09-J0000-90

Original Effective Date: 03/15/09

Reviewed: 06/14/23

Revised: 07/15/23

Subject: Octreotide Acetate (Sandostatin LAR® Depot, Mycapssa Capsule®)

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

DESCRIPTION:

Octreotide acetate is a somatostatin analog that has similar effects in the body as those of the naturally occurring hormone. It inhibits the secretion of growth hormone, glucagon, insulin, gastrin, vasoactive intestinal peptide, secretin, motilin and pancreatic polypeptide. In addition, it suppresses the response of luteinizing hormone (LH) in response to gonadotropin releasing hormone (GnRH) and decreases splenic blood flow. Octreotide acetate is available as an immediate-release formulation (Sandostatin®), a long-acting formulation (Sandostatin LAR® Depot), and in a delayed-release oral capsule (Mycapssa®). Octreotide acetate suppresses secretion of growth hormone (GH) and secondarily suppresses insulin-like growth factor-1 (IGF-1, somatomedin C) and is a treatment option for those with acromegaly. Studies have shown that after immediate-release octreotide acetate administration, growth hormone and IGF-1 levels are normalized in 50 to 60% of patients. Octreotide acetate also suppresses the release of the peptides and amines secreted from carcinoid tumors and vasoactive intestinal peptide tumors (VIPomas), which subsequently reduces the severe diarrhea and flushing associated with this disease. Sandostatin LAR was granted orphan designation by the FDA in 1998 for the treatment of severe diarrhea and flushing associated with malignant carcinoid tumors, acromegaly, and diarrhea associated with VIPoma; and, then in 2010, for the treatment of neuroendocrine tumors.

POSITION STATEMENT:

I. Initiation of octreotide acetate long-acting injection (Sandostatin LAR® Depot) **meets the definition of medical necessity** when **ALL** of the following are met:

1. When administered for an indication listed in Table 1 below and **ALL** of the associated criteria are met
2. The member will not receive treatment in combination with lanreotide, octreotide delayed-release capsules, or pasireotide long-acting injection

Table 1

Indication	Specific Criteria
Acromegaly	**ALL** of the following: 1. Sandostatin LAR will be used as long-term therapy for the member's acromegaly 2. The dosage will not exceed 40 mg per 28-day treatment cycle 3. **EITHER** of the following are met: a. Member has had an inadequate response to surgery and/or radiotherapy b. Member is not a candidate for surgery and/or radiotherapy.
Carcinoid Tumors (neuroendocrine tumors of the GI tract, lung, and thymus)	**ALL** of the following: 1. Treatment for **ONE** of the following: a. Metastatic, locoregional advanced, or recurrent disease b. Carcinoid syndrome c. Unresected primary gastrinoma d. Locoregional bronchopulmonary or thymic disease that is unresectable e. Multiple lung nodules or tumorlets and evidence of diffuse idiopathic pulmonary neuroendocrine cell hyperplasia (DIPNECH) 2. The dosage will not exceed 30 mg per 28-day treatment cycle.
Meningiomas	**ALL** of the following: 1. All of the following are met: a. The member has surgically inaccessible, recurrent or progressive disease b. Radiation is not possible c. Will be used in combination with everolimus 2. The dosage will not exceed 30 mg per 28-day treatment cycle

Pancreatic neuroendocrine tumor	**ALL** of the following: 1. Use is for **ONE** of the following: a. To treat symptoms associated with **ONE** of the following: i. Gastrinoma ii. Glucagonoma iii. Vasoactive intestinal peptide tumors (VIPomas) iv. Insulinoma **AND** tumor is somatostatin-receptor positive– documentation must be provided b. For tumor control in member's with unresectable disease, locoregional advanced disease, recurrent, or metastatic disease 2. The dosage will not exceed 30 mg per 28-day treatment cycle.
Pheochromocytoma or paraganglioma	**ALL** of the following: 1. When used for **ONE** of the following: a. Locally unresectable disease b. Metastatic disease 2. The dosage will not exceed 30 mg per 28-day treatment cycle
Thymomas and Thymic carcinomas	**ALL** of the following: 1. **ONE** of the following: a. When used as second-line therapy b. Member is unable to tolerate first-line therapy 2. The dosage will not exceed 20 mg every two weeks
Well-differentiated neuroendocrine tumors of unknown primary	**ALL** of the following: 1. Treatment of metastatic or unresectable locally advanced disease 2. The dosage will not exceed 30 mg per 28-day treatment cycle.
Well-differentiated, grade 3 neuroendocrine tumors	**ALL** of the following: 1. Treatment of metastatic or unresectable locally advanced disease

