

## PRIOR AUTHORIZATION POLICY

**POLICY:** Cinacalcet (Sensipar) Prior Authorization Policy

- Sensipar® (cinacalcet tablets – Amgen, generic)

**REVIEW DATE:** 02/10/2021

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### Overview

Cinacalcet (Sensipar, generic), a calcium-sensing receptor agonist (calcimimetic), is indicated for the following uses:<sup>1</sup>

- **Hypercalcemia** in adult patients with **parathyroid carcinoma**.
- **Hypercalcemia** in adult patients with **primary hyperparathyroidism** for whom parathyroidectomy would be indicated on the basis of serum calcium levels, but who are unable to undergo parathyroidectomy.
- **Secondary hyperparathyroidism** in adult patients with chronic kidney disease (CKD) on dialysis.

### Disease Overview

Secondary hyperparathyroidism is a frequent complication of CKD caused by a reduction in circulating calcitriol levels and disturbances in calcium and phosphorous metabolism.<sup>2</sup> This leads to increases in the parathyroid hormone (PTH) levels, which then leads to osteoclastic activity resulting in bone resorption and marrow fibrosis.

Parathyroid carcinoma is a rare malignant cancer and is an uncommon cause of primary hyperparathyroidism.<sup>3</sup> The condition is associated with higher serum calcium and PTH levels than primary hyperparathyroidism due to benign adenoma. The primary cause of morbidity in patients with parathyroid carcinoma is due to complications of hypercalcemia (e.g., cardiac arrhythmias, renal failure). Surgical resection of the malignancy may relieve symptoms and reduce serum calcium levels. Medical therapy with cinacalcet and intravenous bisphosphonates are useful adjunct therapies to control hypercalcemia.

### Guidelines

The Kidney Disease: Improving Global Outcomes (KDIGO) clinical practice guidelines (2017) for the treatment of CKD-mineral bone disorder (MBD) recommend the use of cinacalcet, calcitriol, vitamin D analogues, or a combination of these agents in CKD stage 5D (dialysis) patients with elevated or rising PTH levels.<sup>4</sup> The guidelines recognize that there are no randomized controlled trials showing that treatment to achieve a specific PTH level results in improved outcomes. There is no established “cause and effect” relationship between the measured biochemical variables and observed outcomes. Therefore, the guidelines recommend interpreting changes in PTH in conjunction with calcium and phosphorous levels to guide therapeutic decisions. In general, in patients with CKD stage 5D, the KDIGO guidelines suggest maintaining intact PTH (iPTH) levels in the range of approximately two to nine times the upper limit of normal for the assay. Changes in therapy are suggested if there are marked changes in PTH levels in either direction within this range. If iPTH levels fall below two times the upper limit of normal for the assay, the use of calcimimetics, calcitriol, or vitamin D analogues should be reduced or discontinued.

### Other Uses with Supportive Evidence

The KDIGO clinical practice guidelines (2017) for the treatment of CKD-MBD note that although cinacalcet is not approved for the treatment of hyperparathyroidism in kidney transplant recipients, it is used in these patients, especially those with significant hypercalcemia.<sup>4</sup>

### POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of cinacalcet. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with cinacalcet as well as the monitoring required for adverse events and long-term efficacy, approval requires cinacalcet to be prescribed by or in consultation with a physician who specializes in the condition being treated.

**Automation:** When available, the ICD-9/ICD-10 codes for Malignant Neoplasm of Parathyroid Gland (ICD-9: 194.1\* and ICD-10: C75.0\*) AND “oncologist or endocrinologist” will be used as part of automation to allow approval of the requested medication.

#### RECOMMENDED AUTHORIZATION CRITERIA

Coverage of cinacalcet is recommended in those who meet the following criteria:

##### FDA-Approved Indications

1. **Hypercalcemia due to Parathyroid Carcinoma.** Approve for 1 year if cinacalcet is prescribed by or in consultation with an oncologist or endocrinologist.
2. **Hypercalcemia in Patients with Primary Hyperparathyroidism.** Approve for 1 year if the patient meets both of the following criteria (A and B):
  - A) Patient has failed or is unable to undergo a parathyroidectomy due to a contraindication; AND
  - B) The medication is prescribed by or in consultation with a nephrologist or endocrinologist.
3. **Secondary Hyperparathyroidism.** Approve for 1 year if the patient meets the following criteria (A, B, and C):
  - A) Patient has chronic kidney disease and is on dialysis; AND
  - B) The baseline (prior to starting cinacalcet therapy) intact parathyroid hormone (iPTH) level is at least two times the upper limit of normal as defined by the laboratory reference value measured on two separate occasions; AND
  - C) The medication is prescribed by or in consultation with a nephrologist or endocrinologist.

##### Other Uses with Supportive Evidence

4. **Hyperparathyroidism in Post-Renal Transplant Patients.** Approve for 1 year if the patient meets both of the following conditions (A and B):
  - A) The baseline (prior to starting cinacalcet therapy) calcium and intact parathyroid hormone (iPTH) levels are above the normal range, as defined by the laboratory reference values; AND
  - B) The medication is prescribed by or in consultation with a transplant physician, nephrologist, or endocrinologist.

#### CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of cinacalcet is not recommended in the following situations:

1. **Patients with Primary Hyperparathyroidism eligible for Parathyroidectomy.** Parathyroidectomy is the primary treatment for primary hyperparathyroidism.
2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

## REFERENCES

1. Sensipar® [prescribing information]. Thousand Oaks, CA: Amgen Inc.; December 2019.
2. Crockell YJ. Management of chronic kidney disease: An emphasis on delaying disease progression and treatment options. *Formulary*. 2012;47:228-236.
3. Sharretts JM, Kebebew E, Simonds WF. Parathyroid Cancer. *Semin Oncol*. 2010;37:580-590.
4. Kidney Disease Improving Global Outcomes (KDIGO). KDIGO clinical practice guideline for the diagnosis, evaluation, prevention, and treatment of chronic kidney disease-mineral and bone disorder (CKD-MBD). © 2017 KDIGO. Available at: <http://www.kdigo.org/pdf/KDIGO%20CKD-MBD%20GL%20KI%20Suppl%20113.pdf>. Accessed on February 4, 2021.