



CEDAC FINAL RECOMMENDATION on RECONSIDERATION and REASONS for RECOMMENDATION

CINACALCET (Sensipar™—Amgen Canada Inc.)

Description:

Cinacalcet is a calcimimetic agent that modulates the activity of the calcium-sensing receptor on the parathyroid gland. It is indicated for the treatment of secondary hyperparathyroidism in patients with chronic kidney disease.

Recommendation:

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

Reasons for Recommendation:

1. Nine double-blind randomized controlled trials compared cinacalcet with placebo, usually in addition to conventional therapy. Cinacalcet significantly reduced parathyroid hormone and serum calcium levels. Phosphorus and calcium x phosphorus product were also reduced in most trials.
2. There was insufficient evidence in these trials that cinacalcet has any effect on clinically important outcomes such as quality of life, symptomatic bone disease (bone pain, fractures), hospitalization, cardiovascular disease, or mortality.
3. The additional medication cost of adding cinacalcet to the management regimens of patients with chronic kidney disease is between \$4,000 and \$23,500 per patient per year, depending upon the dose (ranging from 30 to 180 mg/day). A pharmacoeconomic evaluation, submitted by the manufacturer, was also considered by CEDAC.

Of Note:

1. Conventional therapy for secondary hyperparathyroidism (oral phosphate binders and oral or parenteral vitamin D analogs) is likely to be used in conjunction with cinacalcet therapy as it was in all the clinical trials.
2. Both published and unpublished data were reviewed and taken into consideration in making this recommendation.