

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2023 P 2103-10
Program	Prior Authorization/Medical Necessity
Medication	Sensipar® (cinacalcet)
P&T Approval Date	8/2016, 8/2017, 8/2018, 8/2019, 8/2020, 8/2021, 8/2022, 9/2023
Effective Date	12/1/2023

1. Background:

Sensipar (cinacalcet hydrochloride) is a calcium-sensing receptor agonist indicated for the treatment of secondary hyperparathyroidism (HPT) in adult patients with chronic kidney disease (CKD) on dialysis, hypercalcemia in adult patients with parathyroid carcinoma (PC), and for 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.

Sensipar is not indicated for use in patients with CKD who are not on dialysis.

2. Coverage Criteria^a:

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) **All** of the following:

- (a) Diagnosis of primary hyperparathyroidism (HPT)

- (b) Severe hypercalcemia (serum calcium level greater than 12.5 mg/dL) due to primary HPT
- (c) Patient is unable to undergo parathyroidectomy

Authorization will be issued for 12 months.

2. Reauthorization

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

- (1) Patient has experienced a reduction in serum calcium from baseline

Authorization will be issued for 12 months.

^a State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class

4. References:

1. Sensipar [package insert]. Thousand Oaks, CA: Amgen Inc.; December 2019.
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. Ketteler M, Block GA, Evenepoel P, Fukagawa M, Herzog CA, McCann L, Moe SM, Shroff R, Tonelli MA, Toussaint ND, Vervloet MG, Leonard MB. KDIGO 2017 Clinical Practice Guideline Update For The Diagnosis, Evaluation, Prevention, And Treatment Of Chronic Kidney Disease–Mineral And Bone Disorder (CKD-MBD). *Ann Intern Med.* 2018 Mar 20;168(6):422-430.

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Change Control	
8/2016	New program.
11/2016	Administrative change. Added California coverage information.
8/2017	References updated. State mandate reference language updated.
8/2018	Annual review. Updated references.
12/2018	Administrative change to add statement regarding use of automated processes.
8/2019	Annual review. Updated references.
8/2020	Annual review with no change to coverage criteria. Updated reference.
8/2021	Annual review with no change to coverage criteria. Updated reference formatting.
8/2022	Annual review. Broke out primary hyperthyroidism section into separate requirements for diagnosis and calcium level for clarity without change to clinical intent.
9/2023	Annual review with no changes.