Pharmacy Medical Necessity Guidelines: Sensipar® (cincalcet)

Effective: October 22, 2018

<table>
<thead>
<tr>
<th>Prior Authorization Required</th>
<th>Type of Review – Care Management</th>
<th>Type of Review – Clinical Review</th>
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</thead>
<tbody>
<tr>
<td>✓</td>
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<td>✓</td>
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<tr>
<td>Not Covered</td>
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<tr>
<td>Pharmacy (RX) or Medical (MED) Benefit</td>
<td>Department to Review</td>
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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
- 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
- MM: 888.415.9055
- PRECERT: 617.972.9409

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 severe hypercalcemia in patients with primary HPT who are unable to undergo parathyroidectomy.

COVERAGE GUIDELINES
The plan may authorize coverage of Sensipar® (cincalcet) 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:
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, Adding Tufts Health RITogether to the template
6. 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. 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.