

Sensipar (cinacalcet)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Sensipar (cinacalcet)	May be subject to quantity limit

APPROVAL CRITERIA

Initial requests for Sensipar (cinacalcet) may be approved when the following criteria are met:

- I. Individual is 18 years of age or older; **AND**
- II. Individual has a diagnosis of secondary hyperparathyroidism (HPT); **AND**
- III. Individual is currently on dialysis for chronic kidney disease (CKD); **AND**
- IV. Individual has a serum corrected total calcium greater than 8.4 mg/dl; **AND**
- V. Individual has a serum intact plasma parathyroid hormone (iPTH) level greater than 150 pg/ml; **AND**
- VI. Individual has had an inadequate response or intolerance to treatment with oral phosphate binders or oral generic vitamin D analogs;

OR

- VII. Individual is 18 years of age or older; **AND**
- VIII. Individual has a diagnosis of parathyroid carcinoma with hypercalcemia; **AND**
- IX. Individual has a serum corrected total calcium greater than or equal to 10.2 mg/dL (NKF 2003);

OR

- X. Individual is 18 years of age or older; **AND**
- XI. Individual has a diagnosis of primary HPT with severe hypercalcemia; **AND**
- XII. Individual is unable to undergo parathyroidectomy; **AND**
- XIII. Individual has a serum corrected total calcium greater than 1 mg/dL above normal (Wilhelm 2016);

OR

- XIV. Individual is 18 years of age or older; **AND**
- XV. Individual is a renal transplant recipient with a diagnosis of persistent hyperparathyroid-associated hypercalcemia (DrugPoints B IIa); **AND**
- XVI. Individual has a serum corrected total calcium greater than 10.5 mg/dL (Evenepowl et al. 2014).

Continuation requests for Sensipar (cinacalcet) may be approved when the following criteria are met:

- I. Individual is 18 years of age or older; **AND**
- II. Individual has a diagnosis of Secondary hyperparathyroidism (HPT) and is currently on dialysis for chronic kidney disease (CKD); **AND**
- III. Individual has had clinically significant improvement or stabilization in clinical signs and symptoms of disease;

OR

- IV. Individual is 18 years of age or older; **AND**
- V. Individual has a diagnosis of parathyroid carcinoma with hypercalcemia; **AND**
- VI. Individual has had clinically significant improvement or stabilization in clinical signs and symptoms of disease;

OR

- VII. Individual is 18 years of age or older; **AND**
- VIII. Individual has a diagnosis of primary HPT with severe hypercalcemia and is unable to undergo parathyroidectomy; **AND**
- IX. Individual has had clinically significant improvement or stabilization in clinical signs and symptoms of disease;

OR

- X. Individual is 18 years of age or older; **AND**
- XI. Individual is a renal transplant recipient with a diagnosis of persistent hyperparathyroid-associated hypercalcemia (DrugPoints B IIa); **AND**
- XII. Individual has had clinically significant improvement or stabilization in clinical signs and symptoms of disease.

Sensipar (cinacalcet) may not be approved for the following:

- I. Individual has a diagnosis of secondary hyperparathyroidism with chronic kidney disease and is not on dialysis.

Key References:

- 1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>.
- 2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
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- 4. Block GA, Martin KJ, de Francisco AL, Turner SA, Avram MM, Suranyi MG, Hercz G, Cunningham J, Abu-Alfa AK, Messa P, Coyne DW, Locatelli F, Cohen RM, Evenepoel P, Moe SM, Fournier A, Braun J, McCary LC, Zani VJ, Olson KA, Drüeke TB, Goodman WG. Cinacalcet for secondary hyperparathyroidism in patients receiving hemodialysis. N Engl J Med. 2004 Apr 8;350(15):1516-25. doi: 10.1056/NEJMoa031633. PMID: 15071126.

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7. Kidney Disease: Improving Global Outcomes (KDIGO) 2017 Clinical Practice Guideline Update for the Diagnosis, Evaluation, Prevention, and Treatment of Chronic Kidney Disease-Mineral and Bone Disorder (CKD-MBD). *Kidney Int Suppl*. 2017; 7 (1):1-59. Available from: <https://kdigo.org/wp-content/uploads/2017/02/2017-KDIGO-CKD-MBD-GL-Update.pdf>.
8. Kidney Disease: Improving Global Outcomes (KDIGO) CKD-MBD Work Group. KDIGO Clinical Practice Guideline for the Diagnosis, Evaluation, Prevention, and Treatment of Chronic Kidney Disease-Mineral and Bone Disorder (CKD-MBD). *Kidney Int Suppl*. 2009; 76 (S113):S1-S130. Available from: <https://kdigo.org/guidelines/ckd-mbd/>.
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12. National Kidney Foundation. K/DOQI 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*. 2010; 55 (5):773-799. Available from: <http://www.kidney.org/sites/default/files/docs/kdoqi-ckd-mbd-commentary.pdf>.
13. Qunibi W and Kalantar-Zadeh K. Target Levels for Serum Phosphorus and Parathyroid Hormone. *Seminars in Dialysis*. 2011; 24(1):29-33. DOI: 10.1111/j.1525-139X.2010.00823.x
14. Rayaldee [Package insert]. Miami, FL. OPKO Pharmaceuticals, LLC.; 2016. Available from: http://www.accessdata.fda.gov/drugsatfda_docs/label/2016/208010s000lbl.pdf.
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