Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines
Medical Benefit Drugs
Somatostatin Analogs

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:

- **Acromegaly**
  For the long-term treatment of acromegalic patients who have had an inadequate response to or cannot be treated with surgery and/or radiotherapy.
- **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:

- **Acromegaly**
  To reduce blood levels of growth hormone (GH) and insulin like growth factor (IGF-I) in acromegaly patients who have had inadequate response to or cannot be treated with surgical resection, pituitary irradiation, and bromocriptine mesylate at maximally tolerated doses
- **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:

- **Acromegaly**
  To reduce blood levels of growth hormone (GH) and insulin like growth factor (IGF-I) in acromegaly patients who have had inadequate response to or cannot be treated with surgical resection, pituitary irradiation, and bromocriptine mesylate at maximally tolerated doses
- **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

Signifor LAR (pasireotide) is a somatostatin analog indicated for the treatment of:

- **Acromegaly**
  To reduce blood levels of growth hormone (GH) and insulin like growth factor (IGF-I) in acromegaly patients who have had inadequate response to or cannot be treated with surgical resection, pituitary irradiation, and bromocriptine mesylate at maximally tolerated doses
- **Cushing Disease**
  Patients with Cushing's disease for whom pituitary surgery is not an option or has not been curative.

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

- **Acromegaly**
  For the long-term treatment of acromegalic patients who have had an inadequate response to or cannot be treated with surgery and/or radiotherapy.
- **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

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

Initial Authorization Criteria

1. Documented diagnosis of acromegaly

AND

2. The prescribing physician is an endocrinologist

AND

3. Documentation the Member is not a candidate for surgery and/or radiation, or has had an inadequate response to surgery and/or radiation

AND

4. Request is for Sandostatin LAR, Signifor LAR or Somatuline Depot, documentation the Member has had a treatment failure, is unable to tolerate, or has a contraindication to a treatment regimen that includes generic injectable octreotide or lanreotide

Reauthorization Criteria

1. Documented diagnosis of acromegaly

AND

2. The prescribing physician is an endocrinologist

AND

3. Documentation of a reduction in baseline growth hormone and/or insulin-like growth factor serum concentrations

AND

4. Request is for Sandostatin LAR, Signifor LAR, or Somatuline Depot, documentation the Member has had a treatment failure, is unable to tolerate, or has a contraindication to a treatment regimen that includes generic injectable octreotide or lanreotide

Carcinoid tumors, Carcinoid Syndrome, Vasoactive Intestinal Peptide (VIP, VIPOMAs) Tumors, Metastatic Gastroenteropancreatic Neuroendocrine Tumors (GEP-NETs)

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

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

Cushing's Disease

The plan may authorization coverage of Signifor LAR for Members when all of the following criteria are met:

Initial Authorization Criteria

1. Documented diagnosis of Cushing's disease

AND

2. Documentation that pituitary surgery is not an option or has not been curative for the Member

AND

3. The prescribing physician is an endocrinologist

AND

4. The Member is 18 years of age or older

Reauthorization Criteria

1. Documented diagnosis of Cushing's disease

AND

2. The prescribing physician is an endocrinologist

AND

3. Member is at least 18 years of age

AND

4. Documentation of a reduction in baseline 24-hour urinary free cortisol levels

Limitations

- For Cushing's disease, initial approval will be limited to 3 months. Reauthorization of the requested medication will be provided in 12-month intervals.
- For acromegaly, initial approval will be limited to 6 months. Reauthorization of the requested medication will be provided in 12-month intervals.
- Members new to the Plan stable on the requested medication should be reviewed against Reauthorization Criteria when the requested use is acromegaly or Cushing's disorder.

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
J2502	Injection, pasireotide long acting, 1 mg
J1930	Injection, lanreotide, 1 mg
J1932	Injection, lanreotide, (cipla), 1 mg

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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 (eff 12/1/2023).
- September 10, 2024: Added J1932 Injection, lanreotide, (cipla), 1 mg to the Medical Necessity Guideline. Acromegaly coverage criteria updated to have generic lanreotide added as part of the step requirements due to generic availability, and included brand Somatuline Depot in the step through octreotide or lanreotide (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.