Octreotide
Sandostatin® SC/IV,
Sandostatin LAR Depot®

Place of Service

Sandostatin® SC / IV
HCPCS: J2354 per 25 mcg

Hospital Administration
Outpatient Facility Infusion Administration
Home Infusion Administration
Self-Administration (SC only)
Infusion Center Administration

Sandostatin LAR Depot® - IM only
HCPCS: J2353 per 1 mg

Hospital Administration
Outpatient Facility Infusion Administation
Home Infusion Administration
Infusion Center Administration
Office Administration

Conditions listed in policy (*see criteria for details*)

- Acromegaly
- AIDS-associated diarrhea
- Bleeding esophageal varices
- Carcinoid syndrome
- Chemotherapy-induced diarrhea
- Cryptosporidiosis
- Dumping syndrome
- Lymphorrhagia
- Malignant intestinal obstruction
- Neuroendocrine tumors: GI Tract, Lung, and Thymus
- Neuroendocrine tumors of the pancreas
- Pancreatitis, necrotizing
- Pheochromocytoma and paraganglioma, advanced
- Pituitary adenomas (TSH-secreting)
- Polycystic Ovary Syndrome (PCOS)
- Prevention of postoperative complications of pancreatic surgery
- Radiation-induced diarrhea
- Recurrent meningioma
- Thymoma
- Vasoactive intestinal peptide tumors
- Zollinger-Ellison syndrome

AHFS therapeutic class: Endocrine metabolic agent somatostatin (class)

Mechanism of action: Octreotide is a synthetic polypeptide structurally and pharmacologically related to somatostatin (growth hormone [somatropin] release inhibiting factor).

(1) Special Instructions and Pertinent Information

Sandostatin given by subcutaneous (SC) injection is managed under the outpatient Pharmacy Benefit, **for self-administration.** Please contact the member's Pharmacy Benefit for information on how to obtain this drug.

To submit a request to for SC Sandostatin under the Medical Benefit, please submit clinical information for prior authorization review and include medical rationale why the patient cannot self-administer this drug in the home.

For plans with self-injectables under the Medical Benefit, please submit clinical information for prior authorization review via fax.

Sandostatin LAR (given as an intramuscular injection) is managed under the Medical Benefit, please submit clinical information for prior authorization review via fax.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for octreotide (Sandostatin®, Sandostatin LAR®) NOT listed in section 3 must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Acromegaly

1. Being prescribed by or recommended by an endocrinologist

Covered Doses
Sandostatin IV or SC: Up to 1500 mcg per day
Sandostatin LAR Depot IM: Up to 40 mg IM every 4 weeks

Coverage Period
Sandostatin IV or SC:
Initial: 2 weeks then reassess response
Maintenance: Every 6 months depending on patient response

Sandostatin LAR Depot IM
Cover indefinitely

ICD-10:
E22.0, E34.4

AIDS– associated diarrhea

1. Patient is currently stable on an anti-retroviral therapy (ART) regimen for ≥ 1 month, **AND**
2. Provider attestation for infectious cause for diarrhea symptoms or other treatable causes (e.g. malabsorption, underlying GI disease requiring treatment) have been ruled out), **AND**
3. Patient has inadequate response, intolerance, or contraindication to regular use of generic Lomotil or loperamide (OTC), **AND**
4. Patient has inadequate response, intolerance or contraindication to Mytesi (crofelemer)

Covered Doses
Sandostatin IV or SC: Up to 1800 mcg/day
Sandostatin LAR IM: Up to 40 mg every 4 weeks

Coverage Period
Yearly dependent upon patient response

ICD-10:
K52.2, K52.89, R19.7 + HIV infection B20 or B97.35

Bleeding esophageal varices

Covered Doses
Sandostatin IV or SC: Up to 600 mcg/day
Sandostatin LAR IM: Up to 40 mg every 4 weeks

Coverage Period
Yearly

ICD-10:
I85.01-I85.11

Carcinoid syndrome

Covered Doses
Sandostatin IV or SC: Up to 1500 mcg/day
Sandostatin LAR IM: Up to 40 mg every 4 weeks

