

Clinical Pharmacy Program Guidelines for Sensipar

Program	Prior Authorization
Medication	Sensipar (cinacalcet)
Issue Date	1/2010
Pharmacy and Therapeutics Approval Date	8/2017
Effective Date	10/2017

1. Background:

Sensipar (cinacalcet hydrochloride) is a calcium-sensing receptor agonist indicated for the treatment of secondary hyperparathyroidism (HPT) in patients with chronic kidney disease on dialysis, hypercalcemia in patients with parathyroid carcinoma and for hypercalcemia in patients with primary HPT for whom parathyroidectomy would be indicated on the basis of serum calcium levels, but who are unable to undergo parathyroidectomy.

2. Coverage Criteria:

A. Initial Authorization

1. **Sensipar** will be approved based on **both** of the following criteria:

a. Prescribed by or in consultation with an oncologist, endocrinologist, or nephrologist

-AND-

b. **One** of the following:

(1) **All** of the following:

- (a) Diagnosis of secondary hyperparathyroidism with chronic kidney disease
- (b) Patient is on dialysis
- (c) **Both** of the following:
 - i. Patient has therapeutic failure, contraindication or intolerance to one phosphate binder (e.g., PhosLo, Fosrenol, Renvela, Renagel, etc.)
 - ii. Patient has therapeutic failure, contraindication or intolerance to one vitamin D analog (e.g., calcitriol, Hectorol, Zemplar, etc.)

-OR-

(2) Diagnosis of hypercalcemia with parathyroid carcinoma

-OR-

(3) **Both** of the following:

- (a) Diagnosis of severe hypercalcemia (level greater than 12.5 mg/dL) with primary hyperparathyroidism
- (b) Patient is unable to undergo parathyroidectomy

Authorization will be issued for 12 months.

B. Reauthorization

1. **Sensipar** will be approved based on the following criterion:

- a. Patient has experienced a reduction in serum calcium from baseline

Authorization will be issued for 12 months.

3. References:

1. Sensipar Prescribing Information. Amgen Inc., Thousand Oaks, CA. May 2017.
2. Marcocci C1, Bollerslev J, Khan AA, Shoback DM. Medical management of primary hyperparathyroidism: proceedings of the fourth International Workshop on the Management of Asymptomatic Primary Hyperparathyroidism. *J Clin Endocrinol Metab.* 2014 Oct;99(10):3607-18. doi: 10.1210/jc.2014-1417. Epub 2014 Aug 27.
3. Uhlig K, Berns JS, Kestenbaum B, et al. KDOQI US Commentary on the 2009 KDIGO Clinical Practice Guideline for the Diagnosis, Evaluation, and Treatment of CKD–Mineral and Bone Disorder (CKD-MBD). *Am J Kidney Dis* 55:773-799 2010.

Program	Prior Authorization –Sensipar (cinacalcet)
Change Control	
Date	Change
1/2010	New Policy
5/2010	Added criteria for persistent secondary hyperparathyroidism after kidney transplantation.
3/2011	Annual review; no change
3/2012	Added criteria for new FDA approved indication, primary hyperparathyroidism (section III.C.)

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3/2013	Annual review; no change
12/2015	Annual review; no change
8/2016	Updated clinical criteria to align with Employer and Individual's policy. Updated policy to new template.
8/2017	Annual review. Updated references.