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

Original Implementation Date : 10/01/2020
Version [D] Date : 5/20/2026
PARP Approved Date: 04/22/2026
Last Reviewed Date: 5/20/2026

PRODUCT VARIATIONS

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

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 Vasoactive Intestinal Peptide (VIP)-secreting tumors.

OFF-LABEL USE

The requests for off-label use of Somatostatin Lar will be considered on an individual basis in consistence with medical literature and local practices.

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 a specialist- Endocrinologist, Oncologist, Hematologist, or Surgeon.
2. The member is 18 years of age or older.
3. Initial treatment with Sandostatin immediate release was effective and tolerated.

Initial Approval

3 months for the following diagnoses:

1. Enterocutaneous fistulae
2. Perioperative management in pancreatic resection (including fistulae)

6 months for the following diagnoses:

1. Acromegaly with one of the following:
   A) Inadequate response to surgery or radiation treatment, or the patient is not a candidate for surgery or radiation
   B) Members have elevated pretreatment levels for IGF-1 for patients age and gender according to the reporting lab

2. Neuroendocrine Tumor(s) [NETs] of the Gastrointestinal Tract, Lung, Thymus (Carcinoid Tumors), and Pancreas (including glucagonomas, gastrinomas, vasoactive intestinal peptides-secreting tumors [VIPomas], insulinomas).

RENEWAL CRITERIA

1.Acromegaly - the member's IGF-1 level has decreased or normalized since initiation of therapy;

2.NETs, Carcinoid syndrome, VIPomas, pheochromocytoma/paraganglioma, thymomas/thymic carcinomas-the member is experiencing clinical benefit as evidenced by improvement or stabilization in clinical signs and symptoms since initiation of therapy

3. All other indications- member meets initial approval criteria and documentation shows improvement of symptoms on Sandostatin Lar therapy.

DOSAGE AND ADMINISTRATION

Per package labeling

RISK FACTORS/SIDE EFFECTS

Per package labeling

MONITORING

Labs:

- Acromegaly
  - Serum IGF-1 (somatomedin C), Growth Hormone.
- Carcinoid
  - 5-HIAA (urinary 5-hydroxyindole acetic acid), plamsa seotonin and plasma substance P.
- VIPomas
  - Plasma vasoactive intestinal peptide at baseline and periodic total and/or free T4 measurements should be performed during chronic therapy.

BLACK BOX WARNING

N/A

CLINICAL EVIDENCE

Acromegaly

Clinical trials evaluating SANDOSTATIN LAR DEPOT were conducted in patients previously treated with Sandostatin (octreotide) injection for periods ranging from weeks to up to 10 years. Most enrolled patients had already achieved good hormonal control on subcutaneous therapy, typically with growth hormone (GH) levels below 5 ng/mL, although some were partial responders with GH reduced by more than 50% but not fully suppressed.

Across three clinical trials, SANDOSTATIN LAR DEPOT was administered every four weeks at doses ranging from 10 mg to 40 mg, with most patients receiving 20 mg or 30 mg. In the first two trials (101 total patients), GH and IGF 1 levels remained as well controlled on SANDOSTATIN LAR DEPOT as they had been with subcutaneous injections, and this control was maintained over 27–28 treatment cycles. In the third 12-month study (151 patients), patients began with 20 mg every four weeks, followed by dose adjustments to 10, 20, or 30 mg based on GH suppression. Hormone control and symptom management were comparable to results with subcutaneous therapy.

Among 25 partial responders, one patient achieved GH < 2.5 ng/mL and eight achieved GH < 5 ng/mL on SANDOSTATIN LAR DEPOT. Additionally, two open label studies in 143 treatment naïve acromegaly patients demonstrated meaningful tumor shrinkage, with median volume reductions of approximately 20–25% at 24 weeks and up to 36% at 48 weeks.

