
Prior Authorization DRUG Guidelines

**SANDOSTATIN®; SANDOSTATIN LAR®
(Octreotide)**

Effective Date: 7/28/05

Date Developed: 7/11/05 by C. Wilhelmy MD

Last Approval Date: 1/26/16, 1/24/17, 1/23/18, 1/22/19

Octreotide is an antidiarrheal Somatostatin Analog. It mimics natural somatostatin by inhibiting serotonin release, and the secretion of gastrin, VIP, insulin, glucagon, secretin, motilin, and pancreatic polypeptide. It decreases growth hormone and IGF-1 in acromegaly.

Pre-Authorization Criteria:

Octreotide is used for control of symptoms in patients with metastatic carcinoid and vasoactive intestinal peptide-secreting tumors (VIPomas); pancreatic tumors, gastrinoma, secretory diarrhea, and acromegaly. Other unlabeled or investigational uses include AIDS-associated secretory diarrhea, control of bleeding of esophageal varices, breast cancer, cryptosporidiosis, Cushing's syndrome, insulinomas, small bowel fistulas, postgastrectomy dumping syndrome, chemotherapy-induced diarrhea, graft-versus-host disease (GVHD) induced diarrhea, Zollinger-Ellison syndrome, and congenital hyperinsulinism.

VCHCP authorizes use of this drug for the above documented indications.

Approved Indications and Usage Guidelines:

Octreotide may be used for any one of the following conditions:

- Treatment of acromegaly
- For management of gastrointestinal neuroendocrine tumors (NETs), such as **any** of the following:
 - Treatment of severe diarrhea and flushing episodes associated with carcinoid tumors; or
 - Prophylactic treatment to prevent carcinoid crises prior to surgery for carcinoid tumor; or

- To reverse life-threatening hypotension due to carcinoid crisis during induction of anesthesia; or
 - For the treatment of the profuse watery diarrhea associated with vasoactive intestinal polypeptide-secreting tumors (VIPomas); or
 - Prophylactic treatment prior to surgery for functioning gastrinoma (Zollinger Ellison syndrome); or
 - Prophylactic treatment prior to hepatic artery embolization for nonresectable multiple and hormone-secreting neuroendocrine tumors
- Stabilization of blood glucose levels in persons with functioning islet cell tumors (insulinomas or glucagonomas);
 - To reduce the incidence and severity of the postoperative complications of high-risk pancreatic surgery;
 - Treatment of chemotherapy and/or radiation therapy-induced diarrhea when oral anti-diarrheal medications such as loperamide have become ineffective;
 - Treatment of severe secretory diarrhea associated with acquired immunodeficiency syndrome (AIDS) when anti-microbial or anti-motility agents have become ineffective;
 - Treatment of acute bleeding and early rebleeding of gastroesophageal varices associated with cirrhosis when used in conjunction with endoscopic band ligation or sclerotherapy or alone, if ligation/sclerotherapy is not immediately available;
 - Treatment of unresectable malignant thymoma that is refractory to standard chemotherapy,
 - To reduce output from gastrointestinal (GI) or pancreatic fistulas,
 - Management of persons with short bowel syndrome if daily intravenous fluid requirements are greater than 3 liters,
 - Management of gastrointestinal symptoms (e.g. nausea, vomiting, and pain) of inoperable bowel obstruction in persons with far advanced cancer,
 - Thyroid stimulating hormone (TSH) hypersecretion due to TSH secreting adenoma,
 - Dumping syndrome following gastric resection refractory to dietary changes and the addition of fiber

DOSING: ADULTS — Dosing is complex. Refer to PDR for latest recommendations.

DOSING: PEDIATRIC — Infants and Children:

Diarrhea: I.V., SubQ: Doses of 1-10 mcg/kg every 12 hours have been used in children beginning at the low end of the range and increasing by 0.3 mcg/kg/dose at 3-day intervals. Suppression of growth hormone (animal data) is of concern when used as long-term therapy.

DOSING: ELDERLY — Refer to adult dosing.

DOSING: RENAL IMPAIRMENT — Half-life may be increased, requiring adjustment of maintenance dose.