	2. The dosage will not exceed 30 mg per 28-day treatment cycle.
Other FDA-approved or NCCN supported diagnosis (not previously listed above)	When **ALL** of the following are met: 1. **ONE** of the following is met: a. Member is diagnosed with a condition that is consistent with an indication listed in the product's FDA-approved prescribing information (or package insert) AND member meets any additional requirements listed in the "Indications and Usage" section of the FDA-approved prescribing information (or package insert) b. Indication **AND** usage is recognized in NCCN Drugs and Biologics Compendium as a Category 1 or 2A recommendation 2. The dose does not exceed the maximum FDA-approved dose

Approval duration: 1 year

II. Continuation of octreotide acetate long-acting injection (Sandostatin LAR Depot) **meets the definition of medical necessity** for members treated for an indication from Table 1 when the following criteria are met:

1. The member has been previously approved by Florida Blue or another healthplan in the past 2 years, **OR** the member has previously met all indication-specific criteria for coverage
2. Member has experienced a beneficial response to octreotide acetate long-acting injection
3. The member will not receive treatment in combination with lanreotide, octreotide delayed-release capsules, or pasireotide long-acting injection
4. Dose does not exceed indication-specific dosing in Table 1

Approval duration: 1 year

I. Initiation of octreotide delayed-release capsules (Mycapssa®) **meets the definition of medical necessity** when **ALL** of the following are met:

a. When used for the long-term maintenance treatment of acromegaly
b. The member has achieved a favorable response to treatment with long-acting injectable octreotide (Sandostatin LAR Depot) or lanreotide (Somatuline Depot, Lanreotide acetate) (e.g., insulin-like growth factor-1 (IGF-1) and symptoms controlled on a stable dose of treatment) – documentation must be submitted

c. The member will not receive treatment in in combination with lanreotide, octreotide acetate long-acting injection, or pasireotide long-acting injection

d. The member's IGF-1 levels will be monitored for appropriate dose titration

e. Dose does not exceed 80 mg per day

Approval duration: 1 year

II. Continuation of octreotide delayed-release capsules (Mycapssa) meets the definition of medical necessity for members the treatment of acromegaly when the following criteria are met:

a. The member has been previously approved by Florida Blue or another healthplan in the past 2 years, **OR** the member has previously met all indication-specific criteria for coverage

b. The member's IGF-1 levels have been monitored for appropriate dose titration - documentation must be submitted

c. The member will not receive treatment in combination with lanreotide, octreotide acetate long-acting injection, or pasireotide long-acting injection

d. Dose does not exceed 80 mg per day

Approval duration: 1 year

DOSAGE/ADMINISTRATION:

THIS INFORMATION IS PROVIDED FOR INFORMATIONAL PURPOSES ONLY AND SHOULD NOT BE USED AS A SOURCE FOR MAKING PRESCRIBING OR OTHER MEDICAL DETERMINATIONS. PROVIDERS SHOULD REFER TO THE MANUFACTURER'S FULL PRESCRIBING INFORMATION FOR DOSAGE GUIDELINES AND OTHER INFORMATION RELATED TO THIS MEDICATION BEFORE MAKING ANY CLINICAL DECISIONS REGARDING ITS USAGE.

Sandostatin LAR

Members not currently receiving octreotide acetate injection subcutaneously:

Acromegaly: To determine tolerance and efficacy, an initial dosage of octreotide acetate injection 50 mcg three times daily should be administered subcutaneously for 2 weeks (may be titrated up to 500 mcg three times daily if needed for maximum effect). Patients who are considered to be "responders" to the drug, based on GH and IGF-1 levels and who tolerate the drug can then be switched to Sandostatin LAR Depot 20 mg every 4 weeks for 3 months.

Carcinoid Tumors: octreotide acetate injection subcutaneously 100 to 600 mcg/day in 2 to 4 divided dose (mean daily dosage is 300 mcg) for 2 weeks followed by Sandostatin LAR 20 mg every 4 weeks for 2 months.

- VIPomas: octreotide acetate injection subcutaneously 100 to 600 mcg/day in 2 to 4 divided dose (mean daily dosage is 300 mcg) for 2 weeks followed by Sandostatin LAR 20 mg every 4 weeks for 2 months.

