
5. Member is responding positively to therapy;
6. If request is for a dose increase, new dose for Sandostatin Injection, Bynfezia Pen, 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:~~
~~Medicaid - 6 months~~

~~**G.** Thymoma and Thymic Carcinoma (off-label) (must meet all):~~
1. ~~Currently receiving medication via Louisiana Healthcare Connections benefit or member has previously met all initial approval criteria;~~
2. ~~Member is responding positively to therapy;~~
3. ~~If request is for a dose increase, new dose for Sandostatin Injection, Bynfezia Pen, 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:~~
~~Medicaid - 6 months~~

H. Other diagnoses/indications (must meet 1 or 2):
1. Currently receiving medication via Louisiana Healthcare Connections benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy ~~for the relevant line of business~~ if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): LA.PMN.53 for Medicaid.

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 policies – LA.PMN.53 for Medicaid or evidence of coverage documents.

IV. 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
- ~~Mycapssa,~~ Sandostatin Injection and Bynfezia Pen:
  - 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.

V. 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
Bynfezia Pen (Octreotide acetate) (SC)	Acromegaly	Up to 1500 mcg in 3 divided doses	1500 mcg/day
	Carcinoid tumors	Up to 1500 mcg in 2 to 4 divided doses	1500 mcg/day
	VIPomas	Up to 750 mcg in 2 to 4 divided doses	750 mcg/day
~~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 ampule: 50 mcg/mL, 100 mcg/mL, 500 mcg/mL Multi-dose vial: 200 mcg/mL, 1000 mcg/mL
Octreotide acetate (Sandostatin LAR Depot)	Single-use kit (vial): 10 mg, 20 mg, 30 mg
Bynfezia Pen (Octreotide acetate)	Single-patient-use pen: 2,500 mcg/mL octreotide as a 2.8 mL
~~Mycapssa (octreotide acetate)~~	~~Delayed-release capsule: 20 mg~~

VII. References

1. **Sandostatin Prescribing Information. East Hanover, NJ: Novartis Pharmaceuticals Corporation; June 2020. Available at**

http://www.pharma.us.novartis.com/product/pi/pdf/sandostatin_inj.pdf. Accessed November 3, 2020.

2. **Bynfezia Pen Prescribing Information. Gurjarat, India. Sun Pharmaceuticals; January 2020. Available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/213224s000lbl.pdf. Accessed November 3, 2020.**
3. **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 3, 2020.**

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.**
5. **Melmed S, Colao A, Barkan A, et al. Guidelines for acromegaly management: an update. J Clin Endocrinol Metab. May 2009; 94(5): 1509-1517.**

Oncology

6. **Octreotide acetate [Sandostatin, Bynfezia]. National Comprehensive Cancer Network Compendium. Available at nccn.org. Accessed November 3, 2020.**
7. **Octreotide acetate (LAR) [Sandostatin LAR Depot]. National Comprehensive Cancer Network Compendium. Available at nccn.org. Accessed November 3, 2020.**
8. **National Comprehensive Cancer Network Guidelines. Neuroendocrine and Adrenal Tumors Version 2.2020. Available at nccn.org. Accessed November 3, 2020.**
9. **National Comprehensive Cancer Network Guidelines. Central Nervous System Cancers Version 3.2020. Available at nccn.org. Accessed November 3, 2020.**
10. **National Comprehensive Cancer Network Guidelines. Thymomas and Thymic Carcinomas Version 1.2020. Available at nccn.org. Accessed November 3, 2020.**

~~11. 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.~~

~~12. 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.~~

~~13. Bynfezia Pen Prescribing Information. Gurjarat, India. Sun Pharmaceuticals; January 2020. Available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/213224s000lbl.pdf. Accessed February 16, 2020.~~

~~14. Melmed S, Colao A, Barkan A, et al. Guidelines for acromegaly management: an update. J Clin Endocrinol Metab. May 2009; 94(5): 1509-1517.~~

~~15. Octreotide acetate and octreotide acetate (LAR). National Comprehensive Cancer Network Compendium. Available at nccn.org. Accessed November 6, 2019.~~

~~16. Octreotide acetate (LAR). In: National Comprehensive Cancer Network Compendium. Available at nccn.org. Accessed November 6, 2019.~~

~~17. Neuroendodrine and adrenal tumors (Version 1.2019). National Comprehensive Cancer Network Guidelines. Available at nccn.org. Accessed November 6, 2019.~~

~~18. Central nervous system cancers (Version 3.2019). National Comprehensive Cancer Network Guidelines. Available at nccn.org. Accessed November 6, 2019.~~
~~19. Thymomas and thymic carcinomas (Version 2.2019). National Comprehensive Cancer Network Guidelines. Available at nccn.org. Accessed November 6, 2019.~~
~~20. Katznelson L, Laws Jr. ER, Melmed S, et al. Acromegaly: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab. 2014;99:3933-3951.~~
~~21. Mycapssa Prescribing Information. Scotland, UK: MW Encap LTD; June 2020. Available at: www.mycapssa.com. Accessed July 14, 2020.~~

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
Converted corporate to local policy.	08/15/2020
1Q 2021 annual review: advanced adrenal pheochromocytoma /paraganglioma added per NCCN; references reviewed and updated. Mycapssa removed from policy.	01.21

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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