

## SPECIALTY GUIDELINE MANAGEMENT

### Cinacalcet

#### POLICY

##### 1. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met, and the member has no exclusions to the prescribed therapy.

##### FDA-Approved Indication

Cinacalcet is indicated for secondary hyperparathyroidism (HPT) in adult patients with chronic kidney disease (CKD) on dialysis, hypercalcemia in adult patients with parathyroid carcinoma, and hypercalcemia in adult patients with primary HPT for whom parathyroidectomy would be indicated on the basis of serum calcium levels, but who are unable to undergo parathyroidectomy.

##### Compendial Use:

Tertiary hyperparathyroidism in post-kidney transplant patients not receiving dialysis

##### Limitations of use

Cinacalcet is not indicated for use in patients with CKD who are not on dialysis.

All other indications are considered experimental/investigational and are not a covered benefit.

##### 2. EXCLUSIONS:

Coverage will not be provided for members with a pretreatment serum calcium level (corrected for albumin) less than 8.4 mg/dL.

##### 3. SUMMARY OF EVIDENCE:

Cinacalcet is a calcium-sensing receptor agonist indicated for Secondary Hyperparathyroidism (HPT) in patients with chronic kidney disease (CKD) on dialysis, hypercalcemia in patients with Parathyroid Carcinoma (PC), and severe hypercalcemia in patients with primary HPT who are unable to undergo parathyroidectomy. Key findings from clinical trials include significant reductions in serum parathyroid hormone (PTH) levels, calcium-phosphorus product, and bone turnover markers. Cinacalcet has been shown to improve mineral and bone metabolism and reduce the risk of hypercalcemia in patients with CKD-associated HPT.

Effective Date: 6/1/2020
Last Reviewed: 3/2020, 1/2021, 1/2022, 1/2023, 12/2023, 01/2024
Pharmacy Scope: Medicaid
Medical Scope: Medicaid, Commercial, MMP

**4. CRITERIA FOR INITIAL APPROVAL**

MMP members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements.

**A. Secondary hyperparathyroidism with CKD on dialysis**

Authorization of 12 months may be granted for members with secondary HPT with CKD on dialysis and a serum calcium level (corrected for albumin) greater than or equal to 8.4 mg/dL.

**B. Tertiary hyperparathyroidism in post-kidney transplant patients not receiving dialysis**

Authorization of 12 months may be granted for members with tertiary hyperparathyroidism not receiving dialysis who have had a kidney transplant and a serum calcium level (corrected for albumin) greater than or equal to 8.4 mg/dL.

**C. Parathyroid carcinoma**

Authorization of 12 months may be granted for members with parathyroid carcinoma and a serum calcium level (corrected for albumin) greater than or equal to 8.4 mg/dL.

**D. Primary hyperparathyroidism**

Authorization of 12 months may be granted for treatment of primary HPT when all of the following criteria are met:

1. The patient has a serum calcium level (corrected for albumin) greater than or equal to 8.4 mg/dL;
2. The patient is unable to undergo parathyroidectomy.

**5. CONTINUATION OF THERAPY**

Authorization of 12 months may be granted for continuation of cinacalcet when either one of the two following criteria is met:

1. The patient has a serum calcium level (corrected for albumin) greater than or equal to 7.5 mg/dL
2. The patient has a serum calcium level (corrected for albumin) less than 7.5 mg/dL, and cinacalcet will be withheld until this level reaches 8 mg/dL

**6. DOSAGE**

Cinacalcet 30mg & 60mg have a quantity limit of 2 tablets per day

Cinacalcet 90mg has a quantity limit of 4 tablets per day

Effective Date: 6/1/2020
Last Reviewed: 3/2020, 1/2021, 1/2022, 1/2023, 12/2023, 01/2024
Pharmacy Scope: Medicaid
Medical Scope: Medicaid, Commercial, MMP

## 7. HCPCS codes

HCPCS Code	Description
J0604	Cinacalcet, oral, 1mg (for esrd on dialysis)

Per §§ 42 CFR 422.101, this clinical medical policy only applies to INTEGRITY in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD).

### Policy Rationale:

Cinacalcet was reviewed by the Neighborhood Health Plan of Rhode Island Pharmacy & Therapeutics (P&T) Committee. Neighborhood adopted the following clinical coverage criteria to ensure that its members use Cinacalcet according to Food and Drug Administration (FDA) approved labeling and/or relevant clinical literature. Neighborhood worked with network prescribers and pharmacists to draft these criteria. These criteria will help ensure its members are using this drug for a medically accepted indication, while minimizing the risk for adverse effects and ensuring more cost-effective options are used first, if applicable and appropriate. For INTEGRITY (Medicare-Medicaid Plan) members, these coverage criteria will only apply in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD) criteria. Neighborhood will give individual consideration to each request it reviews based on the information submitted by the prescriber and other information available to the plan.

### REFERENCES

1. Sensipar [package insert]. Thousand Oaks, CA: Amgen, Inc.; December 2021.
2. Sterrett JR, Strom J, Stummvoll HK, Bahner U, Disney A, Soroka SD, et al. Cinacalcet HCl (Sensipar/Mimpara) is an effective chronic therapy for hemodialysis patients with secondary hyperparathyroidism. *Clin Nephrol*. 2007 Jul; 68: 10-7.
3. Kruse AE, Ensenberger U, Frey FJ, et al. The calcimimetic cinacalcet normalized serum calcium in renal transplant patients with persistent hyperparathyroidism. *Nephrol Dial Transplant*. 2005; 20: 1311-1314.