Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines
Medical Benefit Drugs

Somatostatin Analogs for Oncology Indications

Effective: January 1, 2024

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☐ Harvard Pilgrim Health Care Commercial products; Fax 617-673-0988
☐ Tufts Health Plan Commercial products; Fax 617-673-0988
CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Public Plans Products

☐ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax 617-673-0988
☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; Fax 617-673-0988
☐ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax 617-673-0988
☒ Tufts Health One Care – A Medicare-Medicaid Plan (a dual-eligible product); Fax 617-673-0956
* The MNG applies to Tufts Health One Care members unless a less restrictive LCD or NCD exists.

Senior Products

☐ Harvard Pilgrim Health Care Stride Medicare Advantage; Fax 617-673-0956
☒ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); Fax 617-673-0956
☒ Tufts Medicare Preferred HMO, (a Medicare Advantage product); Fax 617-673-0956
☒ Tufts Medicare Preferred PPO, (a Medicare Advantage product); Fax 617-673-0956

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration (FDA) – Approved Indications

Sandostatin (octreotide) is a somatostatin analog indicated for:

- **Carcinoid Tumors**
  For the symptomatic treatment of patients with metastatic carcinoid tumors where it suppresses or inhibits the severe diarrhea and flushing episodes associated with the disease
- **Vasoactive Intestinal Peptide (VIP)-Secreting Tumors**
  For the treatment of the profuse watery diarrhea associated with VIP-secreting tumors

Sandostatin LAR (octreotide) is a somatostatin analog indicated for:

- **Carcinoid Tumors**
  Long-term treatment of the severe diarrhea and flushing episodes associated with metastatic carcinoid tumors
- **Vasoactive Intestinal Peptide (VIP)-Secreting Tumors**
  For the long-term treatment of the profuse watery diarrhea associated with VIP-secreting tumors

Somatuline Depot (lanreotide) is a somatostatin analog indicated for:

- **Gastroenteropancreatic Neuroendocrine Tumors**
  For the treatment of adult patients with unresectable, well- or moderately-differentiated, locally advanced or metastatic gastroenteropancreatic neuroendocrine tumors (GEP-NETs) to improve progression-free survival

- **Carcinoid Tumors**
  For the treatment of adults with carcinoid syndrome; when used, it reduces the frequency of short-acting somatostatin analog rescue therapy

Note: Providers and Members enrolled with Harvard Pilgrim Stride Medicare Advantage may reference oncology indications for somatostatin analogs located at https://oncohealth.us/medicalpolicies/harvardpilgrim/

Note: For Providers and Members enrolled with Tufts Health Plan, please reference the Medical Necessity Guideline Somatostatin Analogs for *Oncology* Indications for all Non-oncology-related uses.

Clinical Guideline Coverage Criteria

The plan may authorize coverage of Sandostatin, Sandostatin LAR, or Somatuline Depot for Members when the following criteria are met:

1. Documented diagnosis of:
   a. Carcinoid Syndrome
   b. Carcinoid Tumor
   c. Vasoactive Intestinal Peptide (VIP)-Secreting Tumor (aka VIPomas)
   d. Gastroenteropancreatic Neuroendocrine Tumor

Limitations

None

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J2353	Injection, octreotide, depot form for intramuscular injection, 1 mg
J2354	Injection, octreotide, non-depot form for subcutaneous or intravenous injection, 25 mcg
J1930	Injection, lanreotide, 1 mg

References

1. Broder MS, Neary MP, Chang E, et al. Treatments, complications, and healthcare utilization associated with acromegaly: a study in two large United States databases. *Pituitary*. 2014 Aug;17(4):333-41.
2. Colao A, Bronstein MD, Freda P, et al. Pasireotide versus octreotide in acromegaly: a head-to-head superiority study. *J Clin Endocrinol Metab*. 2014 Mar;99(3):791-9.
3. Katznelson L, Atkinson JL, Cook DM et al. American Association of Clinical Endocrinologists. American Association of Clinical Endocrinologists medical guidelines for clinical practice for the diagnosis and treatment of acromegaly--2011 update. *Endocr Pract*. 2011 Jul-Aug; 17 Suppl 4:1- 44.
4. Mathioudakis N, Salvatori R. Management options for persistent postoperative acromegaly. *Neurol Clin N Am*. 2012 Oct; 23(4):621-38.
5. Melmed S, Casanueva FF, Cavagnini F, et al. Guidelines for acromegaly management. *J Clin Endocrinol Metab.* 2002; 87:4054–4058.
6. Melmed S, Colao A, Barkan A, et al. Guidelines for acromegaly management: an update. *J Clin Endocrinol Metab.* 2009; 94:1509–1517.
7. Octreotide injection [prescribing information]. East Brunswick, NJ: Heritage Pharmaceuticals, Inc. May 2019.
8. Sandostatin LAR (octreotide acetate for injectable suspension) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; March 2021.
9. Shlomo, M. Acromegaly. *N Engl J Med*. December 14, 2006; Vol. 355 (24): 2558-2573.
10. Somatuline Depot (lanreotide) [package insert]. Cambridge, MA. Ipsen Biopharmaceuticals. June 2019.
11. The National Endocrine and Metabolic Diseases Information Service. NIH Publication No. 07–3924, April 2007: endocrine.niddk.nih.gov/pubs/acro/acro.htm.
12. Trainer PJ, Drake WM, Katznelson L, et.al. Treatment of acromegaly with the growth hormone- receptor antagonist pegvisomant. *N Engl J Med* 2000; 342:1171-1177.

Approval And Revision History

September 13, 2022: Reviewed by Pharmacy and Therapeutics Committee (P&T).

Subsequent endorsement date(s) and changes made:

- September 21, 2022: Reviewed by the Medical Policy Approval Committee (MPAC)
- September 12, 2023: Minor wording updates to clarify coverage. Administrative update to rebrand Tufts Health Unify to Tufts Health One Care for 2024 (effective 1/1/2024).
- November 2023: Administrative Update in support of calendar year 2024 Medicare Advantage and PDP Final Rule

Background, Product and Disclaimer Information

Point32Health prior authorization criteria to be applied to Medicare Advantage plan members is based on guidance from Medicare laws, National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs). When no guidance is provided, Point32Health uses clinical practice guidance published by relevant medical societies, relevant medical literature, Food and Drug Administration (FDA)-approved package labeling, and drug compendia to develop prior authorization criteria to apply to Medicare Advantage plan members. Medications that require prior authorization generally meet one or more of the following criteria: Drug product has the potential to be used for cosmetic purposes; drug product is not considered as first-line treatment by medically accepted practice guidelines, evidence to support the safety and efficacy of a drug product is poor, or drug product has the potential to be used for indications outside of the indications approved by the FDA. Prior authorization and use of the coverage criteria within this Medical Necessity Guideline will ensure drug therapy is medically necessary, clinically appropriate, and aligns with evidence-based guidelines. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests revisions.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.

Provider Services