



Prior Authorization Approval Criteria

Department of Pharmacy Services

Generic Name: cinacalcet

Brand Name: Sensipar

Medication Class: calcimimetic

FDA Approved Uses:

- Treatment of secondary hyperparathyroidism in patients with chronic kidney disease (CKD) on dialysis.
- Treatment of hypercalcemia in patients with parathyroid carcinoma.

Usual Dose:

- *Chronic kidney disease on dialysis and secondary hyperparathyroidism:*
Starting dose: 30 mg once daily titrated no more frequently than every 2-4 weeks through sequential doses of 60, 90, 120, and up to a maximum of 180mg once daily based on target serum iPTH levels between 150 to 300 pg/ml consistent with NKF-K/DOQI guidelines.
- *Parathyroid Carcinoma:*
Starting dose: 30 mg twice daily titrated every 2-4 weeks through sequential of 60 mg twice daily, 90 mg twice daily, and 90 mg three or four times daily based on serum calcium levels.

Duration of Therapy: Indefinite

Criteria for Use: (bullet points below are all inclusive unless otherwise noted)

Initial approval will be for 3 months, if the patient meets the guidelines for continuation of therapy than approval can be extended for 6 months and then 12 months thereafter

- Patient must have **one** of the following documented clinical conditions:
 - Secondary hyperparathyroidism due to chronic kidney disease on dialysisOr
 - Hypercalcemia due to parathyroid carcinoma.
- iPTH levels must be >300 (biPTH > 160) and Ca \geq 8.4 in order to initiate therapy.
- Must have tried and failed or intolerant to all of the following phosphate binders:
 - Calcium carbonate.

Criteria for Continuation of Therapy:

- iPTH levels must be greater than 150 pg/ml and calcium must be greater than 8.4 (see dosing guidelines below).

Contraindications:

- Hypersensitivity to any components of Sensipar

Not approved if:

- Patient does not meet the above stated criteria
- Has any contraindications to the use of Sensipar

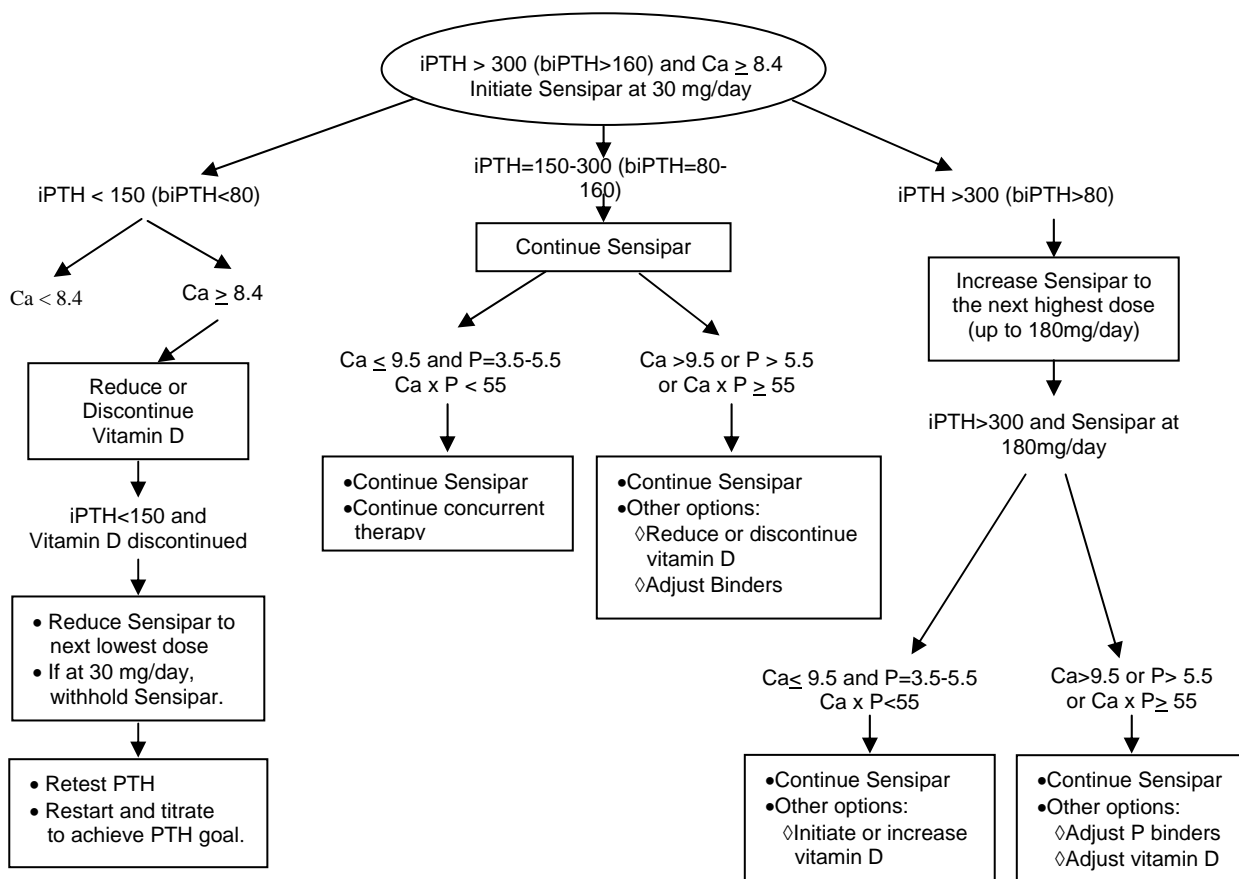
Special considerations

- Sensipar tablets should be taken whole and should not be divided.
- Sensipar lowers serum calcium therefore serum calcium levels need to be closely monitored throughout therapy and patients monitored for symptoms of hypocalcemia.

Recommended Monitoring

- *Chronic kidney disease on dialysis and secondary hyperparathyroidism:*
Serum calcium and serum phosphorus should be measured within 1 week an iPTH should be measured 1 to 4 weeks after initiation or dose adjustment. Once the maintenance dose has been established, serum calcium and serum phosphorus should be measured about once a month and iPTH should be assessed every 1 to 3 months.
- *Parathyroid Carcinoma:*
Serum calcium should be measured within 1 week after initiation and each dosage adjustment. Once maintenance dose has been established, serum calcium should be measured every 2 months.

Dosing guidelines based on iPTH levels and Calcium levels according to NKF-K/DOQI Targets:



P&T Approval: _____ Date: _____