Medical Necessity Guidelines

Medical Benefit Drugs

Somatostatin Analogs for Non-oncology Indications

Effective: December 1, 2023

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

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

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

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.

Note: Providers and Members enrolled with Harvard Pilgrim Health Care may reference HPHC/OncoHealth guideline for oncology indications located at https://oncohealth.us/medicalpolicies/harvardpilgrim/.

For Providers and Members enrolled with Tufts Health Plan, reference the SOMATOSTATIN ANALOGS Medical Necessity Guideline for NON-ONCOLOGY indications for all other uses.

Clinical Guideline Coverage Criteria

Acromegaly
The plan may authorization 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

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

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

- The health plan may authorize initial coverage for up to 6 months when initial coverage criteria are met.
- The health plan may reauthorize coverage for 12 months if reauthorization criteria are met.
- Members new to the Plan stable on the requested medication should be reviewed against Reauthorization Criteria

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.
5. Neurosurg Clin N Am. 2012 Oct; 23(4):621-38.
6. Melmed S, Casanueva FF, Cavagnini F, et al. Guidelines for acromegaly management. J Clin Endocrinol Metab. 2002; 87:4054–4058.
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8. Octreotide injection [prescribing information]. East Brunswick, NJ: Heritage Pharmaceuticals, Inc. May 2019.
9. Sandostatin LAR (octreotide acetate for injectable suspension) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; March 2021.
10. Shlomo, M. Acromegaly. N Engl J Med. December 14, 2006; Vol. 355 (24): 2558-2573.
11. Signifor LAR (pasireotide) [prescribing information]. Lebanon, NJ; Recordati Rare Diseases. June 2020.
12. Somatuline Depot (lanreotide) [prescribing information]. Cambridge, MA; Ipsen Biopharmaceuticals, Inc. June 2019.
13. The National Endocrine and Metabolic Diseases Information Service. NIH Publication No. 07–3924, April 2007: endocrine.niddk.nih.gov/pubs/acro/acro.htm.
14. 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).
- November 14, 2023: Removed the following Limitation All other indications will be approved for 12-months when covered criteria are met. Administrative update to clarify review process for members new to the plan stable on the medication (eff 12/1/2023).
- November 2023: Administrative update to rebrand Tufts Health Unify to Tufts Health One Care for 2024.

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.