Pharmacy Medical Necessity Guidelines: Acromegaly Agents

Effective: November 16, 2020

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX/ MED	Department to Review	RXUM /MM

These pharmacy medical necessity guidelines apply to the following:

Commercial Products

☐ Tufts Health Plan Commercial products – large group plans
☐ Tufts Health Plan Commercial products – small group and individual plans
☐ Tufts Health Freedom Plan products – large group plans
☐ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Public Plans Products

☐ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☒ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☒ Tufts Health RITogether – A Rhode Island Medicaid Plan

Fax Numbers:

RXUM: 617.673.0988 - *Somavert*

MM: 888.415.9055 - *octreotide, Sandostatin LAR, Signifor LAR*

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

Octreotide is a samatostatin 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 Tumors**
  For the treatment of the profuse watery diarrhea associated with Vasoactive Intestinal Peptide-secreting tumors

Bynfezia Pen (octreotide)

- **Acromegaly**
  To reduce blood levels of growth hormone (GH) and insulin like growth factor (IGF-I) in adult patients with acromegaly who have had inadequate response to or cannot be treated with surgical resection, pituitary irradiation, and bromocriptine mesylate at maximally tolerated doses
- **Carcinoid Tumors**
  Treatment of adults patients with severe diarrhea and flushing episodes associated with metastatic carcinoid tumors
- **Vasoactive Intestinal Peptide Tumors**
  Treatment of adult patients with the profuse watery diarrhea associated with Vasoactive Intestinal Peptide-secreting tumors

Mycapssa (octreotide)

- **Acromegaly**
  Long-term maintenance treatment in acromegaly patients who have responded to and tolerated treatment with octreotide or lanreotide

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
- **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**
  Patients with acromegaly who have had an inadequate response to surgery and/or for whom surgery is not an option
- **Cushing's disease**
  Cushing's disease for whom pituitary surgery is not an option or has not been curative

Somavert (pegvisomant) is a growth hormone receptor antagonist indicated for the treatment of:

- **Acromegaly**
  Acromegaly in patients who have had an inadequate response to surgery or radiation therapy, or for whom these therapies are not appropriate

COVERAGE GUIDELINES

Acromegaly

The plan may authorization coverage of octreotide, Bynfezia (octreotide), Mycapssa (octreotide) Sandostatin LAR (octreotide), Signifor LAR (pasireotide), or Somavert (pegvisomant) for Members when all of the following criteria are met:

Initial Therapy

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

In addition to the above criteria, the plan may authorize coverage of Bynfezia (octreotide), Mycapssa (octreotide), Sandostatin LAR (octreotide), Signifor LAR (pasireotide), or Somavert (pegvisomant) for Members when all of the following criteria are met:

1. Documentation the Member has had a failure of, or is unable to tolerate, a treatment regimen that included generic injectable octreotide or Somatuline Depot (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

In addition to the above criteria, the plan may authorize coverage of Bynfezia (octreotide), Mycapssa (octreotide), Sandostatin LAR (octreotide), Signifor LAR (pasireotide), or Somavert (pegvisomant) for Members when all of the following criteria are met:

1. Documentation the Member has had a failure of, or is unable to tolerate, a treatment regimen that included generic injectable octreotide or Somatuline Depot (lanreotide)

Carcinoid tumors, Vasoactive Intestinal Peptide Tumors
The plan may authorize coverage of octreotide, Bynfezia (octreotide) or Sandostatin LAR (octreotide) for Members when all of the following criteria are met:
1. Documented diagnosis of one of the following:
    a. Carcinoid tumor
    b. Vasoactive intestinal peptide tumor

Cushing's disease
The plan may authorize coverage of **Signifor LAR** for Members when all of the following criteria are met:
Initial Therapy
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. 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 coverage of Sandostatin (octreotide) immediate-release is limited to 90 single dose vials or 30 multidose vials per 28 days.
- The coverage of Sandostatin LAR (octreotide) is limited to 1 kit per 28 days.
- The coverage of Somatuline Depot (lanreotide) is limited to 1 kit per 28 days.
- The coverage of Somavert (pegvisomant) is limited to a maximum daily dose of two; up to 32 single dose vials for the first 28 days then up to 56 single dose vials per 28 days.
- For Signifor LAR for the treatment of Cushing's disease, initial approval will be limited to 3 months. Reauthorization of Signifor LAR (pasireotide) 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 HCPCS/CPT code(s) are:

Code	Description
J1930	Injection, lanreotide, 1 mg
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

REFERENCES

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APPROVAL HISTORY

April 14, 2015: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:
1. May 12, 2015: Added Signifor LAR (pasireotide) to Medical Necessity Guidelines.
2. June 9, 2015: Administrative update: added HCPCS code C9454 to policy.
3. January 1, 2016: Administrative change to rebranded template.
4. May 10, 2016: Administrative update: Replaced C9454 with J2502.
5. February 14, 2017: Removed somatuline depot from the Medical Necessity Guideline.
6. April 11, 2017: Administrative update, Adding Tufts Health RITogether to the template
7. February 13, 2018: Effective February 19, 2018, Medical Necessity Guideline applies to Tufts Health RITogether. Administrative update: Removed Limitation #5 (Signifor LAR [pasireotide] is covered under the medical benefit only) to be in line with current coverage.
8. February 12, 2019: For Acromegaly, updated the criteria to "Documentation the Member has a diagnosis of acromegaly from an endocrinologist." Added coverage criteria for Signifor LAR for new supplemental indication for Cushing's disease.
9. April 14, 2020: Effective July 1, 2020, modified reauthorization criteria for acromegaly and Cushing's disease and added the following Limitation: "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." Updated coverage criteria to require a documented diagnosis of Cushing's disease. Aligned coverage criteria with FDA-approved indications for medications included in the Medical Necessity Guideline and removed any off-label indications from coverage criteria.

10. November 10, 2020: Added Mycapssa (octreotide) and Bynfezia (octreotide) to the Medical Necessity Guideline. Updated the coverage criteria for Acromegaly to require "Documentation the Member has had a failure of, or is unable to tolerate, a treatment regimen that included injectable octreotide or Somatuline Depot (lanreotide)" now that additional brand formulations are available.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be 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 the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy 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 Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.