	TTER HEALTH® Policy/Guideline	<b>*ae</b>	etna™	
Name:	Sensipar		Page:	1 of 3
Effective Date: 4/7/2024			Last Review Date:	4/2024
Applica	□Illinois	□Florida	⊠Florida Kids	
Applies to:	⊠New Jersey	⊠Maryland	□Michigan	
	🛛 Pennsylvania Kids	⊠Virginia	□Texas	

#### Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Sensipar (cinacalcet) under the patient's prescription drug benefit.

## **Description:**

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

#### A. FDA-Approved Indications

- 1. Secondary hyperparathyroidism (HPT) in adult patients with chronic kidney disease (CKD) on dialysis
- 2. Hypercalcemia in adult patients with parathyroid carcinoma
- 3. 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

#### B. Compendial Use

Tertiary hyperparathyroidism in post-kidney transplant patients not receiving dialysis

All other indications are considered experimental/investigational and not medically necessary.

## **Applicable Drug List:**

Sensipar (cinacalcet)

#### **Policy/Guideline:**

#### Criteria for Initial Approval:

Note: requests for brand Sensipar require that the patient is unable to take the preferred generic cinacalcet for the given diagnosis due to a trial and inadequate treatment response or intolerance, or a contraindication along with rationale.

## A. Secondary Hyperparathyroidism with CKD on Dialysis

Authorization of 12 months may be granted for treatment of secondary hyperparathyroidism in a member with chronic kidney disease on dialysis who has a

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serum calcium level (corrected for albumin) greater than or equal to 8.4 mg/dL (see Appendix).

## B. Primary Hyperparathyroidism

Authorization of 12 months may be granted for treatment of primary hyperparathyroidism in a member who is not able to undergo parathyroidectomy and has a serum calcium level (corrected for albumin) greater than or equal to 8.4 mg/dL (see Appendix).

# C. Tertiary Hyperparathyroidism in Post-Kidney Transplant Patients Not Receiving Dialysis

Authorization of 12 months may be granted for treatment of tertiary hyperparathyroidism in a member who has had a kidney transplant, is not receiving dialysis, and has a serum calcium level (corrected for albumin) greater than or equal to 8.4 mg/dL (see Appendix).

## D. Parathyroid Carcinoma

Authorization of 12 months may be granted for the treatment of parathyroid carcinoma in a member who has a serum calcium level (corrected for albumin) greater than or equal to 8.4 mg/dL (see Appendix).

## Criteria for Continuation of Therapy:

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in criteria for initial approval when the following criteria are met:

# A. Secondary Hyperparathyroidism with CKD on Dialysis

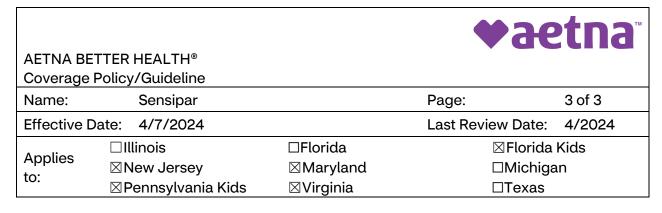
Member is experiencing benefit from therapy as evidenced by a decrease in intact parathyroid hormone (iPTH) levels from pretreatment baseline.

## B. All other indications

Member is experiencing benefit from therapy (e.g., decreased or normalized corrected serum calcium levels since starting therapy).

# Appendix

Corrected calcium = measured total calcium + 0.8(4.0 - serum albumin)



## **Approval Duration and Quantity Restrictions:**

#### Approval: 12 months

## **Quantity Level Limit:**

- Sensipar (cinacalcet) 30 mg & 60 mg tablets: 60 per 30 days
- Sensipar (cinacalcet) 90mg tablets: 120 per 30 days

#### **References:**

- 1. Cinacalcet [package insert]. Cranbury, NJ: Sun Pharmaceuticals Industries, Inc.; December 2021.
- 2. Sensipar [package insert]. Thousand Oaks, CA: Amgen, Inc.; December 2019.
- 3. Micromedex Solutions [database online]. Truven Health Analytics, Inc. Ann Arbor, MI. Available at: www.micromedexsolutions.com. Accessed October 5, 2023.
- 4. AHFS DI (Adult and Pediatric) [database online]. Lexi-Comp, Inc. Hudson, OH. Available at: http://online.lexi.com/lco/action/index/dataset/complete\_ashp [available with subscription]. Accessed October 5, 2023.
- 5. Clinical Pharmacology [Internet]. Elsevier. Tampa (FL). Available at: <u>http://www.clinicalpharmacology.com</u>. Accessed October 5, 2023.
- 6. 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;14:2545-2555.2023.
- Kruse AE, Ensenberger U, Frey FJ, et al. The calcimimetic cinacalcet normalizes serum calcium in renal transplant patients with persistent hyperparathyroidism. *Nephrol Dial Transplant*. 2005;20:1311-1314.
- 8. Srinivas TR, Schold JD, Womer KL, et al. Improvement in hypercalcemia with cinacalcet after kidney transplantation. *Clin J Am Soc Nephrol*. 2006;1:323–326.
- 9. Shoback D. Hypoparathyroidism. NEJM. 2008;359: 391-403.