

Drug Policy

Policy:	Sandostatin LAR (octreotide)	Annual Review Date: 11/16/2023 Last Revised Date: 11/16/2023
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OVERVIEW

Sandostatin LAR is a somatostatin analog indicated for the treatment of patients with acromegaly who have had an inadequate response to or for whom surgery, radiation, and bromocriptine are not appropriate. Sandostatin LAR is also indicated for symptomatic treatment of patients with metastatic carcinoid syndrome and diarrhea associated with vasoactive intestinal peptide (VIP)-secreting tumors. Treatment is indicated in patients who have responded to and tolerated Sandostatin subcutaneous injection.

POLICY STATEMENT

This policy involves the use of Sandostatin LAR. Prior authorization is recommended for pharmacy benefit coverage of Sandostatin LAR. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Sandostatin LAR as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Sandostatin LAR be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Sandostatin LAR is recommended in those who meet the following criteria:

1. Acromegaly

Criteria. *Patient must meet the following criteria*

- A. The medication is prescribed by or in consultation with an endocrinologist; AND
- B. The patient has had an inadequate response to or is ineligible for surgery, radiation, or bromocriptine OR is experiencing negative effects due to tumor size (e.g. optic nerve compression); AND
- C. The patient had a baseline (prior to initiation of any somatostatin analog [Signifor LAR, Somatuline Depot, Sandostatin LAR], dopamine agonist [bromocriptine, cabergoline] or Somavert) IGF-1 level above the upper limit of normal (ULN) for age and gender per the laboratory's standard reference values; AND
- D. The patient has failed on an adequate trial of Somatuline Depot; AND
- E. The patient has responded to and tolerated Sandostatin subcutaneous injection

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2. **Carcinoid Syndrome**

Criteria. *Patient must meet the following criteria*

- A. The medication is prescribed by or in consultation with an endocrinologist, oncologist, or gastroenterologist;
AND
- B. The patient has severe diarrhea/flushing episodes associated with metastatic carcinoid tumors; AND
- C. The patient has responded to and tolerated Sandostatin subcutaneous injection

3. **Vasoactive Intestinal Peptide (VIP)-Secreting Tumors**

Criteria. *Patient must meet the following criteria*

- A. The medication is prescribed by or in consultation with an endocrinologist, oncologist, or gastroenterologist;
AND
- B. The patient has profuse watery diarrhea associated with VIP-secreting tumors; AND
- C. The patient has responded to and tolerated Sandostatin subcutaneous injection

Other Uses with Supportive Evidence

4. **Pheochromocytoma/Paraganglioma**

Criteria. *Approve if the medication is prescribed by or in consultation with an oncologist, endocrinologist, or neurologist.*

5. **Thymomas and Thymic Carcinomas**

Criteria. *Patient must meet the following criteria*

- A. The medication is prescribed by or in consultation with a hematologist or oncologist; AND
- B. Sandostatin LAR will be used as second line therapy

6. **Meningiomas**

Criteria. *Patient must meet the following criteria*

- A. The medication is prescribed by or in consultation with a hematologist or oncologist; AND
- B. The patient has surgically inaccessible recurrent or progressive disease

7. **Patients with another indication that is not listed but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation**

Criteria. *Prescriber will provide specific diagnosis for documentation*

8. **Patient has been started on Sandostatin LAR**

Criteria. *Approve for an indication or condition addressed as an approval in this document*

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Initial Approval/ Extended Approval.

- A) *Initial Approval:* 1 year
B) *Extended Approval:* 1 year

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Sandostatin LAR has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Sandostatin LAR Depot [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation. July 2016.
2. Giustina A, Chanson P, Kleinberg D, et al. A consensus on the medical treatment of acromegaly. *Nat Rev Endocrinol.* 2014;10(4):243-248.
3. Katznelson L, Laws ER Jr, Melmed S, et al; Endocrine Society. Acromegaly: an Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab.* 2014;99:3933-3951.
4. Melmed S. Acromegaly. *N Engl J Med.* 2006;355:2558-2573.
5. Christofides EA. Clinical importance of achieving biochemical control with medical therapy in adult patients with acromegaly. *Patient Pref Adherence.* 2016;10:1217-1225.
6. Oberg K, Lamberts SW. Somatostatin analogues in acromegaly and gastroenteropancreatic neuroendocrine tumours: past, present and future. *Endocr Relat Cancer.* 2016;23(12):R551-566.
7. Manjila S, Wu OC, Khan FR, et al. Pharmacological management of acromegaly: a current perspective. *Neurosurg Focus.* 2010;29(4):E14.
8. Colao A, Bronstein MD, Freda P, et al. Pasireotide versus octreotide in acromegaly: a head-to-head superiority study. *J Clin Endocrinol Metab.* 2014;99(3):791-799.
9. Octreotide acetate. In: DRUGDEX [online database]. Truven Health Analytics; Greenwood Village, CO. Last updated 14 November 2019. Accessed on 21 November 2019.
10. The NCCN Drugs and Biologics Compendium. © 2019 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed 21 November 2019.