

## Clinical Policy: Cinacalcet (Sensipar)

Reference Number: PA.CP.PHAR.61

Effective Date: 01/18

Last Review Date: 07/18

[Coding Implications](#)

[Revision Log](#)

### Description

**The intent of the criteria is to ensure that patients follow selection elements established by Pennsylvania Health and Wellness® clinical policy for cinacalcet (Sensipar®).**

### FDA Approved Indication(s)

Sensipar is indicated:

- For the treatment of secondary hyperparathyroidism (HPT) in adult patients with chronic kidney disease (CKD) on dialysis
- For the treatment of hypercalcemia in adult patients with parathyroid carcinoma (PC)
- For the treatment of 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 of health plans affiliated with Pennsylvania Health and Wellness® that Sensipar 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  $\geq$  18 years;
4. Member is on dialysis;
5. Recent (within the last 3 months) intact parathyroid hormone (iPTH)  $>$  300 pg/mL despite prior medical therapy which includes a phosphate binder;
6. Failure of a trial of calcium acetate (at up to maximally indicated doses), unless contraindicated or clinically significant adverse effects are experienced;
7. At the time of request, member has none of the following contraindications:
  - a. Serum calcium is less than the lower limit of the normal range;
8. Dose does not exceed 180 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  $\geq$  18 years;

4. Dose does not exceed 360 mg/day.

**Approval duration: 6 months**

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

**II. Continued Approval**

**A. Secondary Hyperparathyroidism** (must meet all):

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Responding positively to therapy (e.g., decrease in iPTH);
3. Prescribed dose does not exceed 180 mg per day.

**Approval duration: 12 months**

**B. Parathyroid Carcinoma and Primary Hyperparathyroidism** (must meet all):

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Responding positively to therapy (e.g., decrease in serum calcium);
3. Prescribed dose does not exceed 90 mg four times daily.

**Approval duration: 12 months**

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

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

**Background**

*Description/Mechanism of Action:*

Sensipar (cinacalcet) is a calcimimetic agent that increases the sensitivity of the calcium-sensing receptor to activation by extracellular calcium. Sensipar tablets contain the hydrochloride salt of cinacalcet. The calcium-sensing receptor on the surface of the chief cell of the parathyroid gland is the principal regulator of PTH synthesis and secretion. Cinacalcet, the active ingredient in Sensipar, directly lowers PTH levels by increasing the sensitivity of the calcium-sensing receptor to extracellular calcium. The reduction in PTH is associated with a concomitant decrease in serum calcium levels.

*Formulations:*

Tablets: 30, 60, and 90 mg tablets

**Appendices**

**Appendix A: Abbreviation Key**

CKD: chronic kidney disease  
HPT: hyperparathyroidism  
iPTH: intact parathyroid hormone  
PTH: parathyroid hormone

**Coding Implications**

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
N/A	

Reviews, Revisions, and Approvals	Date	Approval Date
Included calcium acetate as the required formulary alternative phosphate binder. Removed the requirement for parathyroidectomy (medical procedure). References reviewed and updated	02/18	

**References**

1. Sensipar Prescribing Information. Thousand Oaks, CA: Amgen, Inc.; May 2017. Available at: [www.sensipar.com](http://www.sensipar.com). Accessed November 21, 2017.
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 November 21, 2017.
3. National Kidney Foundation: KDOQI clinical practice guidelines for bone metabolism and disease in chronic kidney disease. *Am J Kidney Dis.* 2003; 42(Suppl. 3): S1-S201. Available at [http://www2.kidney.org/professionals/KDOQI/guidelines\\_bone/index.htm](http://www2.kidney.org/professionals/KDOQI/guidelines_bone/index.htm).
4. Bilezikian JP, Brandi ML, Eastell R, et al. Guidelines for the management of asymptomatic primary hyperparathyroidism: summary statement from the Fourth International Workshop. *J Clin Endocrinol Metab.* 2014; 99: 3561-3569.
5. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed November 21, 2017.