Clinical Policy: Cinacalcet (Sensipar)

Reference Number: CP.PHAR.61
Effective Date: 05.01.11
Last Review Date: 02.18 Revision Log
Line of Business: Medicaid

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
- 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
Provider must submit documentation (which may include office chart notes and lab results) 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 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. Recent (within the last 3 months) intact parathyroid hormone (iPTH) > 300 pg/mL;
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 ≥ 18 years;
4. Dose does not exceed 360 mg/day.

Approval duration: 6 months

C. Other diagnoses/indications

1. Refer to CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Approval

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

1. Currently receiving medication via Centene benefit or member has previously met all initial approval criteria;
2. Responding positively to therapy (e.g., decrease in iPTH);
3. If request is for a dose increase, new 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 Centene benefit or member has previously met all initial approval criteria;
2. Responding positively to therapy (e.g., decrease in serum calcium);
3. If request is for a dose increase, new dose does not exceed 360 mg per day.

Approval duration: 12 months

C. 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 CP.PMN.53 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 – CP.PMN.53 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration
CKD: chronic kidney disease
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
calcium acetate (PhosLo®)	3-4 capsules orally with each meal (667 mg per capsule)	8004 mg/day

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.

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.; May 2017. Available at: 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.
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.

Reviews, Revisions, and Approvals	Date	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 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.	03.16	04.16
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: removed	03.17	04.17

Reviews, Revisions, and Approvals	Date	Approval Date
requirements related to reasons to discontinue Sensipar therapy; added max dose. References updated.		
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

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.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

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.