Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines

Medical Benefit Drugs

Somatostatin Analogs for Oncology Indications

Effective: January 1, 2025

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 617-673-0939

☐ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax 617-673-0939

☐ 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 - Approved Indications

Lanreotide is a somatostatin analog indicated for the treatment of:

- **Gastroenteropancreatic Neuroendocrine Tumors (GEP-NETs)**
  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.

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 (aka VIPomas)

Sandostatin LAR (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

- **VIPomas**
  Long-term treatment of the profuse watery diarrhea associated with VIP-secreting tumors

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

- **Gastroenteropancreatic Neuroendocrine Tumors (GEP-NETs)**
  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 Syndrome**
  For the treatment of adults with carcinoid syndrome; when used, it reduces the frequency of short-acting somatostatin analog rescue therapy.

Clinical Guideline Coverage Criteria

The plan may authorize coverage of a Somatostatin Analog for Members when the following criteria are met:

1. Documented diagnosis of **one (1)** of the following:
    a. Carcinoid tumor
    b. Carcinoid syndrome
    c. Vasoactive intestinal peptide tumor (VIP, VIPOMA)
    d. Metastatic Gastroenteropancreatic neuroendocrine tumor (GEP-NET)

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
J1932	Injection, lanreotide, (cipla), 1 mg

References

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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. Lanreotide [prescribing information]. Warren, NJ: Cipla USA Inc; Dec 2021.
5. Mathioudakis N, Salvatori R. Management options for persistent postoperative acromegaly.
6. Neurosurg Clin N Am. 2012 Oct; 23(4):621-38.
7. Melmed S, Casanueva FF, Cavagnini F, et al. Guidelines for acromegaly management. J Clin Endocrinol Metab. 2002; 87:4054–4058.
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9. Octreotide injection [prescribing information]. East Brunswick, NJ: Heritage Pharmaceuticals, Inc. May 2019.
10. Sandostatin LAR (octreotide acetate for injectable suspension) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; March 2021.
11. Shlomo, M. Acromegaly. N Engl J Med. December 14, 2006; Vol. 355 (24): 2558-2573.

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Approval And Revision History

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

September 21, 2022: Reviewed by the Medical Policy Approval Committee (MPAC).

Subsequent endorsement date(s) and changes made:

- November 14, 2023: Removed the following Limitation All other indications will be approved for 12-months when covered criteria are met. Expanded diagnosis requirements to be in line with FDA-approved indications (eff 12/1/2023).
- September 10, 2024: Added J1932 Injection, lanreotide, (cipla), 1 mg to the Medical Necessity Guideline (eff 1/1/25).
- September 2024: Administrative Update: Rebranded from Tufts Health Unify to Tufts Health One Care.

Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member's benefit document, and in coordination with the Member's physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

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.