# Clinical Policy: Cinacalcet (Sensipar)

Reference Number: PA.CP.PHAR.61
Effective Date: 01/2018
Last Review Date: 07/2025

**Description**
Cinacalcet (Sensipar®) is a calcium-sensing receptor agonist.

**FDA Approved Indication(s)**
Sensipar is indicated for the treatment of:
- Secondary hyperparathyroidism (HPT) in adult patients with chronic kidney disease (CKD) on dialysis
- Hypercalcemia in adult patients with parathyroid carcinoma (PC)
- 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

Limitation(s) of use: Sensipar is not indicated for use in patients with CKD who are not on dialysis.

**Policy/Criteria**
It is the policy PA Health & Wellness® that cinacalcet is **medically necessary** when the following criteria are met:

**I. Initial Approval Criteria**

**A. Secondary Hyperparathyroidism** (must meet all):
1. Diagnosis of secondary hyperparathyroidism due to chronic kidney disease;
2. Prescribed by or in consultation with a nephrologist or endocrinologist;
3. Age ≥ 18 years;
4. Member is on dialysis;
5. One of the following (a or b):
   a. Lab results over the previous 3-6 months show trending increase in iPTH level;
   b. Current (within the last 30 days) labs show iPTH above normal levels;
6. Failure of a vitamin D analog *(see Appendix B)* at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
7. Cinacalcet (Sensipar) is not prescribed concurrently with other calcimimetics (e.g., Parsabiv®);
8. At the time of request, member does not have serum calcium less than the lower limit of the normal range;
9. For Sensipar requests, member must use generic cinacalcet, unless contraindicated or clinically significant adverse effects are experienced;
10. Dose does not exceed 300 mg/day.

**Approval duration: 6 months**

**B. Parathyroid Carcinoma and Primary Hyperparathyroidism** (must meet all):
1. Member has one of the following diagnoses (a or b):
   a. Hypercalcemia due to parathyroid carcinoma;

b. Hypercalcemia due to primary hyperparathyroidism;
2. Prescribed by or in consultation with an oncologist, nephrologist, or endocrinologist;
3. Age ≥ 18 years;
4. For primary HPT, member has failed or is unable to undergo a parathyroidectomy;
5. Cinacalcet (Sensipar) is not prescribed concurrently with other calcimimetics (e.g., Parsabiv);
6. For Sensipar requests, member must use generic cinacalcet, unless contraindicated or clinically significant adverse effects are experienced;
7. Dose does not exceed 360 mg/day (4 tablets/day).

**Approval duration: 6 months**

**C. Other diagnoses/indications:** Refer to PA.CP.PMN.53

## II. Continued Approval

**A. All Indications in Section I** (must meet all)**:**

1. Currently receiving medication via PA Health & Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care policy (PA.PHARM.01) applies;
2. Member is responding positively to therapy as evidenced by a decrease in iPTH (for secondary HPT) or a decrease in serum calcium (for PC or primary HPT), unless request is for a dose increase;
3. Cinacalcet (Sensipar) is not prescribed concurrently with other calcimimetics (e.g., Parsabiv);
4. For Sensipar requests, member must use generic cinacalcet, unless contraindicated or clinically significant adverse effects are experienced;
5. If request is for a dose increase, new dose does not exceed:
   a. Secondary HPT: 300 mg per day;
   b. PC and primary HPT: 360 mg (4 tablets) per day.

**Approval duration: 12 months**

**B. Other diagnoses/indications** (must meet 1 or 2)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.PHARM.01) applies; or
2. Refer to PA.CP.PMN.53

## III. Diagnoses/Indications for which coverage is NOT authorized:

**A.** Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – PA.CP.PMN.53

## IV. Appendices/General Information

*Appendix A: Abbreviation/Acronym Key*

CKD: chronic kidney disease
FDA: Food and Drug Administration
HPT: hyperparathyroidism
iPTH: intact parathyroid hormone

