

July 2007

Patient Update: Answers to Your Questions about Secondary Hyperparathyroidism and Sensipar[®] (cinacalcet)

What is Secondary Hyperparathyroidism?

Secondary hyperparathyroidism is a condition that some dialysis patients develop as a result of an imbalance of phosphorous, calcium and vitamin D levels. In secondary hyperparathyroidism, the parathyroid glands make too much parathyroid hormone (PTH). Some people experience no symptoms; others may have a range of symptoms that can be mild to severe. These may include itching, bone pain or severe arthritis, among others. In some cases, lowering the PTH level improves the symptoms. But sometimes it does not, as these can all be due to problems associated with kidney disease and dialysis.

How is this condition treated?

Strict dietary control of phosphate and phosphate binders is the cornerstone of therapy for hyperparathyroidism. Vitamin D therapy can also lower PTH levels, as can more intensive dialysis (i.e. more time, more frequent). When these therapies are not successful in lowering PTH levels, removal of the glands by surgery may be recommended.

In other instances, treatment for hyperparathyroidism may be attempted with a newer medication called Sensipar[®] (cinacalcet). This expensive medication helps lower PTH, and also helps lower serum calcium and phosphorus lab values. It is only recently available, and is not readily available throughout Canada, Australia or the UK.

At this time, we do not have any evidence that lowering PTH with this medication improves patient survival. There is some individual data that suggests severe symptoms, such as bone pain, calcium deposits in joints leading to severe arthritis and other dramatic symptoms may be improved in some individuals by lowering the PTH level.

Is Sensipar[®] (cinacalcet) funded by The BC Provincial Renal Agency (BCPRA)?

It is important to note that most provinces are not funding Sensipar[®] at all. However, in the spring of 2006, the Pharmacy Formulary Review Committee of BCPRA made the decision to fund this medication on a restricted basis – for patients who failed conventional therapy or who met specific criteria. These criteria include severe symptoms as listed above, as well as patients who are unable to undergo surgery (which is the definitive and more long lasting therapy for this condition).

Nephrologists were asked to submit application forms to BCPRA. These forms were reviewed by a team of three committee members based on laboratory data, the ability to

Health Authority Renal Programs:

BC Children's Provincial Renal Program, Fraser Health, Interior Health, Northern Health, Providence Health Care, Vancouver Coastal Health, Vancouver Island Health

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prove that a parathyroidectomy (surgery) was not an option and that the symptoms warranted the use of this drug. The goal was to fund Sensipar[®] only for those patients who could derive a clinical benefit. If patients were started on the medication and the symptoms did not improve, the medication was to be discontinued.

Has this process been put on hold?

The Pharmacy Formulary Review Committee is reviewing the eligibility criteria for Sensipar[®]. During this review process, BCPRA is authorizing extensions to previous applications that received approval for a six-month course of therapy, and is accepting *urgent* new applications.

The committee hopes to resume all application reviews by the end of summer and will communicate with all nephrologists if the process or application forms have changed.

How does BCPRA decide what medications to fund?

The Pharmacy Formulary Review Committee, which includes renal care providers from around the province, determines which medications are essential for kidney patients and should therefore be funded. They make these decisions based on reviews of published research evidence that show positive health outcomes for patients. Please note that patients are always free to pay for medications/supplements and treatments they believe are helpful to them, based on the advice of their nephrologist. However, as a publicly funded agency, BCPRA – and by extension the health authority renal programs – is unable to fund all medications for everyone.

We know that patients, and in fact all BC residents, expect the health system to be managed as efficiently and responsibly as possible. Given the costs of renal drugs, it is important that we closely assess all funded medications on this basis. The Pharmacy Committee is attempting to ensure equal access to all proven, effective medications for all patients. Sometimes this means making decisions about restricting funding for certain very expensive medications if the evidence is not crystal clear on the benefit.

Can I purchase Sensipar[®] on my own?

Yes, if you have a prescription from your physician, you can purchase Sensipar[®] directly from your pharmacy. If you or your spouse has a private insurance plan that covers the cost of medications, Sensipar[®] may be covered. Ask your doctor or pharmacist to help you with the application if you have this type of insurance.