

<b>Clinical Policy Title:</b>	cinacalcet
<b>Policy Number:</b>	RxA.477
<b>Drug(s) Applied:</b>	cinacalcet
<b>Original Policy Date:</b>	03/06/2020
<b>Last Review Date:</b>	12/11/2025
<b>Line of Business Policy Applies to:</b>	All lines of business (except Medicare)

## Criteria

### I. Initial Approval Criteria

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

1. Diagnosis of secondary HPT due to CKD;
2. Member is on dialysis;
3. 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;
4. Trial and failure of a vitamin D analog at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
5. At the time of request, member does not have serum calcium less than the lower limit of the normal range.

#### Approval duration

**All Lines of Business (except Medicare):** 12 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.

#### Approval duration

**All Lines of Business (except Medicare):** 12 months

### II. Continued Therapy Approval

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

1. Member is currently receiving medication in the past 120 days that has been authorized by RxAdvance or the member has met initial approval criteria.

#### Approval duration

**All Lines of Business (except Medicare):** 12 months

## References

1. 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: <https://kdigo.org/wp-content/uploads/2017/02/2017-KDIGO-CKD-MBD-GL-Update.pdf>. Accessed March 24, 2025.

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.

2. Eknoyan G, Levin A, Levin NW. Bone metabolism and disease in chronic kidney disease. American Journal of Kidney Diseases. 2003;42:1-201; Available at: [https://www.ajkd.org/article/S0272-6386\(03\)00905-3/fulltext](https://www.ajkd.org/article/S0272-6386(03)00905-3/fulltext). Accessed March 24, 2025.
3. 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 March 24, 2025.

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"> <li>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.</li> <li>2. Continued therapy criteria II.A.1 was rephrased to “Currently receiving medication that has been authorized by Rxadvance.</li> <li>3. Appendix D was updated.</li> <li>4. References were reviewed and updated.</li> </ol>	08/31/2020	12/07/2020
Policy was reviewed: <ol style="list-style-type: none"> <li>1. Statement about drug listing format in Appendix B is rephrased to "Therapeutic alternatives are listed as generic (Brand name®) when the drug is available by both generic and brand; Brand name® when the drug is available by brand only and generic name when the drug is available by generic only".</li> <li>2. Appendix D, General Information: Updated to include clause recommending for patients with hepatic impairment to have regular serum calcium, serum phosphorus, and iPTH level monitoring.</li> <li>3. References were reviewed and updated.</li> </ol>	12/07/2021	12/07/2021
Policy was reviewed: <ol style="list-style-type: none"> <li>1. Background: Updated indication from Cinacalcet (Sensipar®) is a calcium-sensing receptor agonist. to Cinacalcet (Sensipar®) is a positive modulator of the calcium-sensing receptor agonist.</li> <li>2. Dosing Information, Indication Hypercalcemia in patients with PC or primary HPT: Updated from Starting dose: 30 mg orally twice daily Titrate every 2-4 weeks through sequential doses of 30 mg twice daily, 60 mg twice daily, 90 mg twice daily, and 90 mg three times daily or four times daily as necessary to normalize serum calcium levels to Starting dose: 30 mg orally twice daily Titrate every 2-4 weeks through sequential doses of 30 mg twice daily, 60</li> </ol>	04/05/2022	07/18/2022

<p>mg BID, and 90 mg three times daily or four times daily as necessary to normalize serum calcium levels.</p> <p>3. Continued Therapy Approval Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...".</p> <p>4. Statement about drug listing format in Appendix B is rephrased to "Therapeutic alternatives are listed as generic (Brand name®) when the drug is available by both generic and brand; Brand name® when the drug is available by brand only and generic name when the drug is available by generic only.</p> <p>5. Disclaimer about contraindications "Contraindications listed reflect statements made in the manufacturer's package insert..." was added to Appendix C.</p> <p>6. References were reviewed and updated.</p>		
<p>Policy was reviewed:</p> <p>1. References were reviewed and updated.</p>	04/27/2023	07/13/2023
<p>Policy was reviewed.</p>	10/19/2023	10/19/2023
<p>Policy was reviewed:</p> <p>1. Updated drug applied with generic.</p> <p>2. Removed prescriber criteria.</p> <p>3. Updated continuation of therapy language.</p> <p>4. Updated approval duration verbiage.</p> <p>5. References were reviewed and updated.</p>	03/24/2025	04/10/2025
<p>Policy reviewed</p>	12/11/2025	12/11/2025