

SPECIALTY GUIDELINE MANAGEMENT

SENSIPAR (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 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

1. Tertiary hyperparathyroidism in post-kidney transplant patients not receiving dialysis

All other indications are considered experimental/investigational and are not a covered benefit.

II. INITIAL CRITERIA FOR APPROVAL

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

Authorization of 12 months may be granted for the 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 the 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 the 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

All members (including new members) requesting authorization for continuation of therapy must meet ALL initial authorization criteria.

IV. APPENDIX

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

V. REFERENCES

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4. Clinical Pharmacology [Internet]. Elsevier. Tampa (FL). Available from: <http://www.clinicalpharmacology.com>. Accessed November 18, 2016.
5. 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.
6. 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.
7. 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.
8. Shoback D. Hypoparathyroidism. *NEJM*. 2008;359: 391-403.