

## Clinical Policy: Cinacalcet (Sensipar)

Reference Number: CP.PHAR.61

Effective Date: 05/11

Last Review Date: 04/17

[Coding Implications](#)

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

### Description

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

### Policy/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  $\geq$  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. Sensipar dose titration does not exceed 180 mg per day;
7. At the time of request, member does not have a serum calcium less than the lower limit of the normal range.

**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 and the following (i and ii):
    - i. Parathyroidectomy is indicated based on serum calcium level [serum calcium  $>$  1 mg/dL ( $>$  0.25 mm/L) above the upper limit of normal];
    - ii. Member is unable to undergo parathyroidectomy;
2. Prescribed by or in consultation with an oncologist, nephrologist, or endocrinologist;
3. Age  $\geq$  18 years;
4. Sensipar dose titration does not exceed 90 mg four times daily.
5. At the time of request, member does not have a serum calcium less than the lower limit of the normal range.

**Approval duration: 6 months**

##### C. Other diagnoses/indications: Refer to CP.PHAR.57 - Global Biopharm Policy.

## **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. 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 Centene benefit or member has previously met all initial approval criteria;
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 Centene benefit and documentation supports positive response to therapy; or
2. Refer to CP.PHAR.57 - Global Biopharm Policy.

## **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

### *FDA Approved Indications:*

Sensipar (cinacalcet) is a calcium-sensing receptor agonist/oral tablet indicated for:

- Treatment of secondary hyperparathyroidism (HPT) in adult patients with chronic kidney disease (CKD) on dialysis.

### Limitations of use:

- Sensipar is not indicated for use in adult patients with CKD who are not on dialysis because of an increased risk of hypocalcemia.
- Treatment of hypercalcemia in adult patients with parathyroid carcinoma.

- 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.

**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
No changes	04/12	05/12
Converted to Centene Clinical Policy Template	06/13	06/13
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	03/16	04/16

Reviews, Revisions, and Approvals	Date	Approval Date
<p>“prior medical therapy including a phosphate binder.”; upper limit of target iPTH range (300pg/mL) specified per PI and KDOQI. Added max titrated dose.</p> <p>Parathyroid carcinoma and primary hyperparathyroidism: normal total serum calcium range per NLM, max dose added</p> <p>Primary hyperparathyroidism: Total serum calcium, as an indicator for parathyroidectomy per PI, is added and defined as &gt;1 mg/dL above ULN per Bilezikian guidelines and UptoDate.</p> <p>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.</p> <p>Appendices removed except for abbreviation key.</p>		
<p>All indications: added prescriber specialty; added safety requirement related to contraindications per PI in lieu of the requirement that serum calcium <math>\geq</math> 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.</p>	03/17	04/17

**References**

1. Sensipar Prescribing Information. Thousand Oaks, CA: Amgen, Inc.; November 2014. Available at: [www.sensipar.com](http://www.sensipar.com). Accessed March 22, 2017.
2. Kidney Disease: Improving Global Outcomes (KDIGO) CKD–MBD Work Group. KDIGO clinical practice guideline for the diagnosis, evaluation, prevention, and treatment of chronic kidney disease–mineral and bone disorder (CKD–MBD). *Kidney International* 2009; 76 (Suppl 113): S1–S130.
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.

**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.

**Note: For Medicare members**, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs and LCDs and Medicare Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at <http://www.cms.gov> for additional information.

©2016 Centene Corporation. All rights reserved. All materials are exclusively owned by Centene Corporation and are protected by United States copyright law and international copyright law. No part of this publication may be reproduced, copied, modified, distributed, displayed, stored in a retrieval system, transmitted in any form or by any means, or otherwise published without the prior written permission of Centene Corporation. You may not alter or remove any trademark, copyright or other notice contained herein. Centene® and Centene Corporation® are registered trademarks exclusively owned by Centene Corporation.