Members currently receiving of octreotide acetate injection subcutaneously:

Acromegaly: 20 mg every 4 weeks for 3 months. After 3 months, the dosage should be adjusted based on response as follows:

- GH ≤2.5 ng/mL, IGF-1 normal, and clinical symptoms controlled: maintain Sandostatin LAR Depot dosage at 20 mg every 4 weeks.
- GH >2.5 ng/mL, IGF-1 elevated, and/or clinical symptoms uncontrolled, increase Sandostatin LAR Depot dosage to 30 mg every 4 weeks.
- GH ≤1 ng/mL, IGF-1 normal, and clinical symptoms controlled, reduce Sandostatin LAR Depot dosage to 10 mg every 4 weeks.
- If GH, IGF-1, or symptoms are not adequately controlled at a dose of 30 mg, the dose may be increased to 40 mg every 4 weeks. Doses higher than 40 mg are not recommended.

Carcinoid Tumors and VIPomas: 20 mg every 4 weeks for 2 months. After 2 months, the dosage should be adjusted as follows:

- If symptoms are adequately controlled, consider a dose reduction to 10 mg for a trial period. If symptoms recur, dosage should then be increased to 20 mg every 4 weeks. Many patients can, however, be satisfactorily maintained at a 10-mg dose every 4 weeks.
- If symptoms are not adequately controlled, increase Sandostatin LAR Depot to 30 mg every 4 weeks. Dosages higher than 30 mg are not recommended.

Dosage Adjustments:

- **Hepatic Impairment** - In patients with established liver cirrhosis, the starting dose should be 10 mg and titrated up based on clinical response.
- **Renal Impairment** - In patients with renal failure requiring dialysis, the starting dose should be 10 mg and titrated up based on clinical response.
- See product labeling for drug interactions.

Product Availability: single-use kits containing a 6-mL vial of 10 mg, 20 mg or 30 mg strength; a syringe containing 2 mL of diluent; one vial adapter; and one sterile 1½" 20 gauge safety injection needle. For prolonged storage, stored at refrigerated temperatures between 2°C to 8°C (36°F to 46°F) and protected from light until the time of use.

Mycapssa

For the long-term maintenance treatment in acromegaly patients who have responded to and tolerated treatment with octreotide or lanreotide:

- Initiate dosage at 20 mg twice daily.
- Monitor IGF-1 levels and patient's signs and symptoms every two weeks during the dose titration or as indicated.
- Titrate the dosage based on IGF-1 levels and patient signs and symptoms.
- Increase the dose in increments of 20 mg.

- Do not exceed 40 mg twice daily (max: 80 mg daily)

Dose adjustments:

- Renal Impairment – 20 mg once daily; titrate based on IGF-1 levels, patient signs and symptoms and tolerability
- Drug interactions: see prescribing information for dose adjustment.

Product Availability: 20 mg delayed-release capsules

PRECAUTIONS:

Contraindications:

Mycapssa - Hypersensitivity to octreotide or any of the components of Mycapssa

Warnings:

Cholelithiasis and Gallbladder sludge: Gallbladder abnormalities may occur. Monitor periodically and discontinue if complications are suspected.

Blood glucose effects: hypoglycemia or hyperglycemia may occur. Glucose monitoring is recommended and antidiabetic treatment may need adjustment.

Thyroid effects: hypothyroidism may occur. Monitor thyroid levels periodically.

Cardiovascular effects: bradycardia, arrhythmia or conduction abnormalities may occur. Use with caution in at-risk members.

Monitoring: Lab tests that may be helpful as biomarkers vary based on tumor type (e.g. Acromegaly measure GH and IGF-1; Carcinoid measure urinary 5-hydroxyindole acetic acid, plasma serotonin, plasma Substance P; VIPoma measure plasma vasoactive intestinal peptide and free T4)

Nutritional effects: Octreotide may alter absorption of dietary fats. Depressed vitamin B12 levels and abnormal Schilling tests have been observed in some persons receiving octreotide therapy, and monitoring of vitamin B12 levels is recommended during therapy with octreotide.

Renal function impairment: In members with severe renal failure requiring dialysis, the half-life of octreotide may be increased, necessitating adjustment of the maintenance dosage.

Hepatic function impairment: (Sandostatin LAR) In members with established liver cirrhosis, the starting dose of Sandostatin LAR Depot should be 10 mg. Up-titrate the dose based on clinical response and speed of response as deemed necessary by the health care provider. Once at a higher dose, maintain the member or adjust the dose based on response and tolerability as in any noncirrhotic members.

