

Specialty Guideline Management

cinacalcet-Sensipar

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Sensipar	cinacalcet

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications^{1,2}

- Secondary hyperparathyroidism (HPT) in adult patients with chronic kidney disease (CKD) on dialysis
- Hypercalcemia in adult patients with parathyroid carcinoma
- 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

Compendial Uses^{3,6-8,10}

Hypercalcemia in renal transplant recipients with persistent hyperparathyroidism

All other indications are considered experimental/investigational and not medically necessary.

Reference number(s)
1624-A

Documentation

Submission of the following information is necessary to initiate the prior authorization review, if applicable:

- Serum calcium levels
- Intact parathyroid hormone (iPTH) levels (if applicable)

Prescriber Specialties

This medication must be prescribed by or in consultation with an endocrinologist, a nephrologist, or an oncologist.

Coverage Criteria

Secondary Hyperparathyroidism with CKD on Dialysis^{1,2,11}

Authorization of 12 months may be granted for treatment of secondary hyperparathyroidism in a member with chronic kidney disease on dialysis who meets the following criteria:

- Member has a serum calcium level (corrected for albumin) greater than or equal to 8.4 mg/dL (see Appendix).
- Member has an intact parathyroid hormone (iPTH) level above the normal range as defined by the laboratory reference value.

Primary Hyperparathyroidism^{1,12}

Authorization of 12 months may be granted for treatment of primary hyperparathyroidism in a member who meets the following criteria:

- Member is not able to undergo parathyroidectomy.
- Member has a serum calcium level (corrected for albumin) greater than or equal to 8.4 mg/dL (see Appendix).

Persistent Hyperparathyroidism in Renal Transplant Recipients^{3,8,9}

Authorization of 12 months may be granted for treatment of persistent hyperparathyroidism in a member who meets the following criteria:

- Member has had a kidney transplant.

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- Member has a serum calcium level (corrected for albumin) greater than or equal to 8.4 mg/dL (see Appendix).
- Member has intact parathyroid hormone (iPTH) levels above the normal range as defined by the laboratory reference values.

Parathyroid Carcinoma^{1,2,12}

Authorization of 12 months may be granted for the treatment of parathyroid carcinoma in a member who has a serum calcium level (corrected for albumin) greater than or equal to 8.4 mg/dL (see Appendix).

Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria section when the following criteria are met:

Secondary Hyperparathyroidism with CKD on Dialysis¹

Member is experiencing benefit from therapy as evidenced by a decrease in intact parathyroid hormone (iPTH) levels from pretreatment baseline.

All Other Indications^{1-2,8}

Member is experiencing benefit from therapy (e.g., decreased or normalized corrected serum calcium levels since starting therapy).

Appendix⁹

Corrected calcium = measured total calcium + 0.8(4.0 – serum albumin)

References

1. Cinacalcet [package insert]. Warren, NJ: Cipla USA Inc.; August 2025.
2. Sensipar [package insert]. Thousand Oaks, CA: Amgen, Inc.; February 2024.
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4. AHFS DI (Adult and Pediatric) [database online]. Lexi-Comp, Inc. Hudson, OH. Available at: http://online.lexi.com/lco/action/index/dataset/complete_ashp [available with subscription]. Accessed October 1, 2025.

Reference number(s)
1624-A

5. Lexicomp [Database online]. Lexi-Comp, Inc. Hudson, OH. Available at: [Cinacalcet \(Lexi-Drugs\) - UpToDate® Lexidrug™](#). Accessed September 30, 2025.
6. Dynamed [Database online]. EBSCO Information Services. Ipswich, MA. Available at: www.dynamed.com. Accessed October 1, 2025.
7. Clinical Pharmacology [Internet]. Elsevier. Tampa (FL). Available at: <http://www.clinicalpharmacology.com>. Accessed September 30, 2025.
8. Evenepoel P, Cooper K, Holdaas H, et al. A randomized study evaluating cinacalcet to treat hypercalcemia in renal transplant recipients with persistent hyperparathyroidism. *Am J Transplant* 2014;14:2545-2555.
9. Kruse AE, Ensenberger U, Frey FJ, et al. The calcimimetic cinacalcet normalizes serum calcium in renal transplant patients with persistent hyperparathyroidism. *Nephrol Dial Transplant*. 2005;20:1311-1314.
10. Palumbo VD, Damiano G, Messina M, et al. Tertiary hyperparathyroidism: a review. *Clin Ter*. 2021;172(3):241-246.
11. Smit MA, Kinschot CMJ, Linden JVD, et al. Clinical guidelines and PTH measurements: Does assay generation matter? *Endocrine Review*. 2019; 40 (6): 1468-1480.
12. Alore EA, Suliburk JW, Ramsey DJ, et al. Diagnosis and amangemetn of primary hyperparathyroidism across the Veterans Affairs Health Care System. *JAMA Intern Med*. 2019; 179 (9): 1220-1227.