PC: parathyroid carcinoma

*Appendix B: Therapeutic Alternatives*
*This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.*

| Drug Name | Dosing Regimen | Dose Limit/ Maximum Dose |
|---|---|---|
| calcitriol (Rocaltrol®) | Oral: 0.25 mcg PO QD or QOD; may increase dose by 0.25 mcg/day at 4 to 8 week intervals<br>IV: 1 to 2 mcg/day IV 3 times weekly on approximately every other day; may increase by 0.5 to 1 mcg/dose at 2 to 4 week intervals | Oral: 1 mcg/day<br>IV: 4 mcg/day |
| doxercalciferol (Hectorol®) | Oral: 10 mcg PO 3 times weekly at dialysis; increase dose as needed at 8 week intervals in 2.5 mcg increments if iPTH is not lowered by 50% and fails to reach the target range<br>IV: 4 mcg IV bolus 3 times weekly at the end of dialysis, increase dose as needed at 8 week intervals by 1 to 2 mcg increments if iPTH is not lowered by 50% and fails to reach the target range | Oral: 20 mcg 3 times weekly<br>IV: 18 mcg/week |
| paricalcitol (Zemplar®) | 1 mcg PO daily if baseline iPTH level is 500 picog/mL or less; 2 mcg PO daily if baseline iPTH level is greater than 500 picog/mL; may titrate dose at 2 to 4 week intervals | 0.24 mcg/kg |

*Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.*

*Appendix C: Contraindications/Boxed Warnings*
- Contraindication(s): serum calcium is less than the lower limit of the normal range
- Boxed warning(s): none reported

## V. Dosage and Administration

| Indication | Dosing Regimen | Maximum Dose |
|---|---|---|
| Secondary HPT | Starting dose: 30 mg PO QD<br>Titrate no more frequently every 2-4 weeks through sequential doses of 30, 60, 90, 120, and 180 mg QD as necessary to achieve targeted iPTH levels | 300 mg/day |
| Hypercalcemia in patients with PC or primary HPT | Starting dose: 30 mg PO BID<br>Titrate every 2-4 weeks through sequential doses of 30 mg BID, 90 mg BID, and 90 mg TID or QID as necessary to normalize serum calcium levels | 360 mg/day |

## VI. Product Availability
Tablets: 30 mg, 60 mg, 90 mg

## VII. References

1. Sensipar Prescribing Information. Thousand Oaks, CA: Amgen, Inc.; December 2019. Available at: https://www.pi.amgen.com/-/media/Project/Amgen/Repository/pi-amgen-com/Sensipar/sensipar_pi_hcp_english.pdf. Accessed April 14, 2025.
2. Kidney Disease: Improving Global Outcomes (KDIGO) CKD–MBD 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 International Supplements 2017; 7:1–59. Available at: http://kdigo.org/wp-content/uploads/2017/02/2017-KDIGO-CKD-MBD-GL-Update.pdf. Accessed May 17, 2022.
3. Bilezikian JP, Khan AA, Silverberg SJ. International Workshop on Primary Hyperparathyroidism. Evaluation and Management of Primary Hyperparathyroidism: Summary Statement and Guidelines from the Fifth International Workshop. *J Bone Miner Res*. 2022 Nov;37(11):2293-2314. doi: 10.1002/jbmr.4677.
4. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed May 10, 2024.

| Reviews, Revisions, and Approvals | Date |
|---|---|
| Included calcium acetate as the required formulary alternative phosphate binder. Removed the requirement for parathyroidectomy (medical procedure). References reviewed and updated | 02/2018 |
| 3Q 2019 annual review: No changes per Statewide PDL implementation 01-01-2020 | 07/2019 |
| Removed the requirement of PTH levels >300 pg/ml in the initial approval criteria; updated the initial approval criteria to require that lab results over the previous 3-6 months show trending increase in iPTH level or current (within the last 30 days) labs show iPTH above the normal levels; removed the trial of calcium acetate and replaced with vitamin D analog; added the requirement that Sensipar not be used concomitantly with any other calcimimetic agents for consistency with other policies addressing secondary HPT; increased maximum dose limit for secondary HPT to 300 mg/day, supported by Clinical Pharmacology; revised positive response to therapy criterion to allow continuation of therapy if request is for dose increase; references reviewed and updated. | 01/2020 |
| 3Q 2020 annual review: added the requirement that Sensipar not be used concomitantly with any other calcimimetic agents for consistency with other policies addressing secondary HPT; references reviewed and updated. | 07/2020 |
| 3Q 2021 annual review: no significant changes; references reviewed and updated. | 07/2021 |
| 3Q 2022 annual review: no significant changes; references reviewed and updated. | 07/2022 |
| 3Q 2023 annual review: no significant changes; references reviewed and updated. | 07/2023 |

| Reviews, Revisions, and Approvals | Date |
|---|---|
| 3Q 2024 annual review: for all indications, added criteria to use generic cinacalcet over brand Sensipar; references reviewed and updated. | 07/2024 |
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