

Cinacalcet

Product:

CINACALCET (Sensipar®)
30mg, 60mg, 90mg tablets

Class of drugs:

Calcimimetic agent

Indication:

Treatment of secondary hyperparathyroidism in patients with chronic kidney disease

Manufacturer:

Amgen Canada Inc.

CED Recommendation

The CED recommended that cinacalcet (Sensipar) not be funded, on the basis that there is no convincing evidence this drug provides important clinical benefits or value for money compared with available alternatives.

Executive Officer Decision

Based on the CED's recommendation, the Executive Officer decided not to fund cinacalcet (Sensipar) through the Ontario Public Drug Programs.

Status

No funding through the Ontario Public Drug Programs.

Highlights of Recommendation:

- ◆ Cinacalcet (Sensipar) is indicated for the treatment of secondary hyperparathyroidism in patients with chronic kidney disease who are on dialysis.
- ◆ Clinical trial evidence supports that cinacalcet (Sensipar) improves biochemical markers of hyperparathyroidism (i.e., blood levels of the parathyroid hormone, calcium and phosphorus).
- ◆ However, cinacalcet (Sensipar) has not been proven to provide important clinical benefits, such as improvement in survival and reductions in the risk of bone fractures, cardiovascular disease, and hospitalizations.
- ◆ The Committee noted no major safety concerns with cinacalcet (Sensipar). A small number of cases of hypocalcemia (low blood calcium) and seizures have been reported.
- ◆ The cost of cinacalcet (Sensipar) ranges from \$4,000 to \$23,500 per year, depending on the dosage. This drug is very expensive compared to other treatments used in patients with chronic kidney disease. Value for money has not been established, primarily because evidence of important clinical benefits is not available to justify the high treatment costs.
- ◆ **Overall, the Committee noted that cinacalcet (Sensipar) has not been shown to provide important health benefits or value for money.**

Background:

Hyperparathyroidism is the excess production of parathyroid hormone (PTH) by the parathyroid glands. Parathyroid hormone controls calcium, phosphorus, and vitamin D levels within the blood and bone. Hyperparathyroidism can reduce bone density, making it easier for bones to break, as well as stiffen the arteries, creating heart problems.

Excess production of parathyroid hormone that is caused by another medical condition is known as secondary hyperparathyroidism. The most frequent cause of secondary hyperparathyroidism is chronic kidney disease. Secondary hyperparathyroidism from chronic kidney disease is characterized by an increased level of PTH and an imbalance of phosphorus and calcium levels in the body.

Standard treatments for secondary hyperparathyroidism in patients with chronic kidney disease on dialysis include vitamin D and phosphate binders. Vitamin D increases calcium absorption from the gut; this in turn leads to a decrease in parathyroid hormone production. Phosphate binders prevent the absorption of phosphorus from food.

Cinacalcet (Sensipar) is used in addition to vitamin D and phosphate binders in the management of secondary hyperparathyroidism from chronic kidney disease. Cinacalcet (Sensipar) works on the parathyroid gland to lower parathyroid hormone, calcium and phosphorus levels.

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Detailed Discussion:

- ◆ The Committee considered the funding of cinacalcet (Sensipar) on two occasions, initially in April 2005 and again in June 2008.
- ◆ Randomized controlled trials comparing cinacalcet (Sensipar) to placebo have shown that this drug lowers levels of parathyroid hormone, blood calcium and phosphorus, and the calcium-phosphorus product (a measure of both calcium and phosphorus levels). There is currently no good evidence that improvements in these biochemical markers in the clinical trials resulted in improvements in patient health outcomes, such as improved survival, reduced incidence of bone fractures or a decreased incidence of cardiovascular events.
- ◆ The Committee noted that there is a study underway to assess whether the use of cinacalcet (Sensipar) lowers the incidence of cardiovascular events. The Committee expressed an interest in reviewing this study once the results are available.
- ◆ Cinacalcet (Sensipar) has been associated with cases of hypocalcemia and seizures. Other adverse effects may include nausea, vomiting, diarrhea, dizziness, loss of appetite, muscle pain and high blood pressure.
- ◆ The cost of cinacalcet (Sensipar) ranges from \$4,000 to \$23,500 per year, depending on the dosage. This drug is significantly more expensive than other treatments for chronic kidney disease (e.g., calcium carbonate, a phosphate binder, costs \$70-\$1000 a year). Value for money has not been established, primarily because evidence of important clinical benefits is not available to justify the high treatment costs.
- ◆ Overall, the Committee noted that cinacalcet (Sensipar) has not been shown to provide important health benefits or value for money. Studies measuring clinically meaningful outcomes are required before its therapeutic role and cost-effectiveness can be assessed.

CEDAC Recommendation:

(<http://www.cadth.ca/index.php/en/cdr/recommendations>)

The Canadian Expert Drug Advisory Committee (CEDAC) recommended that cinacalcet (Sensipar) not be listed.



Ministry of
Health and Long-Term Care
Ontario Public Drug Programs

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