BILLING/CODING INFORMATION:

The following codes may be used to describe:

HCPCS Coding

J2353	Injection, octreotide, depot form for intramuscular injection, 1 mg
J8499	Prescription drug, oral, non-chemotherapeutic, Not Otherwise Specified

ICD-10 Diagnosis Codes That Support Medical Necessity:

C70.0 – C70.9	Malignant neoplasm of meninges
C74.10 – C74.92	Malignant neoplasm of medulla and unspecified part of adrenal gland
C75.5	Malignant neoplasm of aortic body and other paraganglia
C7A.00	Malignant carcinoid tumor of unspecified site
C7A.010	Malignant carcinoid tumor of the duodenum
C7A.011	Malignant carcinoid tumor of the jejunum
C7A.012	Malignant carcinoid tumor of the ileum
C7A.019	Malignant carcinoid tumor of the small intestine, unspecified portion
C7A.020	Malignant carcinoid tumor of the appendix
C7A.021	Malignant carcinoid tumor of the cecum
C7A.022	Malignant carcinoid tumor of the ascending colon
C7A.023	Malignant carcinoid tumor of the transverse colon
C7A.024	Malignant carcinoid tumor of the descending colon
C7A.025	Malignant carcinoid tumor of the sigmoid colon
C7A.026	Malignant carcinoid tumor of the rectum
C7A.029	Malignant carcinoid tumor of the large intestine, unspecified portion
C7A.090	Malignant carcinoid tumor of the bronchus and lung
C7A.091	Malignant carcinoid tumor of the thymus
C7A.092	Malignant carcinoid tumor of the stomach
C7A.093	Malignant carcinoid tumor of the kidney
C7A.094	Malignant carcinoid tumor of the foregut, unspecified
C7A.095	Malignant carcinoid tumor of the midgut, unspecified
C7A.096	Malignant carcinoid tumor of the hindgut, unspecified
C7A.098	Malignant carcinoid tumors of other sites
C7A.1	Malignant poorly differentiated neuroendocrine tumors
C7A.8	Other malignant neuroendocrine tumors
C7B.00 – C7B.04	Secondary carcinoid tumors of distant lymph nodes, liver, bone, peritoneum
C7B.09	Secondary carcinoid tumors of other sites
C7B.8	Other secondary neuroendocrine tumors
C25.0 – C25.9	Malignant neoplasm of pancreas
C37	Malignant neoplasm of thymus
D3A.00	Benign carcinoid tumor of unspecified site
D3A.010 – D3A.012	Benign carcinoid tumor of the duodenum, jejunum, ileum
D3A.019 – D3A.029	Benign carcinoid tumor of the large intestine, unspecified portion, appendix, cecum, ascending colon, transverse colon, descending colon, sigmoid colon, rectum
D3A.090 – D3A.098	Benign carcinoid tumor of the bronchus and lung, thymus, stomach
D3A.8	Other benign neuroendocrine tumors

D13.7	Benign neoplasm of endocrine pancreas
D15.0	Benign neoplasm of thymus
D32.0 – D32.9	Benign neoplasm of meninges
D35.2	Benign neoplasm of pituitary gland
D35.3	Benign neoplasm of craniopharyngeal duct
D37.9	Neoplasm of uncertain behavior of digestive organ, unspecified
D42.0 – D42.9	Neoplasm of uncertain behavior of meninges
E16.1	Other hypoglycemia
E16.3	Increased secretion of glucagon
E16.4	Abnormality of secretion of gastrin
E16.8	Other specified disorders of pancreatic internal secretion
E22.0	Acromegaly and pituitary gigantism
E34.0	Carcinoid syndrome

REIMBURSEMENT INFORMATION:

Refer to section entitled **POSITION STATEMENT**.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage Products: No National Coverage Determination (NCD) or Local Coverage Determination (LCD) were found at the time of the last guideline revised date.

DEFINITIONS:

Table 3

NCCN Categories of Evidence Consensus	
Category 1	Based upon high-level evidence; there is uniform NCCN consensus that the intervention is appropriate
Category 2A	Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate
Category 2B	Based upon lower-level evidence, there NCCN consensus that the intervention is appropriate
Category 3	Based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate

Table 4

Compendium	**Covered Uses †**
AHFS-DI	Narrative text is supportive
Clinical Pharmacology	Narrative text is supportive
Lexicomp	Evidence rating A, B or G

Thomson Micromedex DrugDex	Meets requirements for BOTH of the following: • Strength of recommendation: Class I (Recommended) or IIa (Recommended, In Most Cases) • Efficacy: Class I (Effective) or IIa (Evidence Favors Efficacy)
† If covered use criteria are not met, the request should be denied. AHFS-DI, American Hospital Formulary Service Drug Information; For additional information regarding designated compendia, please refer to the "Definitions" section.	

