Medical Policy

Healthcare Services Department

Policy Name	Policy Number	Scope	
Octreotide Agents (Sandostatin®, Sandostatin LAR®)	MP-RX-FP-65-23	☒ MMM MA	☒ MMM Multihealth

Service Category

☐ Anesthesia
☐ Surgery
☐ Radiology Procedures
☐ Pathology and Laboratory Procedures
☐ Medicine Services and Procedures
☐ Evaluation and Management Services
☐ DME/Prosthetics or Supplies
☒ Part B DRUG

Service Description

This document addresses the use of Octreotide Agents (Sandostatin®, Sandostatin LAR®) , a drug approved by the Food and Drug Administration (FDA) for the treatment of Acromegaly, Carcinoid Tumors and Vasoactive Intestinal Peptide Tumors (VIPomas).

Background Information

Octreotide acetate agents exerts pharmacologic actions similar to the natural hormone somatostatin, but is a more potent inhibitor of GH, glucagon, and insulin than somatostatin. Like somatostatin, it also suppresses luteinizing hormone (LH) response to gonadotropin-releasing hormone (GnRH), decreases splanchnic blood flow, and inhibits release of serotonin, gastrin, vasoactive intestinal peptide, secretin, motilin, and pancreatic polypeptide.

Octreotide acetate agents are approved by the FDA to treat acromegaly, to reduce flushing episodes and watery diarrhea caused by cancerous tumors (carcinoid syndrome) and tumors called vasoactive intestinal peptide tumors (VIPomas).

Acromegaly is a rare condition that occurs if a tumor causes excess growth hormone secretion, that in turn increases IGF-1 levels. The increase in the hormones causes the hands, feet, lips, nose, and tongue to become larger, bone changes, headaches, joint aches, and vision problems. Complications may develop such as type 2 diabetes, high blood pressure, heart disease, sleep apnea, and arthritis. Estimates are there are 3,000 new cases of acromegaly per year with a prevalence of about 25,000 patients in the US. Treatment includes surgery, radiation, and medications. Medications are used if surgery is impractical or not successful. Medications for acromegaly include somatostatin analogs, growth hormone receptor antagonist, and dopamine agonist. Dopamine agonist (e.g., cabergoline) has a limited role in the treatment of acromegaly for those with mild disease.

Sandostatin® and Sandostatin LAR® are used for the symptomatic treatment of severe diarrhea in patients with carcinoid tumors and vasoactive intestinal peptide-secreting tumors (VIPomas). Their effect on tumor size, growth rate, and the development of metastases has not been determined.

Octreotide acetate agents may cause cardiac function abnormalities, including an increased risk of atrioventricular blocks, bradycardia, arrhythmias, and conduction issues, warranting cardiac monitoring, especially during intravenous administration, and possible dosage adjustments of cardiac medications. It can

also lead to cholelithiasis, requiring periodic monitoring and discontinuation if complications arise. Glucose metabolism disturbances, such as hypoglycemia or hyperglycemia, may occur, necessitating glucose monitoring and adjustments in anti-diabetic treatments. Additionally, hypothyroidism may develop, requiring periodic thyroid function monitoring. Patients may experience steatorrhea and malabsorption of dietary fats, requiring evaluation for pancreatic exocrine insufficiency if symptoms worsen.

The safety and/or efficacy of octreotide acetate have not been established for treating the following conditions. The peer-reviewed published medical literature consists of case reports, small case series, RCTs of small sample sizes, and non-randomized or uncontrolled trials which preclude drawing reliable conclusions on the safety and net health benefit of octreotide acetate for other conditions, including but not limited to:

1. AIDs-related diarrhea (Panel 2018);
2. Chyle fistula management following neck dissection surgery (Swanson, 2015);
3. Chylothorax in adults (Fujita, 2014; Ismail, 2015) and neonates (Das and Shah, 2010; Testoni, 2015);
4. Graves' ophthalmopathy (thyroid eye disease) (Stan, 2006);
5. Hypothalamic obesity (insulin hypersecretion) (Lustig, 2003; Michalsky, 2012);
6. Other carcinomas, such as:
    - Advanced, metastatic breast cancer (Bajetta, 2002; Chapman, 2015);
    - Hepatocellular cancer (Jia, 2010);
    - Prostate cancer (including castration-resistant) (Friedlander, 2012);
7. Other GI tract conditions, such as:
    - Bleeding from vascular malformations (such as, angiodysplasias, angioectasias, or/GI tract AVM (Brown, 2010; Junquera, 2007; Loyaga-Rendon, 2015, Szilagyi and Ghali, 2006);
    - Gastroparesis (Edmunds, 1998);
    - Non-variceal upper GI bleeding (Archimandritis, 2000);
    - Pancreatitis (Xu, 2013);
    - Short bowel syndrome (Nehra, 2001);
    - Small intestinal dysmotility associated with systemic sclerosis (scleroderma) (Nikou, 2007; Perlemuter, 1999; Soudah, 1991; Verne, 1995); and
8. Polycystic kidney or liver disease (Caroli, 2013; Hogan, 2010; Ruggenenti, 2005).

