PRIOR AUTHORIZATION POLICY

POLICY: Cinacalcet Prior Authorization Policy
- Sensipar® (cinacalcet tablets – Amgen, generic)

REVIEW DATE: 03/12/2025

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

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

- **Hypercalcemia due to 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]

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.

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is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

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 a Patient with Primary Hyperparathyroidism.** Approve for 1 year if the patient meets BOTH of the following (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 ALL of the following (A, B, C, and D):
   A) Patient has chronic kidney disease; AND
   B) Patient 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 Patient.** Approve for 1 year if the patient meets BOTH of the following (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

- **Sensipar® (cinacalcet tablets – Amgen, generic)**

is(are) considered experimental, investigational or unproven for ANY other use(s) including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

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

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.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	03/01/2023

Annual Revision	No criteria changes.	03/27/2024
Annual Revision	No criteria changes.	03/12/2025