Octreotide Acetate Long-Acting Dosage Form (Sandostatin® LAR)

NDC CODE(S)
00078-0797-XX SANDOSTATIN LAR DEPOT 20MG Powder for Suspension (NOVARTIS)
00078-0804-XX SANDOSTATIN LAR DEPOT 30MG Suspension Reconstituted (NOVARTIS)
00078-0811-XX SANDOSTATIN LAR DEPOT 10MG Kit (NOVARTIS)
00078-0818-XX SANDOSTATIN LAR DEPOT 20MG Kit (NOVARTIS)
00078-0825-XX SANDOSTATIN LAR DEPOT 30MG Kit (NOVARTIS)
00078-0790-XX SANDOSTATIN LAR DEPOT 10MG Suspension Reconstituted (NOVARTIS)

DESCRIPTION

Octreotide acetate is a synthetic analogue of the natural hormone somatostatin. More potent than the natural hormone, it inhibits the release of growth hormone, glucagon, and insulin. It also suppresses the response of luteinizing hormone (LH) to gonadal releasing hormone (GnRH), decreases splanchnic blood flow and inhibits the release of serotonin, gastrin, vasoactive intestinal peptide, secretin, motilin and pancreatic polypeptide.

By confining octreotide in microspheres of the biodegradable glucose star polymer, D, L-lactic and glycolic acids copolymer, it maintains all of the pharmacological characteristics of immediate release octreotide but adds the feature of slow release as the polymer biodegrades, primarily through hydrolysis. This allows less frequent administration, generally once every four weeks. It is designed to be injected intramuscularly (intragluteally) for long-acting repeatable dosage.

POLICY

- Octreotide acetate, long-acting dosage form, for the treatment of the following is considered ***medically necessary*** if the medical appropriateness criteria are met. **(See Medical Appropriateness below.)**
  - Acromegaly
  - Carcinoid tumors/Neuroendocrine tumors
  - Thymomas and thymic carcinomas
- Octreotide acetate, long-acting dosage form for the treatment of diarrhea associated with vasoactive intestinal peptide tumors (VIPomas) is considered medically necessary if the medical appropriateness criteria are met. **(See Medical Appropriateness below.)**
- Octreotide acetate, long-acting dosage form for the treatment of other conditions/diseases is considered ***investigational.***

MEDICAL APPROPRIATENESS

INITIAL APPROVAL CRITERIA

- Patient is at least 18 years of age; **AND**
- Patient is being treated with octreotide acetate subcutaneously for at least 2 weeks and has shown a response and no adverse effects prior to starting therapy with the LAR formulation; **AND**

Carcinoid tumors/Neuroendocrine tumors (e.g., Gastrointestinal Tract, Lung, Thymus, Pancreas, Adrenal)

- Patient has severe diarrhea/flushing episodes (carcinoid syndrome)
- Used to treat symptoms related to hormone hypersecretion in neuroendocrine tumors of the pancreas; **AND**
  - Patient has a gastrinoma, glucagonoma, or VIPoma; **OR**
- Use as primary treatment of unresected primary gastrinoma; **OR**

- Used for locoregional unresectable bronchopulmonary or thymic disease as primary therapy or as subsequent therapy if progression on first-line therapy (including disease progression on prior treatment with octreotide LAR in patients with functional tumors); **AND**
  - Used for management of hormone symptoms and/or somatostatin receptor positive disease determined by imaging (i.e., 68Ga-dotatate imaging PET/CT or PET/MRI or somatostatin receptor scintigraphy [octreotide scan]); **OR**
- Patient has distant metastatic bronchopulmonary or thymic disease; **AND**
  - Used for somatostatin receptor positive disease and/or symptomatic hormonal disease if clinically significant tumor burden and low grade (typical) histology OR evidence of progression OR intermediate grade (atypical histology); **AND**
    - Used as primary therapy or as subsequent therapy if progression on first-line therapy (including disease progression on prior treatment with octreotide LAR in patients with functional tumors); **OR**
  - Used for somatostatin receptor positive disease and/or hormonal symptoms if asymptomatic with low tumor burden and low grade (typical) histology); **OR**
  - Used for somatostatin receptor positive disease and/or chronic cough/dyspnea that is not responsive to inhalers with multiple lung nodules or tumorlets and evidence of diffuse idiopathic pulmonary neuroendocrine cell hyperplasia (DIPNECH); **OR**
- Used for the management of locoregional advanced or distant metastatic disease of the gastrointestinal tract; **AND**
  - Patient is asymptomatic with a low tumor burden; **OR**
  - Patient with a clinically significant tumor burden; **OR**
  - Patient has disease progression and is not already receiving octreotide LAR; **OR**
  - Patient has disease progression with functional tumors and will be continuing treatment with octreotide LAR; **OR**
- Used for tumor control of locoregional advanced and/or distant metastatic neuroendocrine tumors of the pancreas (*****NOTE**: for insulinoma ONLY, patient must have somatostatin-receptor positive disease); **AND**
  - Patient is asymptomatic with a low tumor burden and stable disease; **OR**
  - Patient is symptomatic; **OR**
  - Patient has a clinically significant tumor burden; **OR**
  - Patient has clinically significant progression and is not already receiving octreotide LAR; **OR**
- Patient has pheochromocytoma or paraganglioma; **AND**
  - Patient has symptomatic locally unresectable somatostatin receptor-positive disease; **OR**
  - Patient has distant metastatic disease

