

# Cinacalcet

## Criteria for Use

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VA Pharmacy Benefits Management Services, Medical Advisory Panel and VISN Pharmacist Executives

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. **THE CLINICIAN SHOULD UTILIZE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.**

The Product Information should be consulted for detailed prescribing information.

**Exclusion Criteria** *If the answer to the item below is met, then the patient should NOT receive cinacalcet*

- Serum calcium < 8.4 mg/dl (corrected for serum albumin<sup>a</sup>)

**Inclusion Criteria** *The answers to one of the following must be fulfilled in order to meet criteria*

- Secondary hyperparathyroidism in a patient with chronic kidney disease (CKD) on chronic dialysis with elevated intact plasma parathyroid hormone (iPTH) level (e.g., greater than 400 pg/ml or significant trend upwards within two to nine times the upper limit normal for the assay) despite management with standard therapy as appropriate (e.g., dietary phosphate restriction, phosphate binders [calcium-based or non-calcium based] and vitamin D)
- Hypercalcemia (e.g., > 12.5 mg/dl, or symptomatic and > 11.3 mg/dl; corrected for serum albumin<sup>a</sup>) in a patient with primary hyperparathyroidism who is not a surgical candidate or with recurrence despite surgical intervention
- Hypercalcemia (e.g., > 12.5 mg/dl, corrected for serum albumin<sup>a</sup>) in a patient with parathyroid carcinoma despite standard therapy to control hypercalcemia prior to surgical intervention, or who is not a surgical candidate, or who has recurrence despite surgical intervention

<sup>a</sup> Calculation for corrected total serum calcium = total calcium + 0.8 (4 - serum albumin). The normal serum albumin of 4.0gm/dl is based on measurements using bromocresol green. If the bromocresol purple method is used, the normal serum albumin should be adjusted accordingly (e.g., 3.5gm/dl). Local laboratory should be contacted to determine if this correction should be applied to the current result.

[4gm/dl (normal serum albumin) - most recent serum albumin]

Ex. Calcium 9.9mg/dl; albumin 3.2gm/dl

[4 - 3.2] = 0.8; 0.8 X 0.8 = 0.64

9.9 + 0.64 = 10.54 (10.5mg/dl is the corrected serum calcium)

### Dosage and Administration

Refer to Product Information

### Issues for Consideration

- Life-threatening events and fatal outcomes associated with hypocalcemia have been reported with cinacalcet. QT prolongation and ventricular arrhythmias related to hypocalcemia with cinacalcet have been reported. Patients should be monitored for development of hypocalcemia, with adjustment of other therapies (e.g., phosphate binders) as indicated.
- Patients receiving cinacalcet were reported to have an increased risk for seizures compared to placebo, with more than half of the reports occurring in patients with a history of seizure disorder; it is recommended that patients with a history of seizure disorder be carefully monitored for the development of hypocalcemia.
- Off-label use:
  - The long-term safety and efficacy of cinacalcet in patients with CKD not on dialysis has not been established; there may however be individual cases where treatment of a non-dialysis patient with markedly elevated iPTH (per the criteria above) might be considered. It should be noted that patients treated with cinacalcet who are not on dialysis may be at increased risk for the development of hypocalcemia.
  - Several reports and one controlled clinical trial have shown a reduction in hypercalcemia and iPTH with cinacalcet in patients with hyperparathyroidism after kidney transplantation. Further controlled clinical trials are needed to determine the long-term safety and efficacy in this patient population; appropriate treatment with cinacalcet should be determined on a case by case basis.
- Cinacalcet is Pregnancy Category C: patients should be provided contraceptive counseling and education on potential risk vs. benefit of taking cinacalcet if they were to become pregnant