Approved Indications

Table 1 includes the FDA-approved indications for the somatostatin analogs.

Other Uses

None.

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Table 1: Somatostatin Analogs

Product	Indications
Sandostatin® (octreotide acetate injection)	• Indicated for the treatment of: ○ Patients with acromegaly who have had inadequate response to or cannot be treated with surgical resection, pituitary irradiation, and bromocriptine mesylate at maximally tolerated doses. ○ Carcinoid tumors ○ Vasoactive Intestinal Peptide Tumors (VIPomas)
Sandostatin LAR® depot (octreotide acetate injection)	• Indicated for the treatment of patients who have responded to and tolerated Sandostatin Injection subcutaneous for: ○ Acromegaly ○ Severe diarrhea/flushing episodes associated with metastatic carcinoid tumors ○ Profuse watery diarrhea associated with Vasoactive Intestinal Peptide (VIP) secreting tumors

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Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

HCPCS	Description
J2353	Injection, octreotide, depot form for intramuscular injection, 1 mg [Sandostatin LAR®]
J2354	Injection, octreotide, nondepot form for subcutaneous or intravenous injection, 25 mcg [Sandostatin®]

ICD-10	Description
C18.0-C18.9	Malignant neoplasm of colon [associated bowel obstruction]
C25.0-C25.9	Malignant neoplasm of pancreas [related VIPoma syndrome]
C37	Malignant neoplasm of thymus
C48.1-C48.8	Malignant neoplasm of peritoneum [associated bowel obstruction]
C57.00-C57.4	Malignant neoplasm of other and unspecified female genital organs [associated bowel obstruction]
C70.0-C70.9	Malignant neoplasm of meninges
C75.1	Malignant neoplasm of pituitary gland
C7A.00-C7A.8	Malignant neuroendocrine tumors (carcinoid tumors)
C7B.00-C7B.8	Secondary neuroendocrine tumors
D01.7	Carcinoma in situ of other specified digestive organs [pancreas]
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
D3A.010-D3A.8	Benign neuroendocrine tumors
E05.80-E05.81	Other thyrotoxicosis
E22.0	Acromegaly and pituitary gigantism
E31.20-E31.23	Multiple endocrine neoplasia [MEN] syndrome
E34.0	Carcinoid syndrome
H47.49	Disorders of optic chiasm in (due to) other disorder
I85.11	Secondary esophageal varices with bleeding
K56.690-K56.699	Other intestinal obstruction

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K59.1	Functional diarrhea
K70.0-K75.9	Disease of liver [related bleeding esophageal varices
R19.7	Diarrhea, unspecified
Z85.841	Personal history of malignant neoplasm of brain
Z85.845	Personal history of malignant neoplasm of other parts of nervous tissue

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Medical Necessity Guidelines

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

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

Clinical Criteria:

B vs D Criteria: All drugs included in this PA are subject to B vs D evaluation. Medication must be furnished "incident to" physician service provided and usually not self-administered to be covered by Medicare and to be eligible to be evaluated through part B. If not, medication must be evaluated through part D.

Octreotide (Sandostatin® or Sandostatin LAR®)

A. Criteria For Initial Approval

i. Individual has a diagnosis of acromegaly; **AND**

ii. Diagnosis of acromegaly has been confirmed by, or in consultation with, a board-certified endocrinologist who has reviewed and verified the test results (including, but not limited to: Insulin-like Growth Factor 1 levels; Oral Glucose Tolerance Test with associated Growth Hormone (GH) levels) that are indicative of a positive test; **AND**

iii. Individual has had an inadequate response to any of the following:
A. Surgical resection; **OR**
B. Pituitary irradiation; **OR**
C. Bromocriptine mesylate at maximally tolerated doses;

OR

iv. Surgery and/or radiotherapy is not an option;

OR

v. Individual has a diagnosis of carcinoid tumors and is using for any of the following:
A. Metastatic carcinoid tumor to suppress or inhibit severe diarrhea and flushing episodes associated with the disease;

OR

vi. Individual has a diagnosis of neuroendocrine and adrenal tumors and is using for any of the following:
A. For the management of unresectable locoregional disease or distant metastasis (NCCN 2A); **OR**
B. For the treatment of profuse watery diarrhea associated with VIPomas; **OR**

C. Prophylactic treatment prior to surgery for gastrinoma (AHFS);

OR

vii. Individual is using for bleeding Gastroesophagel (GE) varices and the following criteria are met:
A. Gastroesophageal varices are associated with liver disease (Banares 2002, Corley 2001);
AND
B. Octreotide acetate is used in combination with endoscopic therapy or alone if endoscopic therapy is not immediately available (Garcia-Tsao 2007);

OR

viii. Individual is using for malignant bowel obstruction to manage gastrointestinal symptoms (e.g. nausea, pain, or vomiting) (AHFS);

OR

ix. Individual is using for thymic carcinoma or thymoma with or without prednisone (NCCN 2A);

OR

x. Individual is requesting Sandostatin LAR for meningiomas in central nervous system cancers (NCCN 2A); **AND**

xi. Individual has surgically inaccessible recurrent or progressive disease when radiation is not possible; **AND**

xii. Individual is using in combination with everolimus;

OR

xiii. Individual is requesting Sandostatin for rapid relief of symptoms or for breakthrough symptoms in individuals taking long-acting octreotide acetate when any of the criteria are met for the above uses (NCCN 2A).

