Ascension
Personalized Care

Ascension

Octreotide Depot Formulation for Intramuscular Injection

(SandoSTATIN LAR Depot®) J2353 (1mg)

Covered with prior authorization

Requests for SandoSTATIN LAR Depot® (octreotide depot formulation for IM injection) may be approved if the following criteria are met:

- Patient is at least 18 years of age; **AND**
- Patient has been 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**
- Be used for one of the following conditions and their criteria being met:

Acromegaly

- Patient diagnosis confirmed by elevated (age-adjusted) or equivocal serum IGF-1, as well as inadequate suppression of growth hormone (GH)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 are reported. (Renewal will require reporting of current levels.)

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

- Patient with metastatic gastroenteropancreatic neuroendocrine tumors (GEP-NETs) who has severe diarrhea/flushing episodes (carcinoid syndrome) **OR**
- Used for the management of symptoms related to hormone hypersecretion of locoregional neuroendocrine tumors of the pancreas; **AND**
    - Patient has a gastrinoma, glucagonoma, or VIPoma; **OR**
- Used as primary treatment of unresected primary gastrinoma; **OR**
- Used for locoregional unresectable bronchopulmonary or thymic disease; **AND**
    - Used for somatostatin receptor positive disease and/or symptomatic hormonal disease; **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**

- Patient has distant metastatic bronchopulmonary or thymic disease; **AND**
    - Used for somatostatin receptor (SSR)-positive disease and/or symptomatic hormonal disease; **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); **AND**
            - Patient has clinically significant tumor burden and low grade (typical carcinoid) histology; **OR**
            - Patient has evidence of disease progression; **OR**
            - Patient has intermediate grade (atypical carcinoid) histology; **OR**
            - Patient has symptomatic disease; **OR**
    - Used for SSR-positive disease and/or hormonal symptoms if asymptomatic with low tumor burden and low grade (typical) histology; **OR**
    - Used for SSR-positive disease and/or chronic cough/dyspnea that is not responsive to inhalers in patients 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 SSR-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 SSR-positive disease; **OR**
    - Patient has distant metastatic disease; **OR**
- Patient has well-differentiated grade 3 neuroendocrine tumors; **AND**
    - Patient has unresectable locally advanced or metastatic disease with favorable biology (e.g., relatively low Ki-67 [<55%], positive SSR-based PET imaging); **AND**
    - Patient has SSR-positive disease and/or hormonal symptoms.

Diarrhea associated with Vasoactive Intestinal Peptide tumors (VIPomas)

- Patient has profuse watery diarrhea

Requests for SandoSTATIN LAR Depot® may **not** be approved if the above criteria are not met and for all other indications not included above.

Initial authorizations are for up to 6 months.

Renewal requests are for up to 12 months.

Annual reauthorizations will require medical chart documentation that the patient has been seen within the past 12 months and that markers of disease are improved by therapy.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Exclusion criteria:

- SandoSTATIN LAR Depot® (octreotide depot formulation for IM injection) is not considered medically necessary when any of the following selection criteria is met:
    - The agent is being used/given by self administration.
    - Doses, durations, or dosing intervals that exceed FDA maximum limits for any FDA-approved indication or are not supported by industry-accepted practice guidelines or peer-reviewed literature for the relevant off-label use.
    - Individuals with significant known risk factors unless the record provides an assessment of clinical benefit that outweighs the risk.

Dosage/Administration
Acromegaly

- 20 mg intragluteally 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 > 1 to ≤ 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 intragluteally 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.

NOTE: Renal impairment (patients on dialysis) and hepatic impairment (patients with cirrhosis): starting dose of 10 mg every 4 weeks

U.S. Food and Drug Administration:
This section is to be used for informational purposes. FDA approval alone is not a basis for coverage. Octreotide exerts pharmacologic actions similar to the natural hormone somatostatin. It is an even more potent inhibitor of GH, glucagon, and insulin than somatostatin. Like somatostatin, it also suppresses luteinizing hormone (LH) response to gonadotropin-releasing hormone (GnRH), secretion of thyroid-stimulating hormone, decreases splanchnic blood flow inhibits serotonin, and the secretion of gastrin, vasoactive intestinal peptide (VIP), insulin, glucagon, secretin, motilin, and pancreatic polypeptide. By virtue of these pharmacological actions, octreotide has been used to treat the symptoms associated with metastatic carcinoid tumors (flushing and diarrhea), and VIP-secreting adenomas (watery diarrhea).

Key References Accessed 8/2022:

1. Sandostatin LAR [package insert]. East Hanover, NJ; Novartis Pharmaceuticals Corporation; March 2021.
2. Giustina A, Chanson P, Kleinberg D, et al. Expert consensus document: A consensus on the medical treatment of acromegaly. Nat Rev Endocrinol. 2014 Apr; 10(4):243-8. doi: 10.1038/nrendo.2014.21. Epub 2014 Feb 25.
3. Katznelson L, Laws ER Jr, Melmed S, et al. Acromegaly: an endocrine society clinical practice guideline. J Clin Endocrinol Metab. 2014 Nov; 99(11):3933-51. doi: 10.1210/jc.2014- 2700. Epub 2014 Oct 30.
4. NCCN Drugs & Biologics Compendium (NCCN Compendium®) for Octreotide acetate (LAR). National Comprehensive Cancer Network, 2022. 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.
5. Lancranjan I, Atkinson AB & Sandostatin® LAR® Group#. Results of a European Multicentre Study with Sandostatin® LAR® in Acromegalic Patients. Pituitary 1, 105–114; Published: June 1999.

6. Rubin J, Ajani J, Schirmer W, et al. Octreotide Acetate Long-Acting Formulation Versus Open-Label Subcutaneous Octreotide Acetate in Malignant Carcinoid Syndrome. J Clin Oncol, 17 (2), 600-6; Feb 1999. PMID: 10080605. DOI: 10.1200/JCO.1999.17.2.600.
7. Longo F, De Filippis L, Zivi A, et al. Efficacy and Tolerability of Long-Acting Octreotide in the Treatment of Thymic Tumors: Results of a Pilot Trial. Am J Clin Oncol, 35 (2), 105-9; April 2012.
8. NCCN Drugs & Biologics Compendium (NCCN Compendium®) Neuroendocrine and Adrenal Tumors. Version 4.2021. National Comprehensive Cancer Network, 2022.

Date	Summary of Changes
August 2022	Criteria for use summary developed by the Ascension Medical Specialty Prior Authorization Team.
September 2022	Criteria for use summary approved by the Ascension Ambulatory Care Expert Review Panel.
October 2022	Criteria for use summary approved by the Ascension Therapeutic Affinity Group.

If you have questions, call 833-980-2352 to speak to a member of the Ascension Rx prior authorization team.

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