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Prior Authorization
Cinacalcet tablets (Sensipar®, generic)

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Product Identifier(s)

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National Formulary Medical Necessity

Cigna covers cinacalcet products (Sensipar®) as medically necessary when the following criteria are met for FDA Indications or Other Uses with Supportive Evidence:

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 individuals 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.

FDA Indication(s)

- 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 an individual with Primary Hyperparathyroidism. Approve for 1 year if the individual meets both of the following criteria (A and B):

- A) Individual 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 individual meets the following criteria (A, B, and C):

- A) Individual has chronic kidney disease; AND
- B) Individual is on dialysis; AND
- C) 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
- D) The medication is prescribed by or in consultation with a nephrologist or endocrinologist.

Other Uses with Supportive Evidence

4. Hyperparathyroidism in a Post-Renal Transplant Individual. Approve for 1 year if the individual 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 Covered

Cinacalcet (Sensipar®) is considered experimental, investigational or unproven for ANY other use including the following (this list may not be all inclusive):

1. Individual with Primary Hyperparathyroidism Eligible for Parathyroidectomy. Parathyroidectomy is the primary treatment for primary hyperparathyroidism.

Background

Overview

Cinacalcet, a calcium-sensing receptor agonist (calcimimetic), is indicated for the following uses:¹

- **Hypercalcemia parathyroid carcinoma** in adults.
- **Hypercalcemia with primary hyperparathyroidism** in adults for whom parathyroidectomy would be indicated on the basis of serum calcium levels, but who are unable to undergo parathyroidectomy.
- **Secondary hyperparathyroidism** with chronic kidney disease (CKD) in adults on dialysis.
Limitation of use: Cinacalcet is not indicated for use in patients with CKD who are not on dialysis due to increased risk of hypocalcemia.

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.² 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, a rare malignant cancer, is an uncommon cause of primary hyperparathyroidism.³ 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 (2009; updated 2017) for the treatment of CKD-mineral bone disorder (CKD-MBD) consider calcimimetics (cinacalcet), calcitriol, or vitamin

D analogs (or a combination of these agents) as reasonable first line options for patients with CKD stage 5D who require PTH-lowering therapy.^{4,5} If intact parathyroid hormone (iPTH) levels fall below two times the upper limit of normal for the assay, these products 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.^{4,5}

References

1. Sensipar[®] tablets [prescribing information]. Thousand Oaks, CA: Amgen; 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) CKD – MBD Work Group, KDIGO clinical practice guideline for the diagnosis, evaluation, prevention, and treatment of chronic kidney disease-mineral and bone disorder (CKD-MBD). *Kidney Int Suppl*. 2009;76(Suppl 113):S1-S130.
5. 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.

Revision History

| Type of Revision | Summary of Changes | Approval Date |
|------------------|----------------------|---------------|
| Annual Revision | No criteria changes. | 03/01/2023 |

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