

APPLICATION GUIDELINES FOR CINACALCET (SENSIPAR®)

Preamble:

In spring 2006, the BC Provincial Renal Agency approved funding for cinacalcet (Sensipar®) on a restricted basis to individuals who fail conventional therapy or who meet the criteria as described in detail below.

There are currently no outcome studies with evidence that lowering PTH is of benefit with respect to morbidity and mortality. Due to some individual data that suggests that severe symptomatology may be benefited by lowering the PTH level (but not so low as to induce low bone turnover disease), the Pharmacy Formulary Review Committee made the decision to fund on a restricted basis.

The patient's parathyroidectomy candidacy should be determined by a nephrologist, usually in consultation with a surgeon, anesthetist, or another specialist. The specific issue of contraindication to surgery can be absolute or relative, and we ask the nephrologists to consider the suitability based on objective criteria, as might be used in pre-operative assessments for other surgeries. To be fair to all and to help the team equalize access to the drug, we felt that a transparent process describing the aspects of the patients case that deem him/her not a surgical case should be documented, as outlined in the application form. If surgery is contraindicated, long-term cinacalcet therapy will be awarded with semi-annual or annual assessments. If parathyroidectomy could be performed, bridge therapy with cinacalcet is a reasonable option.

As stewards of care of all renal patients, we are wanted to ensure appropriate access to those patients who would benefit from the drug, ensure that drugs are stopped when ineffective, and reviewed periodically with respect to compliance. We understand that as a clinician, being asked to be both a patient advocate and at the same time judicious with expensive therapy can be difficult.

Please understand the adjudication team's need for this documentation in the form of the application

Nephrologists are asked to submit the application form to BCPRA bcpra@bcpra.ca or fax: 604-875-7366.

An adjudication team of three Pharmacy Formulary Review Committee members will review each request, with approval given on a case-by-case basis. The turn-around timeline for notification of approval is 7-10 days. Due to costs, the use of this drug will be closely monitored. The funding policy will be reevaluated after one year.

Criteria for Initial Application

All of the following must be documented on the initial application form:

Please note that additional information may be asked for; this is not an automatic approval process. Please refer to the application form.

Requirements for application:

1. Symptoms clearly related to hyperparathyroidism that are causing significant impairment in quality of life.
2. Standard therapy for hyperparathyroidism has been optimized, including adherence to diet and drug therapy, per current standards of practice.
3. a) The patient has been reviewed by a surgeon/anesthetist or nephrologist and has been deemed to not be a candidate for parathyroidectomy due to 1) high surgical risk, 2) poor wound healing, 3) anesthetic risk, or 4) other, based on validated peri-operative risk scores (e.g. ASA or SRS) in conjunction with clinical judgment (such as poor wound healing). OR
 b) The patient has been wait-listed for parathyroidectomy (i.e. cinacalcet for “bridge” therapy until surgery), OR
 c) The patient has a renal transplant pending imminently (either a living donor transplant within 3-6 months or top of the waitlist for cadaveric donor transplant) and the patient’s transplant nephrologist indicates preference for pre-transplant cinacalcet instead of parathyroidectomy.

Most recent values:

Criteria	Value	Date
PTH > 88 x 2 at least 1 month apart		
Ca++ elevated level x 2 at least 1 month apart		
Adequate dialysis as evidenced by PRU (> 65%) or Dialysis KTV (> 1.2)		

- Past or current Vitamin D therapy Yes No
 Nutritional counseling completed Yes No
 Patient is compliant with medication Yes No

Once the medication has been approved:

Start Cinacalcet at 30 mg daily (\$3950/annum)

Recommended follow up

- Adjust dose q monthly according to fall in PTH, in increments of 15-30 mg to max dose of 120 mg/day (**\$15,662/annum**).
- As hypocalcemia is common, consider continuation/ reinstatement of Vitamin D if Ca < 2.35 and PTH remains elevated
- Consider decrease in dose of Cinacalcet or discontinuation if PTH < 25 pm/L.
- Review Calcium and Phosphate q weekly x 3; if calcium < 2.25, consider re-institution of Vitamin D or calcium supplements or both. Hypocalcemia is not uncommon – consider addition of vitamin D and calcium as necessary.
- If stable values x 3 consecutive weeks, reduce frequency to q 2 weeks x 2, then if stable, resume regular measurement schedule.
- Review PTH monthly x 3, once stable, resume q 3 monthly monitoring.
- Resume intensive measurement schedule after dose changes.