

DEPARTMENT OF RENAL MEDICINE

RJF/YRP

7 September 2006

Dr Carole Longson
Director, Centre for Health Technology Evaluation

Dear Dr Longson,

Re: Health Technology appraisal – Cinacalcet Hydrochloride for the treatment of secondary hyperparathyroidism in patients with end stage renal disease on maintenance haemodialysis.

Appraisal consultation document

Thank you for asking me to comment on the Appraisal Consultation Document 2 for Cinacalcet Hydrochloride.

I am pleased to see that an indication for the usage of Cinacalcet Hydrochloride has been recognised. I agree that Cinacalcet is not first line or routine treatment for secondary hyperparathyroidism in patients with end stage renal failure.

However the wording of section 1.2 is confusing. It implies that Cinacalcet usage should be based purely on the levels of intact parathyroid hormone. However a PTH level can only be interpreted in the context of knowing a patient's serum calcium and I would suggest that this paragraph requires rewording to read "Cinacalcet Hydrochloride is recommending in patients with refractory secondary hyperparathyroidism (typically defined as an intact PTH level >85 pmol/L (or 800pmol/L), with a normal or high serum calcium) and in whom a surgical parathyroidectomy is contra-indicated. "

The final paragraph of section 1.2 is a reasonable overall statement. However I would suggest that 6 months treatment would be required to ascertain response. This reflects the practicality of blood test monitoring in patients on dialytic therapies which generally occur at monthly intervals. Such a pattern would not allow a suitable titration pathway to be achieved in a three month period.

I would also draw your attention to an abstract published at the British Renal Society/ Renal Association meeting 2006. This outlines our preliminary experience of this agent in a cohort of patients with refractory hyperparathyroidism. I enclose the abstract and the poster presentation related for information. Not only were PTH target levels achieved in a proportion of this population but target levels of calcium and phosphate were also achieved with greater success. This was achieved at a substantially lower dose of Cinacalcet that has been reported in literature (median daily dose 30mg).

Many thanks for asking me to comment on the appraisal.

Yours sincerely