Pharmacy Medical Necessity Guidelines: Cinacalcet

Effective: March 16, 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

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

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

OVERVIEW

FDA-APPROVED INDICATIONS

Sensipar® (cincalcet) is indicated for secondary hyperparathyroidism (HPT) in patients with chronic kidney disease (CKD) on dialysis, hypercalcemia in patients with parathyroid carcinoma and hypercalcemia in patients with primary HPT who are unable to undergo parathyroidectomy.

COVERAGE GUIDELINES

The plan may authorize coverage of cinacalcet for Members when **all** the following criteria are met and limitations do not apply:

1. Member has a diagnosis of secondary hyperparathyroidism due to chronic kidney disease and is on dialysis and meets one of the following:
   a) Member has tried and failed treatment with, or has documentation from the prescriber of clinical inappropriateness to at least one generic phosphate binder or vitamin D analog

   OR

   b) Member is new to the plan and has been stabilized on cinacalcet prior to enrollment

   OR

2. Member has one of the following diagnoses:
   a. Hypercalcemia associated with primary hyperparathyroidism and is unable to undergo a parathyroidectomy
   b. Hypercalcemia associated with parathyroid carcinoma

LIMITATIONS

1. Requests for brand-name products, which have AB-rated generics, will be reviewed according to the Brand Name criteria.

CODES

None

REFERENCES

1. Sensipar® [package insert]. Amgen; Thousand Oaks, CA: December 2019. Peacock M, et al. Cinacalcet Hydrochloride Maintains Long-Term Normocalcemia in Patients with Primary Hyperparathyroidism. J. Clin. Endocrinol. Metab. 2005 90:135-141.
2. Lindberg J, et al. Cinacalcet HCl, an Oral Calcimimetic Agent for the Treatment of Secondary Hyperparathyroidism in Hemodialysis and Peritoneal Dialysis: A Randomized, Double-Blind, Multicenter Study. J Am Soc Nephrol 2005; 16: 800–807.

3. Moe SM, et al. Long-term treatment of secondary hyperparathyroidism (HPT) with the calcimimetic cinacalcet HCl [abstract]. American Society of Nephrology Annual Meeting; November 12-17, 2003; San Diego, CA. Abstract SA-PO753.
4. Peacock M, et al. The calcimimetic AMG 073 reduces serum calcium (Ca) in patients with primary hyperparathyroidism (PHPT) [abstract]. 23rd Annual Meeting of the American Society of Bone and Mineral Research; 2001. Abstract 1106. (www.asbmr.org) Accessed January 8, 2004.
5. Chonchol M, et al. A randomized, double-blind, placebo-controlled study to assess the efficacy and safety of cinacalcet HCl in participants with CKD not receiving dialysis. Am J Kidney Dis 2009 Feb;53(2):197-207.

APPROVAL HISTORY

January 20, 2011: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:
1. August 12, 2014: No changes.
2. September 16, 2015: No changes.
3. January 1, 2016: Administrative change to rebranded template.
4. September 13, 2016: No changes
5. May 9, 2017: Administrative update. Effective 6/1/2017, Medical Necessity Guideline applies to Tufts Health RITogether. Updated criteria to state that a member much try and fail at least one generic phosphate binder.
6. September 12, 2017: No changes
7. October 16, 2018: Administrative update to template.
8. April 9, 2019: Removed "severe" from the diagnosis "hypercalcemia associated with primary hyperparathyroidism and is unable to undergo a parathyroidectomy."
9. October 15, 2019: Effective 10/21/19, removed the requirement for trial and failure with a phosphate binder for the diagnoses of hypercalcemia associated with primary hyperparathyroidism and hypercalcemia associated with parathyroid carcinoma.
10. March 10, 2020: Effective March 16, 2020, updated the criteria for secondary hyperparathyroidism due to chronic kidney disease to allow trial and failure with a generic vitamin D analog as an appropriate previous treatment. Added "Requests for brand-name products, which have AB-rated generics, will be reviewed according to the Brand Name criteria" to the limitations section of the MNG and updated the title of the MNG from "Sensipar" to "Cinacalcet".

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