

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	NA

Sensipar (cinacalcet)

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

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

APPROVAL CRITERIA

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

- I. Individual has been on Sensipar (cinacalcet) in the past 180 days (medication samples/ coupons/ discount cards are excluded from consideration as a trial);
- OR**
- II. Individual is 18 years of age or older; **AND**
 - III. Individual has a diagnosis of secondary hyperparathyroidism (HPT); **AND**
 - IV. Individual is currently on dialysis for chronic kidney disease (CKD); **AND**
 - V. Individual has a serum corrected total calcium greater than 8.4 mg/dl; **AND**
 - VI. Individual has a serum intact plasma parathyroid hormone (iPTH) level greater than 150 pg/ml; **AND**
 - VII. Individual has had an inadequate response or intolerance to treatment with oral phosphate binders or oral generic vitamin D analogs;
- OR**
- VIII. Individual is 18 years of age or older; **AND**
 - IX. Individual has a diagnosis of parathyroid carcinoma with hypercalcemia; **AND**
 - X. Individual has a serum corrected total calcium greater than or equal to 10.2 mg/dL (NKF 2003);
- OR**
- XI. Individual is 18 years of age or older; **AND**
 - XII. Individual has a diagnosis of primary HPT with severe hypercalcemia; **AND**
 - XIII. Individual is unable to undergo parathyroidectomy; **AND**
 - XIV. Individual has a serum corrected total calcium greater than 1 mg/dL above normal (Wilhelm 2016);

PAGE 1 of 3 11/18/2019

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

CRX-ALL-0464-19

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	NA

OR

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

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.

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2019. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. Available from: <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed on: July 24, 2019.
3. DrugPoints® System [Internet Database]. Greenwood Village, CO: Thomson Reuters (Healthcare) Inc. Updated periodically.
4. Evenepowl 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; 14(11):2545-55. Available from: <http://onlinelibrary.wiley.com/doi/10.1111/ajt.12911/epdf>. Accessed on: July 24, 2019.
5. Executive summary of the 2017 KDIGO Chronic Kidney Disease-Mineral and Bone Disorder (CKD-MBD) Guideline Update: what's changed and why it matters. *Kidney International.* 2017; 92: 26-36. Accessed on: July 24, 2019.
6. 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>. Accessed on: July 24, 2019.
7. 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: <http://www.kdigo.org/pdf/KDIGO%20CKD-MBD%20GL%20K1%20Suppl%20113.pdf>. Accessed on: July 24, 2019.
8. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; Updated periodically.
9. Guideline for the Evaluation and Management of CKD. *Am J Kidney Dis.* 63(5):713-735. Available from: [http://www.ajkd.org/article/S0272-6386\(14\)00491-0/pdf](http://www.ajkd.org/article/S0272-6386(14)00491-0/pdf). Accessed on: July 24, 2019.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	NA

10. National Kidney Foundation [homepage on the internet]. New York (NY): National Kidney Foundation, Inc; c2010 [cited November 11, 2010]. Kidney Disease; [2 screens]. Available from: <http://www.kidney.org/kidneyDisease/>. Accessed July 24, 2019
11. National Kidney Foundation. Kidney Disease Quality Outcomes Initiative (K/DOQI) clinical practice guidelines. Bone metabolism and disease in chronic kidney disease. *Am J Kidney Dis*. 2003; 42(Suppl 3): S1-S201.
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-BMD). *Am J Kidney Dis*. 2010; 55 (5):773-799. Available from: <http://www.kidney.org/sites/default/files/docs/kdoqi-ckd-mbd-commentary.pdf>. Accessed on: July 24, 2019.
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. Accessed on: July 24, 2019.
15. Saliba W and El-Haddad B. Secondary Hyperparathyroidism: Pathophysiology and Treatment. *J Am Board Fam Med*. 2009; 22:574-581. Available from: <http://www.jabfm.org/content/22/5/574.full.pdf>. Accessed on: July 24, 2019.
16. Wilhelm, S, Wang T, and Ruan, D. The American Association of Endocrine Surgeons Guidelines for Definitive Management of Primary Hyperparathyroidism. *JAMA Surg*. 2016;151:959-968. Available from: <https://jamanetwork.com/journals/jamasurgery/fullarticle/2542667> . Accessed on July 24, 2019.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.