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

Reference Number: IN.CP.PHAR.40
Effective Date: 01.01.2022
Last Review Date: 12.21
Line of Business: Medicaid

Coding Implications
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) is a somatostatin analogue.

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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
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 health plans affiliated with Centene Corporation® that Sandostatin Injection, Bynfezia Pen, Mycapssa, and Sandostatin LAR Depot are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Diagnoses for Sandostatin and Sandostatin LAR.

Diagnosis	ICD-10 Code
Acromegaly	E22.0
Acquired immunodeficiency syndrome (AIDS)-associated diarrhea	See AIDS ICD-10 codes
Bleeding associated with esophageal varices	I85.01
Chemotherapy-induced diarrhea	See Chemotherapy CPT codes/drug history
Chylothorax; Chyliform effusion	J94.0
Cryptosporidiosis	A07.2
Insulin-dependent diabetes mellitus as adjunct therapy	Z79.4
Metastatic Carcinoid tumor-associated symptoms	E34.0
Necrotizing pancreatitis with pulmonary failure	K85.92
Neuroendrocrine tumor	C7A.8
Ileostomy Present	Z93.2
Pituitary adenoma	D35.2
Polycystic ovary syndrome	E28.2
Polyostotic fibrous dysplasia of bone	Q78.1
Post-gastrectomy dumping syndrome	K91.1
Other specified noninfective disorders of lymphatic vessels and lymph nodes	I89.8

Noninfective disorder of lymphatic vessels and lymph nodes, unspecified	I89.9
Radiation-induced diarrhea	K52.0
Drug-induced hypoglycemia	E16.0
Vasoactive intestinal peptide-secreting tumor-associated diarrhea (VIPoma-associated diarrhea)	No ICD-10 to identify
Zollinger-Ellison syndrome	E16.4
Diarrhea unspecified	R19.7
Noninfective gastroenteritis and colitis	K52.9
Other specified disorders of pancreatic internal secretion	E16.8

Appendix

Diagnosis	**ICD-10 Codes**
AIDS/HIV	042, 795.71, V08, B20

CHEMOTHERAPY: in the last 6 months.

GPI	Drug Name
21**********	ANTINEOPLASTICS AND ADJUNCTIVE THERAPIES

CPT	Procedure
96401	CHEMOTX ADMN SUBQ/IM NON-HORMONAL ANTI-NEO
96402	CHEMOTX ADMN SUBQ/IM HORMONAL ANTI-NEO
96405	CHEMOTX ADMN ILESN UP&W/7
96406	CHEMOTX ADMN ILESN >7
96409	CHEMOTX ADMN IV PUSH TQ 1/1ST SBST/DRUG
96411	CHEMOTX ADMN IV PUSH TQ EA SBST/DRUG
96413	CHEMOTX ADMN IV NFS TQ UP 1 HR 1/1ST SBST/DRUG
96415	CHEMOTX ADMN IV NFS TQ EA HR 1 8 HR
96416	CHEMOTX ADMN TQ INIT PROLNG CHEMOTX NFUS PMP
96417	CHEMOTX ADMN IV NFS TQ EA SEQL NFS TO 1 HR
96420	CHEMOTX ADMN IA PUSH TQ
96422	CHEMOTX ADMN IA NFS TQ UP 1 HR
96423	CHEMOTX ADMN IA NFS TQ EA HR UP 8 HR
96425	CHEMOTX ADMN IA NFS >8 HR PRTBLE IMPLTBL PMP
96440	CHEMOTX ADMN PLEURAL CAVITY REQ&W/THORACNTS
96445	CHEMOTX ADMN PRTL CAVITY REQ&W/PRITONEOCNTS
96450	CHEMOTX ADMN CNS REQ&W/SPI PNXR
96542	CHEMOTX NJX SUBARACHND/INTRAVENTR RSVR 1+ AGENTS

B For Bynfezia and Mycapassa: Trial and Failure of Sandastatin or Sandostatin LAR.
1. Prescribed by or in consultation with an endocrinologist

i. .

Approval duration:
Medicaid – 12 months

III. Continued Therapy

A. History of the requested agents within the past 90 days.

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 – CP.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.

V. Dosage and Administration

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. 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.

4. Melmed S, Colao A, Barkan A, et al. Guidelines for acromegaly management: an update. J Clin Endocrinol Metab. May 2009; 94(5): 1509-1517.
5. Octreotide acetate and octreotide acetate (LAR). National Comprehensive Cancer Network Compendium. Available at nccn.org. Accessed November 6, 2019.
6. Octreotide acetate (LAR). In: National Comprehensive Cancer Network Compendium. Available at nccn.org. Accessed November 6, 2019.
7. Neuroendodrine and adrenal tumors (Version 1.2019). National Comprehensive Cancer Network Guidelines. Available at nccn.org. Accessed November 6, 2019.
8. Central nervous system cancers (Version 3.2019). National Comprehensive Cancer Network Guidelines. Available at nccn.org. Accessed November 6, 2019.
9. Thymomas and thymic carcinomas (Version 2.2019). National Comprehensive Cancer Network Guidelines. Available at nccn.org. Accessed November 6, 2019.
10. Katznelson L, Laws Jr. ER, Melmed S, et al. Acromegaly: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab. 2014;99:3933-3951.
11. 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	P&T Approval Date
For all three indications: Age added per PI; documentation requests removed; dosing parameters added per PI; initial approval period increased to 3 months. Acromegaly: Bromocriptine requirement removed; cabergoline; monitoring parameters edited to include IGF-1, GH and tumor mass; removed requirement that member have clinical evidence of acromegaly per App B. Carcinoid tumors: Clarified that carcinoid tumors are now known as neuroendocrine tumors of the GI tract, lung, and thymus; removed requirement that member be experiencing carcinoid syndrome as outlined in App D; removed question about whether member is a candidate for surgery as surgery can be used with octreotide to cure or control.	03.01.16	05.16

Reviews, Revisions, and Approvals	Date	P&T Approval Date
VIPomas: Removed the requirement that patients try other medications for diarrhea; as with carcinoid tumors, questions about surgery are removed.		
The following criteria in section A "acromegaly" is removed: "If member has received pituitary irradiation Sandostatin LAR Depot will be withdrawn yearly for approximately 8 weeks to assess disease activity (*if GH or IGF-1 levels increase and signs and symptoms recur Sandostatin LAR Depot therapy may be resumed*)." Hypersensitivity removed as a contraindication. Acromegaly continuation criteria edited to allow 12 months of therapy before evidence of efficacy; renewal approval durations throughout policy are lengthened to 12 months. NCCN compendial uses are added for carcinoids and VIPomas in section D.	03.17	03.17
1Q18 annual review: - Policies combined for Medicaid and Commercial lines of business -Specialist added for oncology indications -Requests for non-oncology off-label indications and any oncology off-label indications not outlined above are directed to the off-label use policies referenced in Section I.F. - 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.	11.30.17	02.18
1Q 2019 annual review; HIM line of business added; 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.	11.13.18	02.19
1Q 2020 annual review: specialist added for acromegaly indication for alignment with other somatostatin analogs; references reviewed and updated.	11.06.19	02.20
Added Bynfezia pen to policy.	02.17.20	
RT4: added Mycapssa to policy.	07.14.20	
Revised for IN Medicaid Moratorium	12.21	01.2022