



INLAND EMPIRE HEALTH PLAN

This policy has been developed through review of medical literature, consideration of medical necessity, generally accepted medical practice standards, and approved by the IEHP Pharmacy and Therapeutic Subcommittee.

Drug: Sensipar (cinacalcet)

Class: Calcimimetic, Calcium Regulator

Formulary medication: N/A

Effective date: November 16, 2011

Policy/Criteria:

- I. Treatment of secondary hyperparathyroidism with CKD:
 - a. Confirmation of diagnosis
 - b. Labs indicating parathyroid hormone level > 60 pg/mL
 - c. Failure/intolerance to Calcitriol
- II. Treatment of hypercalcemia associated with parathyroid carcinoma:
 - a. Confirmation of diagnosis
- III. Treatment of severe hypercalcemia in patients with primary hyperparathyroidism who are unable to undergo parathyroidectomy:
 - a. Confirmation of diagnosis
 - b. Lab indicating serum calcium level > 12.5mg/dL

Duration of approval: 12 months

Clinical Justification:

Cinacalcet is a calcimimetic that binds to and modulates the parathyroid calcium-sensing receptor, increasing sensitivity to extracellular calcium and reducing parathyroid hormone secretion. Treatment of secondary hyperparathyroidism in renal dialysis patients is complicated by hypercalcemia and hyperphosphatemia. Cinacalcet targets the calcium-sensing receptor and lowers parathyroid hormone levels without increasing calcium and phosphorus levels. According to the National Kidney Foundation NDOQI Guidelines, vitamin D (i.e. calcitriol) is first line therapy for secondary hyperparathyroidism in patients with chronic kidney disease on dialysis.

References:

1. Product Information: SENSIPAR(R) oral tablets, cinacalcet oral tablets. Amgen, Inc, Thousand Oaks, CA, 2011.
2. Tomasello; Secondary Hyperparathyroidism and Chronic Kidney Disease. Diabetes Spectrum January 2008 vol. 21 no. 1 19-25
3. National Kidney Foundation. K/DOQI clinical practice guidelines for bone metabolism and disease in chronic kidney disease. Am J Kidney Dis 2003;42(Suppl 3):S1-S202.
4. Kovesdy CP, Kalantar-Zadeh K: Bone and mineral disorders in pre-dialysis CKD. Int Urol Nephrol 2008;40:427-440.