Octreotide Acetate Long-Acting Dosage Form

00078-0804-xx SANDOSTATIN LAR DEPOT 30 MG PDR (NOVARTIS PHARMACEUTICALS CORP.)
00078-0811-XX SandoSTATIN LAR Depot 10 MG KIT (NOVARTIS)
00078-0818-XX SandoSTATIN LAR Depot 20 MG KIT (NOVARTIS)
00078-0825-XX SandoSTATIN LAR Depot 30 MG KIT (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 (intraglutely) 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
  - Meningiomas
  - Neuroendocrine (i.e., carcinoid) 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

- Octreotide acetate, long-acting dosage form, is considered medically appropriate if ALL of the following criteria are met:
  - Individual is 18 years of age or older
  - Individual will be initiating or are currently receiving octreotide acetate subcutaneously for at least 2 weeks with no adverse effects prior to starting therapy with the LAR formulation
  - Diagnosis of acromegaly with ALL of the following:
    - Diagnosis confirmed by elevated (age-adjusted) or equivocal serum IGF-1 as well as inadequate suppression of GH after a glucose load
    - Individual has documented inadequate response to surgery and/or radiotherapy or it is not an option for the individual
    - Individual’s tumor has been visualized on imaging studies (i.e., MRI or CT-scan)
Baseline growth hormone (GH) and IGF-I (somatomedin C) blood levels (renewal will require reporting of current levels)

- Diagnosis of meningioma for ALL of the following:
  - Disease is unresectable
  - Individual has recurrent or progressive meningioma
  - Radiation treatment is not possible
  - Individual's disease is octreotide scan positive

- Diagnosis of neuroendocrine/carcinoid tumors (e.g. GI tract, lung, thymus, pancreas and adrenal) tumors and ANY ONE of the following:
  - Symptoms of carcinoid syndrome (severe diarrhea/flushing episodes)
  - Used to treat symptoms related to hormone hypersecretion in pancreatic tumors (e.g., gastrinoma, glucagonoma, VIPoma)
  - Primary treatment of unresected primary gastrinoma
  - Used for locoregional unresectable bronchopulmonary or thymic disease as primary therapy for low grade (typical) histology or as subsequent therapy if progression on first-line therapy and is 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])
  - Individual has distant metastatic bronchopulmonary or thymic disease and used as primary therapy or as subsequent therapy if progression on first line therapy and ANY ONE of the following:
    - 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)
    - Used for somatostatin receptor positive disease and/or hormonal symptoms if asymptomatic with low tumor burden and low grade (typical histology)
    - Used for somatostatin receptor positive disease and/or chronic cough/dyspnea with multiple lung nodules or tumorlets and evidence of diffuse idiopathic pulmonary neuroendocrine cell hyperplasia (DIPNECH)
    - Used for the management of locoregional advanced or metastatic disease of the gastrointestinal tract
    - Used for tumor control of locally advanced and/or metastatic tumors of the pancreas (for insulinoma ONLY, individual must have somatostatin-receptor positive disease)
    - Used for unresectable or metastatic pheochromocytoma or paraganglioma if somatostatin receptor-positive and symptomatic
      - Diarrhea associated with vasoactive intestinal peptide tumors (VIPomas) [pancreatic neuroendocrine (islet cell) tumor, insulinoma, glucagonoma, somatostatinoma, and gastrinoma] and individual has profuse watery diarrhea
      - Thymomas and Thymic carcinomas as second-line therapy with or without prednisone for unresectable or metastatic disease

RENEWAL CRITERIA

- Octreotide acetate, long-acting dosage form, is considered medically appropriate for renewal if ALL of the following:
  - Individual continues to meet initial approval criteria
  - Absence of unacceptable toxicity from the agent, Examples of unacceptable toxicity include the following: biliary tract abnormalities, hypothyroidism, goiter, sinus bradycardia, cardiac arrhythmias, cardiac conduction abnormalities, pancreatitis, etc.
  - Individual exhibits ANY ONE of the following:
    - 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 or decrease in size of tumor or tumor spread
Diagnosis of acromegaly if disease response is indicated by an improvement in signs and symptoms compared to baseline and ANY ONE of the following:
- Reduction of growth hormone level by random testing to < 1.0 mcg/L
- Age-adjusted normalization of serum IGF-1
- Diagnosis of neuroendocrine tumors of the gastrointestinal tract, bronchopulmonary, thymus or pancreas (ONLY) and individual has had disease progression and therapy will be continued in individuals with functional tumors

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<tr>
<th>INDICATION(S)</th>
<th>DOSAGE &amp; ADMINISTRATION</th>
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<tbody>
<tr>
<td>Acromegaly</td>
<td>20 mg intramuscularly every 4 weeks (after 3 months of therapy, doses may be titrated up if required with a maximum dose of 40 mg every 4 weeks)</td>
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<tr>
<td>Carcinoid Tumors and VIPomas</td>
<td>20 mg intramuscularly every 4 weeks (after 2 months of therapy, doses may be titrated up if required with a maximum dose of 40 mg every 4 weeks)</td>
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<tr>
<td>All Other Indications</td>
<td>Up to 40 mg intramuscularly every 28 days</td>
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*Renal impairment (patients on dialysis) and hepatic impairment (patients with cirrhosis): starting dose of 10mg every 4 week

LENGTH OF AUTHORIZATION

Coverage is provided for six months and may be renewed.

Refer to DOSAGE LIMITS below

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**


Lexi-Comp Online. (2019). AHFS DI. Octreotide acetate. Retrieved May 1, 2019 from Lexi-Comp Online with AHFS.


**EFFECTIVE DATE**

8/30/2019

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