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# 5.30.009

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| <b>Section:</b>    | Prescription Drugs            | <b>Effective Date:</b>       | October 1, 2024    |
| <b>Subsection:</b> | Endocrine and Metabolic Drugs | <b>Original Policy Date:</b> | September 23, 2016 |
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**Last Review Date:** September 6, 2024

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## Sandostatin LAR

### Description

#### Sandostatin LAR (octreotide acetate)

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#### 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

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### 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).

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### **Related policies**

Bynfezia, 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

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- 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)

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## 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)

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**AND** the following:

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

## Policy Guidelines

### Pre - PA Allowance

None

### Prior - Approval Limits

**Duration** 12 months

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### 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 2023.
2. NCCN Drugs & Biologics Compendium® Octreotide acetate 2024. National Comprehensive Cancer Network, Inc. Accessed on July 18, 2024.

## Policy History

| Date | Action |
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|----------------|---------------------------------------------------------------------------------------------------------------------------------------------|
| 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                                                                                                          |

## Keywords

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**This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 6, 2024 and is effective on October 1, 2024.**