Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines
Medical Benefit Drugs

Somatostatin Analogs for Non-Oncology Indications

Effective: January 1, 2026

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

Public Plans Products

☒ 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

☒ 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

Acromegaly is a rare, chronic disease often caused by a benign pituitary tumor and characterized by excess production of growth hormone and insulin-like growth factor 1 (IGF-1). If left untreated, acromegaly can lead to serious and sometimes life-threatening complications. Acromegaly is primarily treated with surgical resection of the tumor. Somatostatin analogs are the treatment of choice in patients who are poor candidates for surgery or who have an adenoma that is not fully surgically resectable.

Cushing's syndrome refers to a constellation of symptoms that occur from chronic exposure to excess amounts of glucocorticoids (exogenous or endogenous). The first-line treatment for Cushing's disease is microsurgical resection of the adrenocorticotropic hormone-secreting pituitary adenoma. For patients who have not responded after a surgical procedure or are not candidates for surgery, adrenal enzyme inhibitors, pituitary-directed therapies (Signifor LAR), and glucocorticoid receptor-directed therapies are available.

Food and Drug Administration (FDA) – Approved Indications

Lanreotide is a somatostatin analog indicated for:

- **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**
  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 dose
- **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:

- **Acromegaly**
  Long-term maintenance therapy in acromegalic patients who have had an inadequate response to surgery and/or radiotherapy or for whom surgery and/or radiotherapy is not an option. The goal of treatment in acromegaly is to reduce growth hormone and IGF-1 levels to normal
- **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

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

- **Acromegaly**
  Patients with acromegaly who have had an inadequate response to surgery and/ or for whom surgery is not an option
- **Cushing's 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:

- **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**
  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

Lanreotide and **Sandostatin LAR (octreotide)** are the preferred acromegaly products.

Clinical Guideline Coverage Criteria

Acromegaly

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

1. Documented diagnosis of acromegaly

AND

2. Prescribed by or in consultation with 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

Cushing's Disease

The plan may authorize coverage of Signifor LAR for Members when **ALL** of the following criteria are met:

1. Documented diagnosis of Cushing's Disease

AND

2. Prescribed by or in consultation with an endocrinologist

AND

3. Documentation the Member is not a candidate for pituitary surgery, or that pituitary surgery has not been curative.

Limitations

- For Acromegaly, refer to the Medicare Part B Step Therapy Medical Necessity Guideline for additional requirements.

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

References

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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:

- September 12, 2023: Added the following Limitation: Refer to the Medicare Part B Step Therapy Medical Necessity Guideline for additional requirements. 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 Updates: Rebranded from Tufts Health Unify to Tufts Health One Care for 2024 and administrative update in support of calendar year 2024 Medicare Advantage and PDP Final Rule.
- September 10, 2024: Updated preferred Acromegaly Products to Sandostatin LAR (octreotide) and lanreotide. Added Lanreotide (Cipla) to the Medical Necessity Guideline (eff 1/1/25).
- September 2024: Joint Medical Policy and Health Care Services UM Committee review (eff 1/1/25).
- July 2025: Administrative update to remove Harvard Pilgrim Health Care Stride Medicare Advantage from the Medical Necessity Guideline template

- December 9, 2025: No changes (eff 1/1/26)
- December 2025: Joint Medical Policy and Health Care Services UM Committee review (effective 1/1/26)

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 guidelines 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.