Clinical Policy: Cinacalcet (Sensipar)

Reference Number: ERX.SPA.137
Effective Date: 04.01.14
Last Review Date: 08.21
Line of Business: Commercial, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

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
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ 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 HPT due to CKD;
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 the normal levels;
6. Failure of a vitamin D analog *(see Appendix B)* (at up to maximally indicated doses), unless clinically significant adverse effects are experienced or all are contraindicated;
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 300 mg per day.

Approval duration: 6 months

B. Parathyroid Carcinoma and Primary Hyperparathyroidism (must meet all)**:**
1. Diagnosis of one of the following diagnoses (a or b):
   a. Hypercalcemia due to PC;
   b. Hypercalcemia due to primary HPT;
2. Prescribed by or in consultation with an oncologist, nephrologist, or endocrinologist;
3. Age ≥ 18 years;
4. Member is not receiving other calcimimetics;
5. Dose does not exceed 360 mg per day.

Approval duration: 6 months

C. Other diagnoses/indications
1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
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 a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 – ERX.PA.01 or evidence of coverage documents.

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 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

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
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	300 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.; December 2019. Available at: www.sensipar.com. Accessed May 10, 2021.
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, 2021.
3. 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.
4. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed May 10, 2021.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy converted to new template. Added age restriction and max dosing criteria per PI. Removed all safety criteria, requests for documentation, and dose adjustment criteria. Added efficacy criteria for re-auth. Modified approval durations to 3 months for initial and 6 months for re-auth. Removed all appendices except abbreviation key. Removed indication of tertiary hyperparathyroidism. Secondary hyperparathyroism: Removed requirement for use of vitamin D analogues before Sensipar therapy. Replaced “appropriate trial of binder” and “optimal binder therapy” with “prior medical therapy including a phosphate binder.” Primary hyperparathyroidism: Added total serum calcium as an indicator for parathyroidectomy per PI and defined as > 1 mg/dL above ULN per Bilezikian guidelines and UpToDate.	08.16	09.16

Reviews, Revisions, and Approvals	Date	P&T Approval Date
All indications: added prescriber specialty; added safety requirement related to contraindications per PI in lieu of the requirement that serum calcium ≥ 8.4 mg/dL. Secondary HPT: added a time frame of within the last 3 months to iPTH criterion. Re-auth: added max dose. References updated.	06.17	08.17
3Q 2018 annual review: removed the requirement of PTH levels > 300 pg/ml in the initial approval criteria; updated the initial approval criteria to reflect "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 contraindication language from initial approval criteria for hypercalcemia due to PC and HPT as these conditions will inherently have serum calcium levels above the lower limit of normal; references reviewed and updated.	03.27.18	08.18
3Q 2019 annual review: 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; references reviewed and updated.	05.10.19	08.19
Revised positive response to therapy criterion to allow continuation of therapy if request is for dose increase.	11.19.19	02.20
3Q 2020 annual review: no significant changes; references reviewed and updated.	04.28.20	08.20
3Q 2021 annual review: no significant changes; references reviewed and updated.	05.10.21	08.21

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.