

Pharmacy Medical Necessity Guidelines: Signifor® (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	RX	Department to Review	RXUM
<p>These pharmacy medical necessity guidelines apply to the following:</p> <p>Commercial Products</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Tufts Health Plan Commercial products – large group plans <input checked="" type="checkbox"/> Tufts Health Plan Commercial products – small group and individual plans <input checked="" type="checkbox"/> Tufts Health Freedom Plan products – large group plans <input checked="" type="checkbox"/> Tufts Health Freedom Plan products – small group plans • CareLinkSM – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization <p>Tufts Health Public Plans Products</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product) <input checked="" type="checkbox"/> Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans <input checked="" type="checkbox"/> Tufts Health RITogether – A Rhode Island Medicaid Plan 		<p>Fax Numbers:</p> <p>RXUM: 617.673.0988</p>	

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

OVERVIEW

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

Signifor (pasireotide) is a somatostatin analog indicated for the treatment of adult patients with Cushing’s disease for whom pituitary surgery is not an option or has not been curative.

Cushing’s disease is a rare, aggressive endocrine condition that is caused by an ACTH-secreting pituitary adenoma. Cushing’s disease can occur spontaneously in children and adults, and it typically occurs after puberty with similar frequency in males and females. Most adults are diagnosed between 25 years of age and 45 years of age.

In Cushing’s disease, the pituitary adenoma produces excessive ACTH causing adrenal hyperplasia and excessive cortisol production. The normal cortisol feedback mechanism of the hypothalamic-pituitary-adrenal (HPA) axis is interrupted, with loss of circadian rhythm and hypercortisolism. Cushing’s disease is the most frequent cause of Cushing’s syndrome. Complications associated with exposure to excess endogenous glucocorticoids (hypercortisolism) can include obesity, diabetes mellitus, dyslipidemia, hypertension, hypercoagulability, increased risk for infection, bone demineralization which can increase the risk for fracture, depression, cognitive impairment, respiratory complications, severe fatigue and muscle weakness, purplish skin striae, easy bruising, hyperpigmentation, loss of libido, hirsutism, acne, and menstrual disorders. The condition results in significant morbidity and mortality.

The goals of treatment of ACTH-dependent Cushing’s syndrome include reversal of clinical features, normalization of biochemical changes with minimal morbidity, and long-term control without recurrence. Treatment of Cushing’s syndrome is almost always surgical, and targets the site of pathologic hormone overproduction. The treatment of choice is trans-sphenoidal surgery in Cushing’s disease. In patients with microadenomas, the remission rate is between 65% and 90% for those that undergo trans-sphenoidal surgery. However, the remission rate is lower (<65%) for patients with macroadenomas. Despite initial cure, up to 25% of patients will experience a recurrence within 10 years and a second surgery can be performed in selected cases. Radiation therapy is an alternative treatment option that can be considered in patients with remnant or recurrent disease.

COVERAGE GUIDELINES

The plan may authorize coverage of Signifor (pasireotide) for Members when all the following criteria are met and limitations do not apply:

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 at least 18 years of age

Reauthorization Criteria

1. Documented diagnosis of Cushing's disease
- AND
2. The prescribing physician is an endocrinologist
- AND
3. Member is at least 18 year of age
- AND
4. Documentation of a reduction in baseline 24-hour urinary free cortisol levels

LIMITATIONS

- Initial approval will be limited to 3 months. Reauthorization of Signifor (pasireotide) will be provided in 12-month intervals.
- The plan does not cover Signifor (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 (pasireotide) should be reviewed against Reauthorization Criteria.
- Coverage for Signifor (pasireotide) will be limited to 60 ampules per 30 days.

CODES

Medical billing codes may not be used for these medications. These medications must be obtained via the Member's pharmacy benefit.

REFERENCES

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4. Fleseriu M, Petersen S. Medical management of Cushing's disease: what is the future? *Pituitary.* 2012; 15: 330-41.
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7. Gadelha MR, Bronstein MD, Brue T, Coculescu M, Fleseriu M, Guitelman M, Pronin V, Raverot G, Shimon I, Lievre KK, Fleck J, Aout M, Pedroncelli AM, Colao A; Pasireotide C2402 Study Group. 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.
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APPROVAL HISTORY

June 12, 2014: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. June 9, 2015: No changes.
2. January 1, 2016: Administrative change to rebranded template.
3. June 14, 2016: No changes.
4. April 11, 2017: Administrative update. Effective 6/1/2017, Medical Necessity Guideline applies to Tufts Health RITogether.
5. June 13, 2017: No changes.
6. June 12, 2018: No changes.
7. February 12, 2019: No changes.
8. April 14, 2020: Effective July 1, 2020, modified reauthorization criteria and added the following Limitation: "Members new to the plan stable on Signifor (pasireotide) should be reviewed against Reauthorization Criteria." Updated coverage criteria 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.