DR.008.C Sandostatin® LAR Depot (octreotide acetate)

Original Implementation Date : 10/01/2020
Version [C] Date : 05/21/2025
Last Reviewed Date: 05/21/2025

PRODUCT VARIATIONS

This policy applies to all Jefferson Health Plans/Health Partners Plans lines of business unless noted below.

POLICY STATEMENT

Sandostatin® LAR Depot (octreotide acetate) is covered and considered medically necessary when all the prior authorization criteria listed in this policy are met.

FDA APPROVED INDICATIONS

- Sandostatin® LAR is a somatostatin analogue indicated for treatment of Acromegaly.
- Sandostatin® LAR is a somatostatin analogue indicated for treatment of severe diarrhea/flushing episodes associated with metastatic carcinoid Tumors.
- Sandostatin® LAR is a somatostatin analogue indicated for treatment of Profuse watery diarrhea associated with VIP-secreting tumors.

OFF-LABEL USE

Authorization for off-labeled use of medication will be evaluated on an individual basis. Review of an off-labeled request by the Medical Staff will be predicated on the appropriateness of treatment and full consideration of medical necessity. For off-label use Medical Directors will review scientific literature and local practice patterns. Medical Directors will review all the provided documentation to assure that:

1. The diagnosis of the disorder is reasonably certain and based on a thorough history and examination and appropriate laboratory testing (such as imaging studies, X ray, CT scan, MRI, PET scan, serum tests, and biopsy findings).

2. Previous treatment failures are documented (when applicable).

3. The requested dose and interval of administration are consistent with recommendations in peer-reviewed literature and professional guidelines for the requested indication.

4. Once treatment is initiated, there is an adequate documentation of improvement for continued treatment to be medically necessary. An objective, quantitative assessment to monitor the progress is required, when applicable.

5. Depending on the diagnosis and clinical response, the dose can be gradually adjusted. In some cases, the drug can be discontinued.

Off-Labeled use includes the following (not an all-inclusive list):

- AIDS - Diarrhea
- Bleeding esophageal varices
- Chylothorax
- Cryptosporidiosis
- Diabetes mellitus
- Drug-induced hypoglycemia, Sulfonylurea
- Dumping syndrome
- Hypothalamic obesity
- Lymphorrhea
- Neuroendocrine tumor
- Necrotizing pancreatitis, acute; Adjunct
- Non-infective diarrhea
- Pituitary adenoma
- Polycystic ovary syndrome
- Polyostotic fibrous dysplasia of bone; Adjunct
- Zollinger-Ellison syndrome; Adjunct

PRIOR AUTHORIZATION CRITERIA

1. Medication is prescribed by or in consultation with an Endocrinologist, Oncologist, Hematologist, or Surgeon; and
2. The patient is 18 years of age or older; and
3. Previous treatment with Sandostatin immediate release was effective and tolerated; and one of the following:
    A) Approve for 3 months if one of the diagnoses is met:

B) The patient has an Enterocutaneous fistulae (documentation must be attached).

C) The patient has the diagnosis of Perioperative management in pancreatic resection (including fistulae) (documentation must be attached)

4. Approved for 6 months if one of the diagnoses is met:
   The patient has a diagnosis of Acromegaly with one of the following:

   A) Inadequate response to surgery, inadequate response to radiation or the patient is not a candidate for surgery or radiation (documentation must be attached);
   B) Labs showing elevated IGF-1 level for patients age and gender with reference ranges attached; and
   C) Elevated growth hormone defined as a greater than or equal to 1 ng/mL following an oral glucose tolerance test (OGTT); or
5. The patient has a diagnosis of metastatic carcinoid tumor or Vasoactive Intestinal Peptide (VIP) secreting tumor with severe diarrhea with or without flushing episodes (documentation must be attached); or
   A. The patient has a diagnosis of Pituitary adenoma (documentation must be attached).

RENEWAL CRITERIA

1. If using for Acromegaly, documentation showing clinical benefit and tolerance and updated labs showing IGF-1 and GH have decreased or stabilized since starting therapy; or

2. If using for a diagnosis of metastatic carcinoid tumor or Vasoactive Intestinal Peptide (VIP) secreting tumor with severe diarrhea with or without flushing episodes, notes showing a reduction in symptoms and number of episodes; or

3. If using for an Enterocutaneous fistulae, notes documenting treatment response and relief of symptoms; or

4. If using for Perioperative management in pancreatic resection (including fistulae), updated notes documenting response to therapy; or

5. If patient is using for Pituitary adenoma, updated chart notes documenting treatment response.

DOSAGE AND ADMINISTRATION

Patients Not Currently Receiving Sandostatin Injection subcutaneously:

- Acromegaly: 50 mcg three times daily Sandostatin Injection subcutaneously for two weeks followed by Sandostatin LAR 20 mg intragluteally every 4 weeks for 3 months.

