Pharmacy Medical Necessity Guidelines: Cinacalcet

Effective: June 9, 2026

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: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RXUM: 617.673.0939	

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

OVERVIEW

FDA-APPROVED INDICATIONS

Cinacalcet 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 or secondary hyperparathyroidism with hypercalcemia, has chronic kidney disease, and is on dialysis

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. Ketteler M, Block GA, Evenepoel P, et al. Executive summary of the 2017 KDIGO Chronic Kidney Disease-Mineral and Bone Disorder (CKD-MBD) Guideline Update: what's changed and why it matters. Kidney Int 2017;92:26.
2. Kidney Disease: Improving Global Outcomes (KDIGO) CKD-MBD Update Work Group. KDIGO 2017 clinical practice guideline update for the diagnosis, evaluation, prevention, and treatment of chronic kidney disease-mineral and bone disorder (CKD-MBD). *Kidney Int Suppl*. 2017;7:1-59.
3. 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.
4. Sensipar® (cinacalcet) [package insert]. Amgen; Thousand Oaks, CA: December 2019.
5. Peacock M, et al. Cinacalcet Hydrochloride Maintains Long-Term Normocalcemia in Patients with Primary Hyperparathyroidism. J. Clin. Endocrinol. Metab. 2005 90:135-141.

APPROVAL HISTORY

October 11, 2022: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. August 8, 2023: Effective September 1, 2023, removed step through requirements with phosphate binder or vitamin D analog for secondary hyperparathyroidism with CKD on dialysis.
2. May 14, 2024: Effective June 1, 2024, updated RxUM fax number.
3. May 13, 2025: No changes
4. June 9, 2026: No changes.

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