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| **Clinical Policy Title:** | cinacalcet |
| **Policy Number:** | RxA.477 |
| **Drug(s) Applied:** | Sensipar® |
| **Original Policy Date:** | 03/06/2020 |
| **Last Review Date:** | 11/30/2023 |
| **Line of Business Policy Applies to:** | All lines of business |

## Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

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

**Approval duration**
**Commercial:** 12 months
**Medicaid:** 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;
2. Prescribed by or in consultation with an oncologist, a nephrologist, or an endocrinologist;

**Approval duration**
**Commercial:** 12 months
**Medicaid:** 12 months

**II. Continued Therapy Approval**

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

1. Member is currently receiving or has been treated with this medication within the past 90 days, excluding manufacturer samples.

**Approval duration**

**Commercial:** 12 months
**Medicaid:** 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 April 27, 2023.
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. Accessed April 27, 2023.
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 April 27, 2023.


| Review/Revision History | Review/Revision Date | P&T Approval Date |
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| Policy established. | 01/2020 | 03/06/2020 |
| Policy was reviewed:<br>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.<br>2. Continued therapy criteria II.A.1 was rephrased to “Currently receiving medication that has been authorized by Rxadvance.<br>3. Appendix D was updated.<br>4. References were reviewed and updated. | 08/31/2020 | 12/07/2020 |
| Policy was reviewed:<br>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".<br>2. Appendix D, General Information: Updated to include clause recommedning for patients with hepatic impairment to have regular serum calcium, serum phosphorus, and iPTH level monitoring.<br>3. References were reviewed and updated. | 12/07/2021 | 12/07/2021 |
| Policy was reviewed:<br>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.<br>2. Dosing Information, Indication Hypercalcemia in | 04/05/2022 | 07/18/2022 |

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| 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 mg BID, and 90 mg three times daily or four times daily as necessary to normalize serum calcium levels.<br>3. Continued Therapy Approval Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...".<br>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.<br>5. Disclaimer about contraindications "Contraindications listed reflect statements made in the manufacturer's package insert..." was added to Appendix C.<br>6. References were reviewed and updated. | | |
| Policy was reviewed:<br>1. References were reviewed and updated. | 04/27/2023 | 07/13/2023 |
| Policy was reviewed. | 10/19/2023 | 10/19/2023 |