Coverage Period
Yearly

ICD-10:
E34.0

Chemotherapy-induced diarrhea- treatment

Covered Doses
Sandostatin IV or SC: Up to 600 mcg/day
Sandostatin LAR IM: Up to 40 mg every 4 weeks

Coverage Period
Yearly

ICD-10:
Encounter Code for Chemotherapy Z51.11 + Diarrhea K52.2, K52.89, R19.7;
or
J9XXX + K52.2, K52.89, R19.7

Cryptosporidiosis

Covered Doses
Sandostatin IV or SC: Up to 900 mcg/day

Coverage Period
Yearly

ICD-10:
A07.2

Dumping syndrome

Covered Doses
Sandostatin IV or SC: Up to 600 mcg/day

Coverage Period
Yearly

ICD-10:
K91.1

Lymphorrhagia

Covered Doses
Sandostatin IV or SC: Up to 300 mcg/day

Coverage Period
Yearly

ICD-10:
R59

Malignant intestinal obstruction

Covered Doses
Sandostatin IV or SC: up to 300 mcg/ day[1,2]
Sandostatin LAR IM: Up to 40 mg every 4 weeks

Coverage Period
Yearly

ICD-10:
K50.012-K56.69

Neuroendocrine tumors: GI Tract, Lung, and Thymus

Covered Doses
Sandostatin IV or SC: up to 1500 mcg/ day
Sandostatin LAR IM: Up to 40 mg every 4 weeks

Coverage Period
Yearly

ICD-10:
C7A.010-012, C7A.019, C7A.029, C7A.020-026, C7A.00, C7A.090-096, C7A.098, C7A.1, C7A.8, D3A.019, D3A.010-12, D3A.029, D3A.020-026, D3A.00, D3A.8, D3A.090-092, D3A.094-096, C7B.00-04, C7B.09, C7B.8, E34.0, Z85.020, Z85.030, Z85.040, Z85.060, Z85.110, Z85.230, Z85.520, Z85.821

Neuroendocrine tumors of the pancreas

Covered Doses
Sandostatin IV or SC: up to 750 mcg/ day
Sandostatin LAR IM: Up to 40 mg every 4 weeks

Coverage Period
Yearly

ICD-10:
C25.4, E08.649, E16.0, E16.1, E16.3, E16.8, Z85.068, Z85.07, Z85.09, Z85.858, Z85.020, Z85.030, Z85.040, Z85.060, Z85.110, Z85.230, Z85.520, Z85.821

Pancreatitis, necrotizing

Covered Doses
Sandostatin IV or SC: up to 300 mcg/ day[3]

Coverage Period
Yearly

ICD-10:
K85.91, K85.92

Pheochromocytoma and paraganglioma, advanced

1. Diagnosis of unresectable, locally advanced, or metastatic pheochromocytoma or paraganglioma, **AND**
    2. Somatostatin receptor positive imaging and symptomatic

Covered Doses
Sandostatin SC:
Up to 250 mcg SC three times a day
Sandostatin LAR:
Up to 30 mg IM every 4 weeks

Coverage Period
Indefinite

ICD-10:
C74.10-C74.12, C74.90-C74.92, C75.5, C7B.8, Z85.858

Pituitary adenomas (TSH-secreting)

Covered Doses
Sandostatin IV or SC: up to 1500 mcg/ day[3,4]
Sandostatin LAR IM: Up to 40 mg every 4 weeks

Coverage Period
Yearly

ICD-10:
E23.6

Polycystic Ovary Syndrome (PCOS)

Covered Doses
Sandostatin IV or SC: up to 300 mcg/ day

Coverage Period
Yearly

ICD-10:
E28.2

Prevention of postoperative complications

1. Being used to prevent complications of pancreatic surgery, (i.e., abscess formation, sepsis, acute pancreatitis, pancreatic fistula, and peripancreatic fluid collection

Covered Doses
Sandostatin IV or SC:
Up to 300 mcg per day

Coverage Period
Sandostatin IV or SC:
Initial: 2 weeks then reassess response
Maintenance: Every 6 months depending on patient response

