Pharmacy Medical Necessity Guidelines:
Sensipar® (cinacalcet)

Effective: September 12, 2017

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

This Pharmacy Medical Necessity Guidelines applies to the following:

Tufts Health Plan Commercial Plans
☐ Tufts Health Plan Commercial Plans – large group plans
☐ Tufts Health Plan Commercial Plans – small group and individual plans

Tufts Health Public Plans
☐ Tufts Health Direct – Health Connector
☒ Tufts Health Together – A MassHealth Plan
☐ Tufts Health RITogether – A RIt Care + Rhody Health Partners Plan

Tufts Health Freedom Plan products
☐ Tufts Health Freedom Plan - large group plans
☐ Tufts Health Freedom Plan - small group plans

OVERVIEW

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

COVERAGE GUIDELINES
The plan may authorize coverage of Sensipar® (cinacalcet) for Members when all the following criteria are met and limitations do not apply:

1. Member has one of the following diagnoses:
   • Secondary hyperparathyroidism due to chronic kidney disease and is on dialysis
   • Severe hypercalcemia associated with primary hyperparathyroidism and is unable to undergo a parathyroidectomy
   • Hypercalcemia associated with parathyroid carcinoma

   AND

2. 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 of the following medications: calcium acetate, sevelamer, doxercalciferol, or calcitriol

   OR

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

LIMITATIONS
None

CODES
None

REFERENCES

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

Subsequent endorsement date(s) and changes made:
- August 12, 2014: No changes.
- September 16, 2015: No changes.
- January 1, 2016: Administrative change to rebranded template.
- September 13, 2016: No changes
- May 9, 2017: Administrative update, Adding Tufts Health RITogether to the template
- September 12, 2017: 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. They are used in conjunction with a Member's benefit document and in coordination with the Member’s physician(s). 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.

This Pharmacy Medical Necessity Guideline does not apply to Uniformed Services Family Health Plan Members or to certain delegated service arrangements. Unless otherwise noted in the Member's benefit document or applicable Pharmacy Medical Necessity Guideline, Pharmacy Medical Necessity Guidelines do not apply to CareLinkSM Members. For self-insured plans, drug coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a coverage guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern.

Applicable state or federal mandates will take precedence.
For Tufts Health Plan Medicare Preferred, please refer to Tufts Health Plan Medicare Preferred Prior Authorization Criteria.

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