Table 5

Lexicomp Recommendation Ratings	
A	Consistent evidence from well-performed randomized, controlled trials or overwhelming evidence of some other form (eg, results of the introduction of penicillin treatment) to support the off-label use. Further research is unlikely to change confidence in the estimate of benefit.
B	Evidence from randomized, controlled trials with important limitations (inconsistent results, methodological flaws, indirect or imprecise), or very strong evidence of some other research design. Further research (if performed) is likely to have an impact on confidence in the estimate of benefit and risk and may change the estimate.
C	Evidence from observational studies (eg, retrospective case series/reports providing significant impact on patient care), unsystematic clinical experience, or from potentially flawed randomized, controlled trials (eg, when limited options exist for condition). Any estimate of effect is uncertain.
G	Use has been substantiated by inclusion in at least one evidence-based or consensus-based clinical practice guideline.

Table 6

Thomson Micromedex DrugDex Recommendation Ratings: Strength of Recommendation		
Class I	Recommended	The given test or treatment has been proven to be useful, and should be performed or administered
Class IIa	Recommended, in most cases	The given test or treatment is generally considered to be useful, and is indicated in most cases.
Class IIb	Recommended in some cases	The given test or treatment may be useful, and is indicated in some, but not most, cases
Class III	Not recommended	The given test or treatment is not useful and should be avoided
Class Indeterminate	Evidence Inconclusive	

Table 7

Thomson Micromedex DrugDex Recommendation Ratings: Efficacy		
Class I	Effective	Evidence and/or expert opinion suggests that a given drug treatment for a specific indication is effective

Class IIa	Evidence favors efficacy	Evidence and/or expert opinion is conflicting as to whether a given drug treatment for a specific indication is effective, but the weight of evidence and/or expert opinion favors efficacy.
Class IIb	Evidence is inconclusive	Evidence and/or expert opinion is conflicting as to whether a given drug treatment for a specific indication is effective, but the weight of evidence and/or expert opinion argues against efficacy.
Class III	Ineffective	Evidence and/or expert opinion suggests that a given drug treatment for a specific indication is ineffective

RELATED GUIDELINES:

Capecitabine (Xeloda®) Tablets, 09-J1000-42

Docetaxel (Taxotere®) IV, 09-J0000-95

Interferon alfa-n3 (Alferon N Injection®), 09-J0000-33

Lanreotide (Somatuline® Depot) Injection, 09-J1000-20

Paraplatin (Carboplatin®) IV, 09-J0000-93

Pasireotide (Signifor, Signifor LAR) Injection - 09-J1000-94

Temozolomide (Temodar®) Capsule and Injection, 09-J1000-52

OTHER:

None applicable.

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Pharmacy Policy Committee on 06/14/23.

GUIDELINE UPDATE INFORMATION:

03/15/09	New Medical Coverage Guideline.
10/15/09	Revision to guideline; consisting of adding compendia supported indication and updating coding.
01/15/10	Revision to guideline; consisting of updating coding.
11/15/10	Review and revision to guideline; consisting of updating coding and references.
11/15/11	Review and revision to guideline; consisting of updating precautions, coding and references.
12/15/12	Review and revision to guideline; consisting of reformatting position statement, updating coding and references.
06/15/13	Review and revision to guideline; consisting of revising the position statement to include treatment of meningioma and approval duration; reformatting precautions section; updating references, coding, and program exceptions;
02/15/14	Revision to guideline; consisting of adding codes for neuroendocrine tumors.
06/15/14	Review and revision to guideline; consisting of revising position statement, updating references and coding.
06/15/15	Review and revision to guideline; consisting of updating position statement, dosage/administration section, and references.

10/01/15	Revision to guideline consisting of coding updates.
11/01/15	Revision: ICD-9 Codes deleted.
06/15/16	Review and revision to guideline consisting of updating position statement, coding and references.
10/01/16	Update to ICD-10 codes.
06/15/17	Review and revision to guideline consisting of updating position statement and references.
11/15/17	Revision to guideline consisting of updating position statement and references.
06/15/18	Review and revision to guideline consisting of updating position statement, warnings, coding and references.
07/15/19	Review and revision to guideline consisting of updating position statement, coding and references.
06/15/20	Review and revision to guideline consisting of updating position statement, dosing, coding and references.
12/15/20	Review and revision to guideline; consisting of updating the position statement, dosing, coding, and references.
07/15/21	Review and revision to guideline; consisting of updating the position statement and references.
07/15/22	Review and revision to guideline; consisting of updating the position statement and references.
07/15/23	Review and revision to guideline; consisting of removing Bynfezia from the position statement, inclusion of meningiomas in the position statement, and updating coding and references.