## 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**

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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

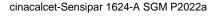
Member is experiencing benefit from therapy (e.g., decreased or normalized corrected serum calcium levels since starting therapy).

#### IV. APPENDIX

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

#### V. REFERENCES

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- 8. Shoback D. Hypoparathyroidism. NEJM. 2008;359: 391-403.
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