B. Criteria For Continuation of Therapy

i. MMM considers continuation of octreotide agents (Sandostatin®, Sandostatin LAR®) therapy medically necessary in members requesting reauthorization for an indication listed in Section A above (Criteria for Initial Approval) if the following information is provided:
   a. Documentation of the patient's response to treatment showing no severe or life-threatening infusion reaction

C. Authorization Duration

i. Initial Approval Duration: Up to 12 months
ii. Reauthorization Approval Duration: Up to 12 months

D. **Conditions Not Covered**
Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive)

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i. Individual is using for the treatment of chylothorax; **OR**
ii. Individual is using for the treatment of diarrhea associated with acquired immunodeficiency disease; **OR**
iii. Individual is using for the treatment of gastrointestinal diseases (e.g. bleeding from vascular malformations, gastroparesis, pancreatitis, prevention of postoperative complications following pancreatic surgery, short bowel syndrome, or upper GI bleeding); **OR**
iv. Individual is using for the treatment of Graves' ophthalmopathy; **OR**
v. Individual is using for the treatment of hypothalamic obesity; **OR**
vi. Individual is using for the treatment of other carcinomas (e.g. advanced breast cancer, hepatocellular cancer, or prostate cancer); **OR**
vii. Individual is using for the treatment of polycystic kidney disease; **OR**
viii. When the above criteria are not met and for all other indications.

Limits or Restrictions

A. Therapeutic Alternatives

The list below includes preferred alternative therapies recommended in the approval criteria and may be subject to prior authorization.

N/A

B. Quantity Limitations

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines. The chart below includes dosing recommendations as per the FDA-approved prescribing information.

Use	Recommended Dosing Schedule
Sandostatin® Injection	
Acromegaly	• Initial dosage: 50 mcg subcutaneously three times daily for the first two weeks of therapy • Maintenance dosage: 100 – 500 mcg three times daily.
Carcinoid Tumors	• Initial dosage: 100 – 600 mcg subcutaneously daily in two to four divided doses during the initial 2 weeks of therapy. • In the clinical studies, the median daily maintenance dosage was approximately 450 mcg but clinical and biochemical benefits were obtained in some patients with as little as 50 mcg, while others required doses up to 1500 mcg/day. However, experience with doses above 750 mcg/day is limited.

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VIPomas	• Initial dosage: 200 – 300 mcg daily in two to four divided doses during the initial 2 weeks of therapy. • Dosage may be adjusted to achieve a therapeutic response, but usually doses above 450 mcg/day are not required.
Sandostatin® LAR Injection	
Acromegaly	• *Patients not currently receiving Sandostatin injection sc*: 50 mcg three times daily Sandostatin Injection subcutaneously for 2 weeks followed by SANDOSTATIN LAR DEPOT 20 mg intragluteally every 4 weeks for 3 months. • *Patients currently receiving Sandostatin injection sc*: 20 mg every 4 weeks for 3 months.
Carcinoid Tumors and VIPomas	• *Patients not currently receiving Sandostatin injection sc*: Sandostatin Injection subcutaneously 100 to 600 mcg/day in 2-4 divided doses for 2 weeks followed by SANDOSTATIN LAR DEPOT 20 mg every 4 weeks for 2 months. • *Patients currently receiving Sandostatin injection sc*: 20 mg every 4 weeks for 2 months.
Exceptions for Sandostatin® LAR	
○ Renal Impairment, Patients on Dialysis: 10 mg every 4 weeks. ○ Hepatic Impairment, Patients with Cirrhosis: 10 mg every 4 weeks. ○ Quantity limits: ○ Sandostatin LAR (octreotide) Depot Kit 20 mg: 2 kits per 28 days ○ Sandostatin LAR (octreotide) Depot Kit 10 mg, 30 mg: 1 kit per 28 days	

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Reference Information

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Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.

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Policy History

Revision Type	Summary of Changes	P&T Approval Date	UM/CMPC Approval Date
Annual Review	○ Update prior 2A recommendation from NCCN for use with Sandostatin LAR product in CNS Meningiomas. Wording and formatting. Coding Reviewed: Updated HCPCS coding description for J2353 to clarify product is Sandostatin LAR depot; updated coding description for J2354 to clarify product is Sandostatin. Added ICD-10-CM D32.0-D32.9. ○ Add NCCN 2A criteria for combination use with everolimus for CNS meningiomas. Wording and formatting updates. ○ Removed obsolete agent, Bynfezia. Wording and formatting changes. Coding Reviewed: Removed Bynfezia from HCPCS J2354.	11/18/2024	12/17/2024
Policy Inception	Elevance Health's Medical Policy adoption.	N/A	11/30/2023

Revised: 10/11/2024.