
5.30.046

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Subsection:	Endocrine and Metabolic Drugs	Original Policy Date:	March 3, 2017
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Last Review Date: September 8, 2023

Sensipar

Description

Sensipar (cinacalcet)

Background

Sensipar (cinacalcet) is a calcimimetic agent that increases the sensitivity of the calcium-sensing receptor to activation by extracellular calcium. These calcium-sensing receptors are on the parathyroid hormone gland and are the principal regulators of PTH (parathyroid hormone) synthesis and secretion. Calcimimetics like Sensipar bind and activate the calcium-sensing receptor of parathyroid glands, thereby inhibiting PTH secretion which leads to lower calcium levels. Reductions in PTH are associated with a decrease in bone turnover and bone fibrosis in patients with CKD (chronic kidney disease) on dialysis and uncontrolled secondary HPT. Sensipar is not indicated for use in adult patients with CKD who are not on dialysis because of an increased risk of hypocalcemia (1).

Regulatory Status

FDA-approved indication: Sensipar is a calcium-sensing receptor agonist indicated for treatment of secondary hyperparathyroidism (HPT) in adult patients with chronic kidney disease (CKD) on dialysis, hypercalcemia in adult patients with parathyroid carcinoma, and 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 (1).

Off-Label Uses:

Sensipar may be used off label in the treatment of persistent hyperparathyroidism in patients who are post renal transplantation (2-3).

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Initial treatment of Sensipar is contraindicated if serum calcium is less than the lower limit of the normal range. Life threatening events and fatal outcomes were reported due to hypocalcemia. Hypocalcemia can prolong QT interval, lower the threshold for seizures, and cause hypotension, worsening heart failure, and/or arrhythmia. Monitor serum calcium carefully for the occurrence of hypocalcemia during treatment. Once the maintenance dose has been established, serum calcium should be measured approximately monthly for patients with secondary hyperparathyroidism with CKD on dialysis, and every 2 months for patients with parathyroid carcinoma or primary hyperparathyroidism (1).

In patients with secondary hyperparathyroidism with chronic kidney disease who are on dialysis, not only should serum calcium and serum phosphorus be measured within 1 week of starting Sensipar, but intact parathyroid hormone (iPTH) should be measured 1 to 4 weeks after initiation or dose adjustment of Sensipar and ideally maintained between 150 to 300 pg/mL (1).

Safety and effectiveness in pediatric patients have not been established (1).

Related policies

Natpara

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Sensipar may be considered **medically necessary** if the conditions indicated below are met.

Sensipar may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnoses

Patient must have **ONE** of the following:

1. Secondary hyperparathyroidism (HPT) with chronic kidney disease (CKD)
 - a. **MUST** be on dialysis

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- b. iPTH level greater than 300 pg/mL
- 2. Hypercalcemia with parathyroid carcinoma (PC)
- 3. Hypercalcemia with primary hyperparathyroidism (HPT)
 - a. Unable to undergo parathyroidectomy
- 4. Persistent hyperparathyroidism post renal-transplant

AND ALL of the following for **ALL** indications:

- a. Serum calcium level (corrected for albumin) greater than or equal to 8.4mg/dL
- b. Prescriber agrees to monitor calcium levels periodically throughout therapy
- c. **Brand Sensipar only:** Patient **MUST** have tried the preferred product (generic Sensipar: cinacalcet) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnoses

Patient must have **ONE** of the following:

- 1. Secondary hyperparathyroidism (HPT) with chronic kidney disease (CKD)
 - a. **MUST** be on dialysis
- 2. Hypercalcemia with parathyroid carcinoma (PC)
- 3. Hypercalcemia with primary hyperparathyroidism (HPT)
- 4. Persistent hyperparathyroidism post renal-transplant

AND the following for **ALL** indications:

- a. Prescriber agrees to monitor serum calcium levels periodically throughout therapy

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- b. **Brand Sensipar only:** Patient **MUST** have tried the preferred product (generic Sensipar: cinacalcet) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 3 months

Prior – Approval *Renewal* Limits

Duration 12 months

Rationale

Summary

Sensipar (cinacalcet) is a calcimimetic agent that increases the sensitivity of the calcium-sensing receptor to activation by extracellular calcium. Sensipar is indicated for treatment of secondary hyperparathyroidism (HPT) in adult patients with chronic kidney disease (CKD) on dialysis, hypercalcemia in adult patients with parathyroid carcinoma, and 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 (1). Sensipar may be used off label in the treatment of persistent hyperparathyroidism in patients who are post renal transplantation (2-3).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Sensipar while maintaining optimal therapeutic outcomes.

References

1. Sensipar [package insert]. Thousand Oaks, CA: Amgen, Inc.; December 2019.
2. Kidney Disease: Improving Global Outcomes (KDIGO) CKD-MBD Update Work Group 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*, 7 (2017), pp. 1-59.

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3. 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 Nov;14(11):2545-55.

Policy History

Date	Action
March 2017	Addition to PA
June 2017	Annual review
February 2018	Addition of the use of this medication for the treatment of hypercalcemia in renal transplant patients with persistent hyperparathyroidism
June 2018	Annual review and reference update
December 2019	Annual review and reference update
December 2020	Annual review and reference update. Added requirement that brand Sensipar has to t/f the preferred product cinacalcet
September 2021	Annual review
September 2022	Annual review
September 2023	Annual review. Per SME, revised background section to clarify Sensipar's mechanism of action

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 8, 2023 and is effective on October 1, 2023.