Pharmacy Medical Necessity Guidelines: Signifor® LAR (pasireotide)

Effective: July 1, 2020

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

All plans except Tufts Health Direct – Health Connector:
PRECERT: 617.972.9409

Tufts Health Direct – Health Connector only:
MM: 888.415.9055

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

OVERVIEW

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

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

- **Acromegaly**
  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

COVERAGE GUIDELINES

The plan may authorize coverage of Signifor LAR (pasireotide) for Members when all of the following criteria are met:

Acromegaly

Initial Therapy

1. Documented diagnosis of acromegaly

AND

2. The prescribing physician is an endocrinologist

AND

3. Documentation the Member has had a failure of, or is unable to tolerate, a treatment regimen that included octreotide (Sandostatin/ Sandostatin LAR Depot), lanreotide (Somatuline Depot) or pegvisomant (Somavert)

AND

4. 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

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. 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 Acromegaly, initial approval will be limited to 6 months. Reauthorization of Signifor LAR (pasireotide) will be provided in 12-month intervals.
- For Cushing's disease, initial approval will be limited to 3 months. Reauthorization of Signifor LAR (pasireotide) will be provided in 12-month intervals.
- The plan does not cover Signifor LAR (pasireotide) for any conditions not listed in the Pharmacy Coverage Guidelines above, unless there is sufficient documentation of efficacy and safety in the published literature.
- Members new to the plan stable on Signifor LAR (pasireotide) should be reviewed against Reauthorization Criteria.

CODES

The following HCPCS/CPT code(s) are:

Code	Description
J2502	Injection, pasireotide long acting, 1 mg

REFERENCES

1. Bernabeu I, Alvarez-Escolá C, Paniagua AE et al. Pegvisomant and cabergoline combination therapy in acromegaly. *Pituitary*. 2012 Mar 7.
2. 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.
3. 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.
4. Gadelha MR, Bronstein MD, Brue T, et al. Pasireotide versus continued treatment with octreotide or lanreotide in patients with inadequately controlled acromegaly (PAOLA): a randomised, phase 3 trial. *Lancet Diabetes Endocrinol*. 2014 Nov;2(11):875-84.
5. 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.
6. Mathioudakis N, Salvatori R. Management options for persistent postoperative acromegaly. *Neurosurg Clin N Am*. 2012 Oct; 23(4):621-38.
7. Melmed S, Casanueva FF, Cavagnini F, et al. Guidelines for acromegaly management. *J Clin Endocrinol Metab*. 2002; 87:4054–4058.
8. Melmed S, Colao A, Barkan A, et al. Guidelines for acromegaly management: an update. *J Clin Endocrinol Metab*. 2009; 94:1509–1517.
9. Plöckinger U. Medical therapy of acromegaly. *Int J Endocrinol*. 2012; 2012:268957.
10. Sheppard M, Bronstein MD, Freda P, et al. Pasireotide LAR maintains inhibition of GH and IGF-1 in patients with acromegaly for up to 25 months: results from the blinded extension phase of a randomized, double-blind, multicenter, Phase III study. *Pituitary*. 2015 Jun;18(3):385-94.
11. Shlomo, M. Acromegaly. *N Engl J Med*. December 14, 2006; Vol. 355 (24): 2558-2573.

12. Signifor LAR (pasireotide) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; June 2018.
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.
15. van der Lely AJ, Biller BM, Brue T et al. Long-term safety of pegvisomant in patients with acromegaly: comprehensive review of 1288 subjects in ACROSTUDY. *J Clin Endocrinol Metab*. 2012 May; 97(5):1589-97.

APPROVAL HISTORY

May 12, 2015: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:
1. January 1, 2016: Administrative update: Added medical billing code to policy. Changed to rebranded template.
2. May 10, 2016: No changes.
3. April 11, 2017: Administrative update, adding Tufts Health RITogether to the template.
4. July 11, 2017: No changes.
5. July 10, 2018: No changes.
6. February 12, 2019: Added coverage criteria for new supplemental indication of Cushing's disease.
7. April 14, 2020: Effective July 1, 2020, modified reauthorization criteria and added the following Limitation: "Members new to the plan stable on Signifor LAR (pasireotide) should be reviewed against Reauthorization Criteria." Updated coverage criteria for Cushing's disease, to require a documented diagnosis of Cushing's disease.

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.

Provider Services