

Clinical Policy Title:	cinacalcet
Policy Number:	RxA.477
Drug(s) Applied:	Sensipar®
Original Policy Date:	03/06/2020
Last Review Date:	12/07/2020
Line of Business Policy Applies to:	All lines of business

Background

Cinacalcet (Sensipar®) is a calcium-sensing receptor agonist.

It 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.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
cinacalcet (Sensipar®)	Secondary HPT with chronic kidney disease on dialysis	Starting dose: 30 mg PO OD Titrate no more frequently every 2-4 weeks through sequential doses of 30, 60, 90, 120, and 180 mg OD 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, 60 mg BID, and 90 mg TID or QID as necessary to normalize serum calcium levels	360 mg/day

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

Dosage Forms

- Tablets: 30 mg, 60 mg, 90 mg

Clinical Policy

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

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 180 mg per day.

Approval duration

Commercial: 6 months

Medicaid: 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

Commercial: 6 months

Medicaid: 6 months

II. Continued Approval

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

1. Member is currently receiving the medication that has been authorized by RxAdvance or member has met initial approval criteria listed in this policy;
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: 180 mg per day;
 - b. PC and primary HPT: 360 mg per day.

Approval duration

Commercial: 12 months

Medicaid: 12 months

III. Appendices

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

Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
calcitriol (Rocaltrol®)	Oral: 0.25 mcg PO OD 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 (Zempar®)	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

APPENDIX D: General Information

- Cinacalcet is a calcimimetic agent that directly lowers PTH levels by increasing the sensitivity of the calcium-sensing receptor to activation by extracellular calcium. The reduction in PTH is associated with a concomitant decrease in serum calcium levels.
- Co-administration with a strong CYP3A4 inhibitor may increase serum levels of cinacalcet.
- Cinacalcet is a strong inhibitor of CYP2D6.
- Sensipar should not be used in adult patients with CKD who are not on dialysis because of an increased risk of low calcium levels.

References

1. Sensipar Prescribing Information. Thousand Oaks, CA: Amgen, Inc.; December 2019. Available at: www.sensipar.com. Accessed August 31, 2020.
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/wpcontent/uploads/2017/02/2017-KDIGO-CKD-MBD-GI-Update.pdf>. Accessed August 31, 2020.
3. National Kidney Foundation: KDOQI clinical practice guidelines for bone metabolism and disease in chronic kidney disease. Am J Kidney Dis. 2003; Available at <https://pubmed.ncbi.nlm.nih.gov/14520607/> Accessed August 31,2020.
4. Bilezikian JP, Brandi ML, Eastell R, et al. Guidelines for the management of asymptomatic primary hyperparathyroidism: summary statement from the Fourth International Workshop. The Journal of Clinical Endocrinology & Metabolism, Volume 99, Issue 10, 1 October 2014, Pages 3561–3569. Available at: <https://academic.oup.com/jcem/article/99/10/3561/2836336>. Accessed August 31, 2020.
5. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed May 10, 2019.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy was reviewed: <ol style="list-style-type: none"> 1. Clinical policy title table updated: Maximum dose updated from 300mg to 180mg and added HIM coverage duration to 6 months for initial therapy and 12 months for continued therapy. 2. Continued therapy criteria II.A.1 was rephrased to “Currently receiving medication that has been authorized by Rxadvance. 3. Appendix D was updated. 4. References were reviewed and updated. 	08/31/2020	12/07/2020