DOSAGE FORMS

Injection, microspheres for suspension, as acetate [depot formulation] (Sandostatin LAR®): 10 mg, 20 mg, 30 mg [with diluent and syringe]

Injection, solution, as acetate (Sandostatin®): 0.05 mg/mL (1 mL); 0.1 mg/mL (1 mL); 1.2 mg/mL (5 mL); 0.5 mg/mL (1 mL); 1 mg/mL (5 mL)

CONTRAINDICATIONS — Hypersensitivity to octreotide or any component of the formulation.

WARNINGS / PRECAUTIONS — Dosage adjustment may be required to maintain symptomatic control; insulin requirements may be reduced as well as sulfonylurea requirements. Monitor patients for cholelithiasis. Use with caution in patients with renal impairment. Somatostatin analogs may affect glucose regulation; in type I diabetes, severe hypoglycemia may occur; in type II diabetes or nondiabetic patients, hyperglycemia may occur.

- Abnormal Schillings test: Chronic treatment has been associated with abnormal Schillings test; monitor vitamin B 12 levels.
- Hypothyroidism: Suppresses secretion of TSH; monitor for hypothyroidism.
- Pancreatitis: May alter absorption of dietary fats; monitor for pancreatitis.
- Cardiovascular disease: Use with caution in patients with heart failure or concomitant medications that alter heart rate or rhythm; bradycardia, conduction abnormalities and arrhythmia have been associated with acromegalic patients.
- Growth Hormone secreting tumors: Tumors which secrete growth hormone may increase in size; monitor.
- Renal impairment: Use with caution in patients with renal impairment; may require dose adjustment.
- QTc-prolonging agents: Octreotide may enhance the adverse/toxic effects of other QTc-prolonging agents.

DRUG INTERACTIONS — Multiple drug-drug interactions have been reported. Consult Lexi-Interact™ Drug Interactions Program for more information.

PREGNANCY RISK FACTOR — B

LACTATION — Enters breast milk/contraindicated

DIETARY CONSIDERATIONS — Schedule injections between meals to decrease GI effects.

REFERENCES

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 4. Jaros, W, Biller, J, Greer, S, et al. Successful Treatment of Idiopathic Secretory Diarrhea of Infancy With the Somatostatin Analogue SMS 201-995. Gastroenterology 1988; 94:189.
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 6. Katz, MD, Erstad, BL. Octreotide, A New Somatostatin Analogue. Clin Pharm 1989; 8:255.
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Revision History:

Date Reviewed/Updated: 7/31/08 by W. Rosario, M.D

Date Revised: 10/17/11 by A. Reeves MD

Date Reviewed/No Updates: 4/2/12; 1/16/13 by A. Reeves, MD

Date Approved by P&T Committee: 7/28/05; 10/27/08; 10/25/11; 4/24/12; 1/29/13

Date Reviewed/No Updates: 1/28/14 by C. Sanders MD Date

Approved by P&T Committee: 1/28/14

Date Reviewed/No Updates: 1/13/15 by C. Sanders, MD

Date Approved by P&T Committee: 1/27/15

Date Reviewed/No Updates: 1/26/16 by C. Sanders, MD; R. Sterling, MD

Date Approved by P&T Committee: 1/26/16

Date Reviewed/No Updates: 1/24/17 by C. Sanders, MD; R. Sterling, MD

Date Approved by P&T Committee: 1/24/17

Date Reviewed/No Updates: 1/23/18 by C. Sanders, MD; R. Sterling, MD

Date Approved by P&T Committee: 1/23/18

Date Reviewed/No Updates: 1/22/19 by C. Sanders, MD; R. Sterling, MD
Date Approved by P&T Committee: 1/22/19

Revision Date	Content Revised (Yes/No)	Contributors	Review/Revision Notes
1/24/17	No	Catherine Sanders, MD; Robert Sterling, MD	Annual review
1/23/18	No	Catherine Sanders, MD; Robert Sterling, MD	Annual review
1/22/19	No	Catherine Sanders, MD; Robert Sterling, MD	Annual review