MEDICAL MUTUAL®

Drug Policy

Policy:	Somatuline Depot (lanreotide) Lanreotide acetate (lanreotide acetate)	Annual Review Date: 11/16/2023 Last Revised Date: 11/16/2023

OVERVIEW

Somatuline Depot is a somatostatin analog indicated for the long-term treatment of patients with acromegaly who have had an inadequate response to surgery and/or radiotherapy, or for whom surgery and/or radiotherapy is not an option. Somatuline Depot is also indicated in patients with unresectable, well-or moderately-differentiated, locally advanced or metastatic gastroenteropancreatic neuroendocrine tumors (GEP-NETs) to improve progression-free survival and for the treatment of adult patients with carcinoid syndrome. When used in this patient population, Somatuline Depot reduces the requirements for short-acting somatostatin analog rescue therapy.

POLICY STATEMENT

This policy involves the use of Somatuline Depot. Prior authorization is recommended for pharmacy benefit coverage of Somatuline Depot. 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 Somatuline Depot as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Somatuline Depot 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 Somatuline Depot and lanreotide acetate recommended in those who meet the following criteria:

1. <u>Acromegaly</u>

Criteria. *Patient must meet the following criteria (A, B, C, D <u>and</u> E):*

A. The medication is prescribed by or in consultation with an endocrinologist; AND

B. The patient meets one of the following (a, b, <u>or</u> c):

a. The patient has had an inadequate response to surgery and/or radiotherapy; OR

b. The patient is NOT an appropriate candidate for surgery and/or radiotherapy; OR

c. The patient is experiencing negative effects due to tumor size (e.g. optic nerve compression); AND

C. The patient has 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 is 18 years of age or older.
E. If request is for lanereotide acetate, patient must have tried Somatuline Depot AND lanreotide acetate is being requested due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives], and per the prescribing provider, would result in a significant allergy or serious adverse reaction.

2. Carcinoid Syndrome
Criteria. *Approve if the medication is prescribed by or in consultation with an oncologist, endocrinologist, or gastroenterologist.*

Note: Requests for lanreotide acetate (NDC: 69097087067) will be directed to Somatuline Depot

3. Neuroendocrine Tumors (NETs) of the Gastrointestinal Tract, Lung, Thymus (Carcinoid Tumors), and Pancreas (including glucagonomas, gastrinomas, vasoactive intestinal peptide-secreting tumors [VIPomas], insulinomas)
Criteria. *Approve if the medication is prescribed by or in consultation with an oncologist, endocrinologist, or gastroenterologist.*

Initial Approval/ Extended Approval.
A) *Initial Approval:* 1 year
B) *Extended Approval:* 1 year

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.*

Note: Requests for lanreotide acetate (NDC: 69097087067) will be directed to Somatuline Depot

5. 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*

6. Patient has been started on Somatuline Depot
Criteria. *Approve for an indication or condition addressed as an approval in this document*

Initial Approval/ Extended Approval.
A) *Initial Approval:* 1 year
B) *Extended Approval:* 1 year

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Somatuline Depot 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. Somatuline® Depot injection [prescribing information]. Basking Ridge, NJ: Ipsen Biopharmaceuticals, Inc.; September 2017.
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. Gardner-Roehnelt NM. Update on the management of neuroendocrine tumors: Focus on somatostatin antitumor effects. *Clin J Oncol Nur*. 2012;16:56-64.
8. Dimitriadis GK, Weickert MO, Randeva HS, et al. Medical management of secretory syndromes related to gastroenteropancreatic neuroendocrine tumors. *Endocr Relat Cancer*. 2016;23(9):R423-436.
9. The NCCN Neuroendocrine and Adrenal Tumors Clinical Practice Guidelines in Oncology (version 1.2019 – March 5, 2019). © 2019 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed 19 November 2019.
10. Strosberg JR, Halfdanarson TR, Bellizi AR, et al. The North American Neuroendocrine Tumor Society consensus guidelines for surveillance and medical management of midgut neuroendocrine Tumors. *Pancreas*. 2017;46(6):707-714.
11. Chanson P, Borson-Chazot F, Kuhn JM, et al; Lanreotide Acromegaly Study Group. Control of IGF-I levels with titrated dosing of lanreotide Autogel over 48 weeks in patients with acromegaly. *Clin Endocrinol (Oxf).* 2008;69:299-305.

12. Caplin ME, Pavel M, Ćwikła JB, et al; CLARINET Investigators. Lanreotide in metastatic enteropancreatic neuroendocrine tumors. *N Engl J Med*. 2014;371:224-233.
13. Bajetta E, Procopio G, Catena L, et al. Lanreotide autogel every 6 weeks compared with Lanreotide microparticles every 3 weeks in patients with well differentiated neuroendocrine tumors: a Phase III Study. *Cancer*. 2006;107:2474-2481.
14. Ruszniewski P, Ish-Shalom S, Wymenga M, et al. Rapid and sustained relief from the symptoms of carcinoid syndrome: results from an open 6-month study of the 28-day prolonged-release formulation of lanreotide. *Neuroendocrinology*. 2004;80:244-251.
15. Khan MS, El-Khouly F, Davies P, et al. Long-term results of treatment of malignant carcinoid syndrome with prolonged release Lanreotide (Somatuline Autogel). *Aliment Pharmacol Ther*. 2011;34:235-242.
16. Vinik AI, Wolin EM, Liyanage N, et al. Evaluation of lanreotide depot/autogel efficacy and safety as a carcinoid syndrome treatment (ELECT): a randomized, double-blind, placebo-controlled trial. *Endocr Pract*. 2016;22(9):1068-1080.
17. Lanreotide acetate. In: DRUGDEX [online database]. Truven Health Analytics; Greenwood Village, CO. Last updated 06 November 2019. Accessed on 19 November 2019.