- Carcinoid Tumors and VIPomas: Sandostatin Injection subcutaneously 100-600 mcg/day in 2-4 divided doses for two weeks followed by Sandostatin LAR 20 mg every 4 weeks for 2 months.

Patients Currently Receiving Sandostatin Injection subcutaneously:

- Acromegaly: 20 mg every 4 weeks for 3 months.
- Carcinoid Tumors and VIPomas: 20 mg every 4 weeks for 2 months.
- Renal Impairment, patients on dialysis: 10 mg every 4 weeks.
- Hepatic Impairment, patients with cirrhosis: 10 mg every 4 weeks.

RISK FACTORS/SIDE EFFECTS

The most common adverse reactions, occurring in ≥ 20% of patients are:

- **Acromegaly:** diarrhea, cholelithiasis, abdominal pain, flatulence.
- **Carcinoid Syndrome:** back pain, fatigue, headache, abdominal pain, nausea, dizziness.

Other clinically significant adverse reaction include:

- Changes in Vitamin B12 levels
- Complete Atrioventricular Block
- Hyperglycemia and Hypoglycemia
- Steatorrhea and Malabsorption of Dietary Fats
- Thryroid Function Abnormalities

MONITORING

Labs:

- Acromegaly
  - Serum IGF-1 or GH.
- Carcinoid
  - 5-HIAA, plamsa seotonin and plasma substance P.
- VIPomas
  - Vasoactive intestinal peptide.

BLACK BOX WARNING

N/A

CODING

Note*:* The Current Procedural Terminology (CPT®), Healthcare Common Procedure Coding System (HCPCS), and the 10th revision of the International Statistical Classification of Diseases and Related Health Problems (ICD-10) codes that *may* be listed in this policy are for reference purposes only. Listing of a code in this policy does not imply that the service is covered and is not a guarantee of payment. Other policies and coverage guidelines may apply. When reporting services, providers/facilities should code to the highest level of specificity using the code that was in effect on the date the service was rendered. This list may not be all inclusive.

CPT Code	Description
N/A	

HCPCS Code	Description
J2353	Injection, octreotide, depot form for intramuscular injection
J2354	Injection, octreotide, non-depot form for subcutaneous or intravenous injection, 25 mcg

ICD 10 Codes
C25.4, C37, C70.0, C70.1, C70.9, C74.01, C74.02, C74.11, C74.12, C74.91, C74.95, C75.5, C7A.00, C7A.10, C7A.11, C7A.12, C7A.019, C7A.020-C7A.029, C7A.090-C7A.098, C7A.1, C7A.8, C7B.00-C7B.8, D13.7, D15.0, D32.0, D32.1, D32.9, D35.01, D35.02, D3A.00, D3A.010, D3A.011, D3A.012, D3A.019, D3A.20-D3A.029, D3A.90-D3A.038, D3A.8, E16.1, E16.3, E16.4, E16.8, E22.0, E34.00, E34.01, E34.09.

DISCLAIMER

Approval or denial of payment does not constitute medical advice and is neither intended to guide nor influence medical decision making. Policy Bulletins are developed by Jefferson Health Plans to assist in administering plan benefits and constitute neither offers of coverage nor medical advice.

This Policy Bulletin may be updated and therefore is subject to change. For Health Partners Plans Medicaid and Health Partners Plans Chip products: Any requests for services that do not meet criteria set in PARP will be evaluated on a case-by-case basis.

POLICY HISTORY

This section provides a high-level summary of changes to the policy since the previous version.

Summary	Version	Version Date
2025 Annual review. Updated to Version C. ICD 10 codes added. Risk Factor section updated.	C	05/21/2025
2024 Annual review. No changes.	B	09/01/2023
2023 Annual review. Prior authorization and renewal criteria were reformatted. Risk factor section was revised. Monitoring section was updated. Reference section was updated accordingly.	B	09/01/2023
2022 annual review. Dates of references updated. Language added to “disclaimer” section.	A	10/01/2020
2021 annual review. No changes to this version of the policy.	A	10/01/2020
New Policy.	A	10/01/2020

REFERENCES

1. LAR Product Information. Novartis Pharmaceuticals. Accessed June 2023.
2. Octreotide (Sandostatin LAR depot): Drug information: Micromedex. Accessed June 2023.