DR.008.A	Sandostatin LAR Depot (octreotide acetate)

Title: Sandostatin LAR Depot (octreotide acetate) **Policy #:** DR.008.A **Type:** Medical **Sub-Type:** Drug (DR)	**Original Implementation Date:** 10/1/2020 **Version [A] Effective Date:** 10/1/2020 **Last reviewed:** 8/17/2022 **Notification Published:** N/A

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PRODUCT VARIATIONS

This policy applies to all Health Partners Plans (HPP) product lines unless noted below.

POLICY STATEMENT

Sandostatin LAR Depot (octreotide acetate) is covered and considered medically necessary for the following approved FDA labeled 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 of 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. Is the medication prescribed by or in consultation with an Endocrinologist, Oncologist, Hematologist, or Surgeon? *If YES, go to question 2. If NO, refer to Medical Director.*

2. Is the patient 18 years of age or older? *If YES, got to question 3. If NO, refer to Medical Director.*

3. Was previous treatment with Sandostatin immediate release effective and tolerated? *If YES, go to question 4. If NO, refer to Medical Director.*

4. Does the patient have the diagnosis of Acromegaly with inadequate response to surgery and/or radiation, unless surgery or radiation is not an option (documentation must be attached). *If YES, go to question 5. If NO, go to question 6.*

5. Labs showing elevated IGF-1 level for patients age and gender with reference ranges attached AND elevated growth hormone defined as a greater than or equal to 1 ng/mL following an oral glucose tolerance test (OGTT). *If YES, approve for 6 months. If NO, refer to Medical Director.*

6. Does the patient have the diagnosis of metastatic carcinoid tumor with severe diarrhea and flushing episodes (documentation must be attached)? *If YES, approve for 6 months. If NO, go to question 7.*

7. Does the member have a diagnosis of VIP-secreting tumor with profuse watery diarrhea? (Documentation must be attached). *If YES, approve 6 months. If NO, go to question 8.*

8. Does the patient have an Enterocutaneous fistulae (documentation must be attached)? *If YES, approve for 3 months. If NO, go to question 9.*

9. Does the patient have the diagnosis of Perioperative management in pancreatic resection (including fistulae)? (Documentation must be attached.) *If YES, approve for 3 months. If NO, go to question 10.*

10. Does patient have diagnosis of Pituitary adenoma? (documentation must be attached). *If YES, approve 6 months. If NO, refer to Medical Director.*

RENEWAL CRITERIA

1. If using for Acromegaly, documentation showing clinical benefit and tolerance. *If YES, go to question 2. If NO, go to question 3.*

2. Updated Labs showing IGF-1 and GH have decreased or stabilized since starting therapy. *If YES, approve 12 months. If NO, refer to Medical Director.*

3. If using for metastatic carcinoid tumor with severe diarrhea and flushing, notes showing member experienced decrease in symptoms and number of episodes. *If YES, approve 12 months. If NO, got to question 4.*

4. If using for VIP-secreting tumor, notes showing member had reduction of profuse watery diarrhea. *If YES approve 12 months. If NO, go to question 5.*

5. If using for an Enterocutaneous fistulae, notes documenting treatment response and relief of symptoms. *If YES, approve 12 months. If NO. go to question 6.*

6. If using for Perioperative management in pancreatic resection (including fistulae), updated notes documenting response to therapy. *If YES, approve for 12 months. If NO, go to question 7.*

7. If patient is using for Pituitary adenoma, updated chart notes documenting treatment response. *If YES, approve 12 months. If NO, refer to Medical Director.*

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

CODING

The Current Procedural Terminology (CPT®), Healthcare Common Procedure Coding System (HCPCS), and 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	

CPT® is a registered trademark of the American Medical Association.

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

DISCLAIMER

Approval or denial of payment does not constitute medical advice and is neither intended to guide nor influence medical decision making.

Per DHS Medicaid and 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

Summary	Version	Version Effective Date
2022 annual review. Dates of references updated. Language added to Disclaimer section.	A	1/1/2020
2021 annual review. No changes to this version of the policy.	A	10/1/2020
New Policy	A	10/1/2020

REFERENCES

1. Sandostatin LAR Product Information. Novartis Pharmaceuticals. Accessed June 2022.

2. Ocreotide (Sandostatin LAR depot): Drug information: Micromedex. Accessed June 2022.