Prior Authorization Review Panel

Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: 02/01/2020**
Policy Number: PA.CP.PHAR.61	**Effective Date: 01/01/2018** **Revision Date: 01/15/2020**
Policy Name: Cinacalcet (Sensipar)	

Type of Submission – Check all that apply:

- ☐ **New Policy**
- ✓ **Revised Policy***
- ☐ **Annual Review - No Revisions**
- ☐ **Statewide PDL -** *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

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.

Name of Authorized Individual (Please type or print): **Francis G. Grillo, MD**	**Signature of Authorized Individual:**

Clinical Policy: Cinacalcet (Sensipar)

Reference Number: PA.CP.PHAR.61
Effective Date: 01/18
Last Review Date: 01/2020

Coding Implications
Revision Log

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 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 ≥ 18 years;
4. Member is on dialysis;
5. 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 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. Member is not receiving other calcimimetics;
8. At the time of request, member does not have serum calcium less than the lower limit of the normal range;
9. 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 ≥ 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. All Indications in Section I (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. 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. Member is not receiving other calcimimetics;
4. 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 per day.

Approval duration: 12 months

B. 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

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 policies – 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 for all relevant lines of business 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 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 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 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 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 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	180 mg/day
Hypercalcemia in patients with PC or primary HPT	Starting dose: 30 mg PO BID 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.; March 2019. Available at: www.sensipar.com. Accessed May 10, 2019.
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 10, 2019.
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.
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 May 10, 2019.

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	
3Q 2019 annual review: No changes per Statewide PDL implementation 01-01-2020	07/17/19	
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	