

SPECIALTY GUIDELINE MANAGEMENT

SENSIPAR (cinacalcet) cinacalcet

POLICY

I. 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.

A. FDA-Approved Indications

1. Secondary hyperparathyroidism (HPT) in adult patients with chronic kidney disease (CKD) on dialysis
2. Hypercalcemia in adult patients with parathyroid carcinoma
3. 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

B. Compendial Use

Tertiary hyperparathyroidism in post-kidney transplant patients not receiving dialysis

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

II. CRITERIA FOR INITIAL APPROVAL

A. **Secondary Hyperparathyroidism with CKD on Dialysis**

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).

B. **Primary Hyperparathyroidism**

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).

C. **Tertiary Hyperparathyroidism in Post-Kidney Transplant Patients Not Receiving Dialysis**

Authorization of 12 months may be granted for treatment of tertiary hyperparathyroidism in a member who has had a kidney transplant, is not receiving dialysis, and has a serum calcium level (corrected for albumin) greater than or equal to 8.4 mg/dL (see Appendix).

D. **Parathyroid Carcinoma**

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).

III. CONTINUATION OF THERAPY

Reference number(s)
1624-A

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

A. Secondary Hyperparathyroidism with CKD on Dialysis

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

B. All other indications

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

IV. APPENDIX

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

V. REFERENCES

1. Cinacalcet [package insert]. Cranbury, NJ: Sun Pharmaceuticals Industries, Inc.; December 2021.
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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 5, 2023.
5. Clinical Pharmacology [Internet]. Elsevier. Tampa (FL). Available at: <http://www.clinicalpharmacology.com>. Accessed October 5, 2023.
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.