ICD-10:
BF1, 0DB, 0DJ, 0WJ, 0F1, 0F5, 0F7, 0F8, 0F9, 0FB, 0FC, 0FF, 0FH, 0FJ, 0FL, 0FM, 0FP-0FW

Radiation-induced diarrhea

Covered Doses
Sandostatin IV or SC: up to 600 mcg/ day[9]
Sandostatin LAR: Up to 30 mg IM every 4 weeks

Coverage Period
Yearly

ICD-10:

Encounter for radiotherapy Z51.0, with
Diarrhea: K52.2, K52.89, R19.7 or Effects of radiation, unspecified: T66XXXA

Recurrent meningioma

Covered Doses
Sandostatin IV or SC: up to 1500 mcg/ day[7,8]
Sandostatin LAR: Up to 30 mg IM every 4 weeks

Coverage Period
Yearly

ICD-10:
C70.0, C70.1, C70.9, D32.0, D32.1, D32.9, D72.0, D42.0, D42.1, D42.9, Z85.841, Z85.848

Thymoma

1. Diagnosis of refractory thymoma, **AND**
2. Used after failure of prior chemotherapy

Covered Doses
Sandostatin IV or SC: Up to 1500 mcg per day
Sandostatin LAR Depot given IM: Up to 40 mg every 4 weeks

Coverage Period
Sandostatin IV or SC: Cover 2 weeks, then reassess patient response
Sandostatin LAR Depot given IM: Cover 2 months, then reassess patient response

Maintenance (Sandostatin/Sandostatin LAR):
Every 6 months dependent upon patient response

ICD-10:
C37, C7A.091, D15

Vasoactive intestinal peptide tumors

Covered Doses
Sandostatin IV or SC: up to 1500 mcg/ day
Sandostatin LAR IM: Up to 40 mg every 4 weeks

Coverage Period
Yearly

ICD-10:
C26.9

Zollinger-Ellison syndrome

Covered Doses
Sandostatin IV or SC: up to 500 mcg/ day

Coverage Period
Yearly

ICD-10:
D3A.092, E16.4

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for octreotide (Sandostatin®, Sandostatin LAR®) must be sent for clinical review and receive authorization prior to drug administration or claim payment. See table below.

(4) This Medication is NOT medically necessary for the following condition(s)

Blue Shield's research indicates there is inadequate clinical evidence to support off-label use of this drug for the following conditions (Health and Safety Code 1367.21):

- Cardiomyopathy
- Diarrhea-Graft vs. Host Disease
- Gastrointestinal Fistula
- Grave's Disease
- Hypercalcemia
- Mccune-Albright Syndrome
- Mesenteric Angina
- Microsporidiosis
- Migraine Headache
- Neonatal Hypoglycemia
- Non-malignant intestinal obstruction
- Pancreatic Pseudocyst
- Peptic Ulcer Disease
- Postprandial Hypoglycemia
- Postprandial Hypotension
- Prolactinoma
- Quinine-Induced Hyperinsulinemia
- Retinal Edema
- Scintigraphy
- Scleroderma
- Tall Stature

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information

(5) Additional Information

How supplied:

Sandostatin SC

1-mL ampuls in 3 strengths, containing 50, 100, or 500 mcg octreotide and sterile 5-mL multi-dose vials in 2 strengths, containing 200 and 1000 mcg/mL of octreotide

Sandostatin LAR

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.

Intestinal obstruction

- Octreotide has been used in 3 patients with chronic intestinal pseudo-obstruction secondary to Sjogren's Syndrome, Systemic Lupus Erythematous, and Systemic Sclerosis.[1]
- Octreotide has also been used in controlling vomiting in 13 patients with bowel obstruction associated with terminal ovarian cancer.[2]
- At least four small randomized trials concluded that octreotide is superior (in reducing nausea and decreasing secretions more rapidly) to an anticholinergic agent alone

(typically scopolamine [hyoscine]) for symptomatic management of malignant bowel obstruction[10-13]

(6) References

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(7) Policy Update

Date of last revision: 1Q2022
Date of next review: 4Q2022
Changes from previous policy version:

- No clinical change to policy following revision.

BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee