Drug Coverage Policy

Effective Date.....06/15/2024
Coverage Policy Number.....IP0464
Policy Title..... Cinacalcet for Individual and Family Plans

Cinacalcet for Individual and Family Plans

- Sensipar® (cinacalcet tablets – Amgen, generic)

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 Healthcare Coverage Policy

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]

Medical Necessity Criteria

Cinacalcet is considered medically necessary when the following criteria are met:

FDA-Approved Indications

1. **Hypercalcemia due to Parathyroid Carcinoma.** Approve for 1 year if the patient meets BOTH of the following (A and B):
   A) The medication is prescribed by or in consultation with an oncologist or endocrinologist; AND
   B) Preferred product criteria is met for the product as listed in the below table

2. **Hypercalcemia in a Patient with Primary Hyperparathyroidism.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):
   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; AND
   C) Preferred product criteria is met for the product as listed in the below table

3. **Secondary Hyperparathyroidism.** Approve for 1 year if the patient meets ALL of the following (A, B, C, D, and E):
   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; AND
E) Preferred product criteria is met for the product as listed in the below table

Other Uses with Supportive Evidence

4. **Hyperparathyroidism in a Post-Renal Transplant Patient.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):
   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; AND
   C) Preferred product criteria is met for the product as listed in the below table

Individual and Family Plans:

Product	Criteria
Sensipar (cinacalcet tablets)	Trial of **cinacalcet tablets** (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction **[may require prior authorization]**

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Conditions Not Covered

Any other use is considered experimental, investigational, or unproven, 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.

Revision Details

Type of Revision	Summary of Changes	Date
Annual Revision	No criteria changes	06/15/2024

The policy effective date is in force until updated or retired.