Diarrhea associated with Vasoactive Intestinal Peptide tumors (VIPomas)

- Patient has profuse watery diarrhea

Acromegaly

- Patient diagnosis confirmed by elevated (age-adjusted) or equivocal serum IGF-1 as well as inadequate suppression of GH after a glucose load; **AND**
- Patient has documented inadequate response to surgery and/or radiotherapy or it is not an option for the patient; **AND**
- Used as long-term maintenance therapy; **AND**
- Patient's tumor has been visualized on imaging studies (i.e., MRI or CT-scan); **AND**
- Baseline growth hormone (GH) and IGF-1 blood levels (renewal will require reporting of current levels)

Thymic Carcinomas/Thymomas

- Used with or without prednisone therapy; **AND**
  - Used as first line therapy or postoperative treatment, in patients who are unable to tolerate first-line combination regimens; **OR**
  - Used as second-line therapy for unresectable or metastatic disease

RENEWAL CRITERIA

- Patient continues to meet indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in the Initial Approval Criteria; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: cholelithiasis and complications of cholelithiasis (i.e. cholecystitis, cholangitis, pancreatitis), hyperglycemia, hypoglycemia, hypothyroidism, sinus bradycardia, cardiac arrhythmias, cardiac conduction abnormalities, depressed vitamin B12 levels, etc.; **AND**
- Disease response with improvement in patient's symptoms including reduction in symptomatic episodes (such as diarrhea, rapid gastric dumping, flushing, bleeding, etc.) and/or stabilization of glucose levels and/or decrease in size of tumor or tumor spread; **OR**
  - **Acromegaly ONLY**: Disease response as indicated by an improvement in signs and symptoms compared to baseline; **AND**
    - Reduction of growth hormone (GH) from pre-treatment baseline; **OR**
    - Age-adjusted normalization of serum IGF-1; **OR**
  - **Neuroendocrine tumors (gastrointestinal tract, bronchopulmonary, thymus, or pancreas) ONLY:** Patient has had disease progression and therapy will be continued in patients with functional tumors.

DOSAGE/ADMINISTRATION

INDICATION	DOSE
Acromegaly	20 mg intramuscularly every 4 weeks for 3 months • After 3 months of therapy, doses may be adjusted as follows (not to exceed 40 mg every 4 weeks): ○ GH ≤ 2.5 ng/mL, IGF-1 normal, and clinical symptoms controlled: maintain SANDOSTATIN LAR DEPOT dosage at 20 mg every 4 weeks; **OR** ○ GH > 2.5 ng/mL, IGF-1 elevated, and/or clinical symptoms uncontrolled, increase SANDOSTATIN LAR DEPOT dosage to 30 mg every 4 weeks; **OR** ○ GH ≤ 1 ng/mL, IGF-1 normal, and clinical symptoms controlled, reduce SANDOSTATIN LAR DEPOT dosage to 10 mg every 4 weeks; **OR** ○ 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
Carcinoid Tumors, Neuroendocrine Tumors, and VIPomas	20 mg intramuscularly every 4 weeks for 2 months • After 2 months of therapy, doses may be adjusted as follows (not to exceed 30 mg every 4 weeks): ○ If symptoms are not adequately controlled, increase the dose to 30 mg every 4 weeks; **OR** ○ If good control has been achieved on a 20 mg dose, the dose may be lowered to 10 mg for a trial period; if symptoms recur, increase the dose to 20 mg every 4 weeks
Thymic Carcinoma /Thymoma	20 mg intramuscularly every 14 days
**Renal impairment (patients on dialysis) and hepatic impairment (patients with cirrhosis): starting dose of 10mg every 4 weeks VI.*	

LENGTH OF AUTHORIZATION

Coverage is provided for six months and may be renewed.

DOSING LIMITS

Max Units (per dose and over time) [HCPCS Unit]:

- Acromegaly: 40 units every 28 days
- Carcinoid Tumors, Neuroendocrine Tumors, and VIPomas: 30 units every 28 days
- Thymic Carcinoma/Thymoma: 20 units every 14 days

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the Medical Policy and a health plan, the express terms of the health plan will govern.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

SOURCES

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4. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for Octreotide acetate (LAR). National Comprehensive Cancer Network, 2021. The NCCN Compendium® is a derivative work of the NCCN Guidelines® NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed March 2021.

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EFFECTIVE DATE 8/31/2021

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