

Clinical Policy: Cinacalcet (Sensipar)

Reference Number: CP.PHAR.61

Effective Date: 05.01.11

Last Review Date: 02.20

Line of Business: HIM, 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.

It is the policy of health plans affiliated with Centene Corporation[®] 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 \geq 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 300 mg per day.

Approval duration: 6 months

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

1. Diagnosis of one of the following (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 \geq 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 the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): HIM.PHAR.21 for health insurance marketplace and CP.PMN.53 for Medicaid.

II. Continued Approval

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

1. Currently receiving medication via Centene benefit or member has previously met all 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 Centene benefit and documentation supports positive response to therapy.
Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): HIM.PHAR.21 for health insurance marketplace and CP.PMN.53 for Medicaid.

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 – HIM.PHAR.21 for health insurance marketplace and CP.PMN.53 for Medicaid 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 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	360 mg/day

Indication	Dosing Regimen	Maximum Dose
	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	

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	P&T Approval Date
Added FDA approved Indications in Description section Updated algorithms for monitoring needs and added timeframes according to monitoring parameters; Added Appendix D	05.14	06.14
Changed approval timeframes to 3 months	07.14	
Added efficacy and metabolism information. Updated safety concerns. Added Appendix E: Vitamin D Analogues. Modified Appendix C to list phosphate binders. Removed the following modifiers from Figure 1 in reference to questions about binder therapy: “appropriate” and “optimal”. Removed boxes in algorithms requesting lab documentation and requests for serum phosphorus. Combined Secondary HPT prior authorization and re-authorization algorithms into one algorithm (Figure 1). Added iPTH requirement to Primary HPT and Parathyroid Carcinoma algorithm.	04.15	05.15
Policy converted to new template. Secondary hyperparathyroidism: use of vitamin D analogues removed as a requirement before	03.16	04.16

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Sensipar therapy. Replaced “prior binder therapy” with “prior medical therapy including a phosphate binder.”; upper limit of target iPTH range (300pg/mL) specified per PI and KDOQI. Added max titrated dose. Parathyroid carcinoma and primary hyperparathyroidism: normal total serum calcium range per NLM, max dose added. Primary hyperparathyroidism: Total serum calcium, as an indicator for parathyroidectomy per PI, is added and defined as >1 mg/dL above ULN per Bilezikian guidelines and UpToDate. For all three indications: age and reasons to discontinue are drawn from the PI; dose adjustment criteria removed; efficacy criteria added on continuation; changed continuation approval from 3 to 6 months. Appendices removed except for abbreviation key.		
All indications: added prescriber specialty; added safety requirement related to contraindications per PI in lieu of the requirement that serum calcium \geq 8.4 mg/dL. Secondary HPT: added a time frame of within the last 3 months to iPTH criterion. Re-auth: removed requirements related to reasons to discontinue Sensipar therapy; added max dose. References updated.	03.17	04.17
1Q18 annual review: Included calcium acetate as the required formulary alternative phosphate binder. Removed the requirement for parathyroidectomy (medical procedure). Converted to new template. References reviewed and updated.	11.21.17	02.18
3Q 2018 annual review: HIM and Medicaid policies combined; 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. 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

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. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. 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. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

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Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

For Health Insurance Marketplace members, when applicable, this policy applies only when the prescribed agent is on your health plan approved formulary. Request for non-formulary drugs must be reviewed using the formulary exception policy.

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