

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^{1-4,9}

- 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^{2,5-6,10}

Hypercalcemia in post-kidney transplant patients with persistent hyperparathyroidism

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

Coverage Criteria

Secondary Hyperparathyroidism with CKD on Dialysis¹

Authorization of 12 months may be granted for treatment of secondary hyperparathyroidism in a member with chronic kidney disease on dialysis who has a serum calcium level (corrected for albumin) greater than or equal to 8.4 mg/dL (see Appendix).

Primary Hyperparathyroidism¹

Authorization of 12 months may be granted for treatment of primary hyperparathyroidism in a member who is not able to undergo parathyroidectomy and has a serum calcium level (corrected for albumin) greater than or equal to 8.4 mg/dL (see Appendix).

Persistent Hyperparathyroidism in Post-Kidney Transplant Patients^{2,5-7,10}

Authorization of 12 months may be granted for treatment of persistent hyperparathyroidism in a member who has had a kidney transplant and has a serum calcium level (corrected for albumin) greater than or equal to 8.4 mg/dL (see Appendix).

Parathyroid Carcinoma¹

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^{1,5}

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]. Cranbury, NJ: Sun Pharmaceuticals Industries, Inc.; January 2024.
2. Sensipar [package insert]. Thousand Oaks, CA: Amgen, Inc.; December 2019.
3. Micromedex Solutions [database online]. Truven Health Analytics, Inc. Ann Arbor, MI. Available at: www.micromedexsolutions.com. Accessed October 7, 2024.
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 7, 2024.
5. Clinical Pharmacology [Internet]. Elsevier. Tampa (FL). Available at: <http://www.clinicalpharmacology.com>. Accessed October 7, 2024.
6. 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;14:2545-2555.2023.
7. 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.
8. Srinivas TR, Schold JD, Womer KL, et al. Improvement in hypercalcemia with cinacalcet after kidney transplantation. *Clin J Am Soc Nephrol*. 2006;1:323-326.
9. Shoback D. Hypoparathyroidism. *NEJM*. 2008;359: 391-403.
10. Palumbo VD, Damiano G, Messina M, et al. Tertiary hyperparathyroidism: a review. *Clin Ter*. 2021;172(3):241-246.