



RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Sensipar (cinacalcet) is a calcimimetic agent that increases the sensitivity of the calcium-sensing receptor to activation by extracellular calcium. These calcium-sensing receptors are on the parathyroid hormone gland and are the principal regulators of PTH (parathyroid hormone) synthesis and secretion. Calcimimetics like Sensipar bind and activate the calcium-sensing receptor of parathyroid glands, thereby inhibiting PTH secretion which leads to lower calcium levels. Reductions in PTH are associated with a decrease in bone turnover and bone fibrosis in patients with CKD (chronic kidney disease) on dialysis and uncontrolled secondary HPT. Sensipar is not indicated for use in adult patients with CKD who are not on dialysis because of an increased risk of hypocalcemia (1).

Regulatory Status

FDA approved indication: Sensipar is a calcium-sensing receptor agonist indicated for treatment of secondary hyperparathyroidism (HPT) in adult patients with chronic kidney disease (CKD) on dialysis, hypercalcemia in adult patients with parathyroid carcinoma, and 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 (1).

Off-label Uses:

Sensipar may be used off label in the treatment of persistent hyperparathyroidism in patients who are post renal transplantation (2-3).

Initial treatment of Sensipar is contraindicated if serum calcium is less than the lower limit of the normal range. Life threatening events and fatal outcomes were reported due to hypocalcemia. Hypocalcemia can prolong QT interval, lower the threshold for seizures, and cause hypotension, worsening heart failure, and/or arrhythmia. Monitor serum calcium carefully for the occurrence of hypocalcemia during treatment. Once the maintenance dose has been established, serum calcium should be measured approximately monthly for patients with secondary hyperparathyroidism with CKD on dialysis, and every 2 months for patients with parathyroid carcinoma or primary hyperparathyroidism (1).

In patients with secondary hyperparathyroidism with chronic kidney disease who are on dialysis,



not only should serum calcium and serum phosphorus be measured within 1 week of starting Sensipar, but intact parathyroid hormone (iPTH) should be measured 1 to 4 weeks after initiation or dose adjustment of Sensipar and ideally maintained between 150 to 300 pg/mL (1).

Safety and effectiveness in pediatric patients have not been established (1).

Summary

Sensipar (cinacalcet) is a calcimimetic agent that increases the sensitivity of the calcium-sensing receptor to activation by extracellular calcium. Sensipar is indicated for treatment of secondary hyperparathyroidism (HPT) in adult patients with chronic kidney disease (CKD) on dialysis, hypercalcemia in adult patients with parathyroid carcinoma, and 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 (1). Sensipar may be used off label in the treatment of persistent hyperparathyroidism in patients who are post renal transplantation (2-3).

Prior authorization is required to ensure the safe, clinically appropriate and cost effective use of Sensipar while maintaining optimal therapeutic outcomes.

References

1. Sensipar [package insert]. Thousand Oaks, CA: Amgen, Inc.; December 2019.
2. Kidney Disease: Improving Global Outcomes (KDIGO) CKD-MBD Update Work Group
KDIGO 2017 Clinical Practice Guideline Update for the Diagnosis, Evaluation, Prevention,
and Treatment of Chronic Kidney Disease–Mineral and Bone Disorder (CKD-MBD) Kidney
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3. 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 Nov;14(11):2545-55