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Section:	Prescription Drugs	**Effective Date:**	October 1, 2025
Subsection:	Endocrine and Metabolic Drugs	**Original Policy Date:**	September 23, 2016
Subject:	Sandostatin LAR	**Page:**	1 of 5

Last Review Date: September 19, 2025

Sandostatin LAR

Description

Sandostatin LAR (octreotide acetate)

Background
Sandostatin LAR (octreotide acetate) is a once a month, long-acting release intramuscular injection for the treatment of acromegaly, diarrhea or flushing episodes that are associated with metastatic carcinoid tumors, and diarrhea that is associated with vasoactive intestinal peptide (VIP)-secreting tumors. Acromegaly is a rare and debilitating endocrine disorder caused by excess production of growth hormone (GH) and insulin-like growth factor-1 (IGF-1). Metastatic carcinoid tumors are found along the gastrointestinal (GI) tract and release too much serotonin into the body, while VIP-secreting tumors cause increased secretions from the intestines. Sandostatin LAR mimics natural somatostatin by inhibiting the secretion of growth hormone, glucagon, insulin, serotonin, gastrin, VIP, secretin, motilin, and pancreatic polypeptide (1).

Regulatory Status
FDA-approved indications: Sandostatin LAR is a somatostatin analogue indicated for the treatment of patients who have responded to and tolerated Sandostatin subcutaneous injections for (1):

1. Long-term maintenance therapy in acromegalic patients who have had an inadequate response to surgery and/or radiotherapy, or for whom surgery and/or radiotherapy is not an option
2. Severe diarrhea/flushing episodes associated with metastatic carcinoid tumors
3. Profuse watery diarrhea associated with VIP-secreting tumors

Limitations of Use: (1)
In patients with carcinoid syndrome and VIPomas, the effect of Sandostatin subcutaneous injection and Sandostatin LAR on tumor size, rate of growth, and development of metastases has not been determined.

Off-Label Uses: (2)
The National Comprehensive Cancer Network (NCCN) includes these additional indications:

1. In the treatment of patients with neuroendocrine tumors (NETs) of the gastrointestinal tract and/or pancreas with carcinoid syndrome.
2. In the treatment of patients with neuroendocrine tumors (NETs) of the gastrointestinal tract and/or pancreas for management of locoregional unresectable disease and/or distant metastases.

Safety and effectiveness of Sandostatin LAR in pediatric patients have not been established (1).

Related policies
Mycapssa, Signifor LAR, Somatuline Depot

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Sandostatin LAR may be considered **medically necessary** if the conditions indicated below are met.

Sandostatin LAR may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age and older

Diagnoses

Patient must have **ONE** of the following:

1. Acromegaly

a. Inadequate treatment response or patient is **NOT** a candidate for **ALL** of the following:
    i. Surgery resection
    ii. Pituitary irradiation
    iii. A dopamine agonist (e.g., bromocriptine, cabergoline, etc.)
b. Response to and tolerance of prior treatment with 2 weeks of immediate release octreotide

2. Severe diarrhea or flushing episodes associated with metastatic carcinoid tumor(s)
    a. Response to and tolerance of prior treatment with 2 weeks of immediate release octreotide
    b. Prescriber agrees to simultaneously administer Sandostatin LAR and immediate release octreotide injections for at least two weeks when initiating therapy

3. Profuse watery diarrhea associated with VIP-secreting tumor(s)
    a. Response to and tolerance of prior treatment with 2 weeks of immediate release octreotide
    b. Prescriber agrees to simultaneously administer Sandostatin LAR and immediate release octreotide injections for at least two weeks when initiating therapy

4. Neuroendocrine Tumor of the Gastrointestinal Tract or Pancreas (GEP-NETs)

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnoses

Patient must have **ONE** of the following:

1. Acromegaly
2. Severe diarrhea or flushing episodes associated with metastatic carcinoid tumor(s)
3. Profuse watery diarrhea associated with VIP-secreting tumor(s)
4. Neuroendocrine Tumor of the Gastrointestinal Tract or Pancreas (GEP-NETs)

AND the following:

a. **NO** disease progression or unacceptable toxicity

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Sandostatin LAR is a somatostatin analog indicated for the treatment of adults with acromegaly, diarrhea or flushing episodes associated with metastatic carcinoid tumors, or diarrhea associated with VIP-secreting tumors. Prior to initiation, patients must show a response to and tolerate Sandostatin subcutaneous injections for at least two weeks. Safety and effectiveness of Sandostatin LAR in pediatric patients have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Sandostatin LAR while maintaining optimal therapeutic outcomes.

References

1. Sandostatin LAR [package insert]. East Hanover, NJ: Novartis Pharmaceuticals. Pharmaceuticals Corporation; July 2024.
2. NCCN Drugs & Biologics Compendium® Octreotide acetate 2025. National Comprehensive Cancer Network, Inc. Accessed on July 31, 2025.

Policy History

Date	Action

September 2016	Addition to PA
December 2016	Annual review
December 2017	Annual editorial review
February 2018	Addition of the diagnosis of Neuroendocrine Tumor of the Gastrointestinal Tract or Pancreas (GEP-NETs) to criteria
March 2018	Annual review
December 2019	Annual review and reference update
September 2020	Annual review and reference update
December 2020	Annual review
September 2021	Annual review and reference update
September 2022	Annual review and reference update
December 2022	Annual review and reference update. Per SME, changed initiation requirement for acromegaly from t/f bromocriptine to t/f a dopamine agonist
September 2023	Annual review and reference update
September 2024	Annual review and reference update
September 2025	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 19, 2025 and is effective on October 1, 2025.