

Effective: January 1, 2024

Guideline Type	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Non-Formulary <input type="checkbox"/> Step-Therapy <input type="checkbox"/> Administrative
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Applies to:

Commercial Products

- Harvard Pilgrim Health Care Commercial products; Fax 617-673-0988
- Tufts Health Plan Commercial products; Fax 617-673-0988
 CareLinkSM – 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

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

Sandostatin (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

Sandostatin LAR (octreotide) and **Somatuline Depot (lanreotide)** are the preferred acromegaly products.

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 oncology-related uses.

Clinical Guideline Coverage Criteria

Acromegaly

The plan may authorize coverage of 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
2. Prescribed by or in consultation with an endocrinologist
3. Documentation the Member is not a candidate for pituitary surgery, or that pituitary surgery has not been curative.

AND

AND

Limitations

- 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

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. *Neurosurg 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. Signifor LAR (pasireotide) [package insert]. Lebanon, NJ. Recordati Rare Diseases; June 2020.
10. Somatuline Depot (lanreotide) [package insert]. Cambridge, MA. Ipsen Biopharmaceuticals. June 2019.
11. Shlomo, M. Acromegaly. *N Engl J Med*. December 14, 2006; Vol. 355 (24): 2558-2573.
12. The National Endocrine and Metabolic Diseases Information Service. NIH Publication No. 07–3924, April 2007: endocrine.niddk.nih.gov/pubs/acro/acro.htm.
13. 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.
14. Katznelson L, et al. Acromegaly: An Endocrine Society Clinical Practice Guideline. *The Journal of Clinical Endocrinology & Metabolism*, Volume 99, Issue 11, 1 November 2014, Pages 3933–3951.
15. Nieman LK, et al. Treatment of Cushing's Syndrome: An Endocrine Society Clinical Practice Guideline. *The Journal of Clinical Endocrinology & Metabolism*, Volume 100, Issue 8, 1 August 2015, Pages 2807–2831.

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.

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.