Carcinoid Syndrome

A 6-month clinical trial in 93 patients with malignant carcinoid syndrome evaluated SANDOSTATIN LAR DEPOT in individuals previously responsive to subcutaneous Sandostatin. Sixty-seven patients were randomized to receive 10 mg, 20 mg, or 30 mg every 28 days, while 26 patients continued their standard subcutaneous injections. After steady-state levels were achieved, about 35–40% of patients receiving SANDOSTATIN LAR DEPOT required short-term supplemental subcutaneous octreotide each month to manage breakthrough symptoms, a rate similar to those maintained on subcutaneous therapy. Over the entire 6-month

period, 50–70% of patients on SANDOSTATIN LAR DEPOT required supplemental dosing at some point. Flushing frequency remained low and comparable across all treatment groups, averaging 0.5–1 episode per day. Among a subset of patients, median urinary 5-HIAA levels were reduced by 38–50%, consistent with expected octreotide responses. Of the original participants, 78 entered a 12-month extension study, during which symptom control for diarrhea and flushing remained stable. As anticipated in progressive malignant carcinoid disease, 10% of patients died from disease progression or related complications, and an additional 22% discontinued the study early due to worsening symptoms or progression.

BACKGROUND

Acromegaly is a rare pituitary disorder characterized by chronic, slowly progressive overproduction of growth hormone (GH) and insulin-like growth factor-1 (IGF-1). Because hormonal excess develops gradually over many years, clinical manifestations can be subtle and lead to delayed diagnosis. Common features include enlargement of the hands and feet, jaw protrusion, joint pain, degenerative arthritis, organomegaly such as cardiomegaly, thyroid enlargement, fatigue, and generalized weakness.

Carcinoid tumors are neuroendocrine tumors (NETs) that secrete serotonin and other bioactive substances responsible for carcinoid syndrome. The hallmark symptoms, including episodic flushing and severe watery diarrhea, result from excessive hormone release into the systemic circulation, particularly in the presence of metastatic disease.

VIPomas, or vasoactive intestinal peptide secreting tumors, are rare pancreatic neuroendocrine tumors that produce abnormally high levels of VIP. Their most prominent clinical manifestation is profound, persistent watery diarrhea that can lead to significant dehydration and electrolyte imbalances.

Acromegaly, carcinoid syndrome, and VIPomas are all treated by addressing both the hormone overproduction and the underlying tumor. Somatostatin analogs (e.g. octreotide and lanreotide) are used to reduce hormone secretion and control symptoms. Octreotide mimics natural somatostatin by inhibiting serotonin release and the secretion of VIP, gastrin, secretin, motilin, and pancreatic polypeptide. It decreases growth hormone (GH) and IGF-1 in acromegaly. Octreotide provides more potent inhibition of GH, glucagon, and insulin compared to endogenous somatostatin, helping control both symptoms and biochemical markers of disease.

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® is a registered trademark of the American Medical Association.

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 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 reviewed 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
2026 Annual Review. Revisions made to Prior Authorization Criteria, Renewal Criteria, Dosage & Administration, Risk Factors/Side Effects, Monitoring, Clinical Evidence and Background Sections. References updated.	D	5/20/2026
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 : https://www.novartis.com/us-en/sites/novartis_us/files/sandostatin_lar.pdf

2. Octreotide (Sandostatin LAR depot): Drug information: Micromedex. Accessed June 2023.

3. Sandostatin LAR Depot (octreotide injection suspension) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2024.

4. Colao A, Merola B, Ferone D, Lombardi G. Acromegaly. *J Clin Endocrinol Metab*. 1997;82(9):2777-2781. doi:10.1210/jcem.82.9.4257

5. Strosberg JR, Halfdanarson TR, Bellizzi AM, et al. The North American Neuroendocrine Tumor Society Consensus Guidelines for Surveillance and Medical Management of Midgut Neuroendocrine Tumors. *Pancreas*. 2017;46(6):707-714.

6. Naraev BG, Halland M, Halperin DM, Purvis AJ, O'Dorisio TM, Halfdanarson TR. Management of Diarrhea in Patients with Carcinoid Syndrome. Pancreas. 2019 Sep;48(8):961-972.

7. Octreotide Acetate injection [prescribing information]. Lake Zurich, IL: Fresenius Kabi; April 2024.