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. By decreasing extracellular calcium (through increasing the sensitivity of the calcium sensing receptors), reduction in PTH is achieved. 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).

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** for patients 18 years of age or older with one of the following: secondary hyperparathyroidism (HPT) with chronic kidney disease (CKD), hypercalcemia with parathyroid carcinoma (PC), hypercalcemia with primary hyperparathyroidism, or persistent hyperparathyroidism post renal transplant and when the conditions indicated below are met.

Sensipar may be considered **investigational** in patients less than 18 years of age and 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
   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

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

**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**

2. Kidney Disease: Improving Global Outcomes (KDIGO) CKD-MBD Update Work Group KDIGO 2017 Clinical Practice Guideline Update for the Diagnosis, Evaluation,


Policy History

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<td>March 2017</td>
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<td>June 2017</td>
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<td>Addition of the use of this medication for the treatment of hypercalcemia in renal transplant patients with persistent hyperparathyroidism</td>
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Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 6, 2019 and is effective on January 1, 2020.