

Vicky Marvin

From: hchci
Sent: 10 November 2005 18:31
To: Reetan Patel; Alana Miller
Subject: FW: Submission in respect of the Cinacalcet Health Technology Appraisal

Attachments: Nice submission Calcimimetics.doc



Nice submission
Calcimimetics....

From: Timothy F Statham OBE [REDACTED]
Sent: 10 November 2005 18:31:17
To: hchci
Subject: Submission in respect of the Cinacalcet Health Technology Appraisal Auto forwarded by a Rule

To
Reetan Patel
Technology Appraisal Administrator
NICE

Dear Reetan,

Please find attached the National Kidney Federation submission for the :-

Cinacalcet hydrochloride for the treatment of secondary hyperparathyroidism in patients with end-stage renal disease on maintenance dialysis therapy.

The National Kidney Federation had previously informed you that it would not be making a submission, however this decision has now been reversed and the submission is attached.

Please acknowledge safe receipt of the file.

You will also be receiving in the post a nomination from the NKF of a patient expert - Steve Rowe.

Kind regards

Timothy

Timothy F Statham OBE
Chief Executive
National Kidney Federation
email tim.statham@btinternet.com
Web www.kidney.org.uk

Delivered via MessageLabs

To
National Institute for Health and Clinical Excellence
Health Technology Appraisal

Cinacalcet HCl for the treatment of secondary hyperparathyroidism in patients with end stage renal disease on maintenance dialysis therapy

Submission by **The National Kidney Federation** – patient group consul tee and commentator

Dated – 10th November 2005

6 Stanley Street, Worksop, Nott's S81 7HX

Submitted by Timothy F Statham – Chief Executive, notified participant.

Confidentiality undertaking signed and submitted

Background

The National Kidney Federation (NKF) originally notified the institute that it would not be making a submission to this appraisal, however this position has been reviewed and reversed

This submission

This submission is made by a patient group, the National Kidney Federation, who represent all 40,000 renal replacement therapy patients. The submission represents the patients' view and cannot therefore be regarded as scientifically rigorous, however the NKF would argue that the patients view is acceptable and essential evidence and is in the spirit of recent announcements to the effect that the NHS is a patient centred service.

The size of the current problem

The NKF notes that figures quoted in the scope relate to 2001. The growth in renal replacement patients is currently running at 8% per annum, and therefore the current numbers of patients are now as follows :-

40,000 RRP in England and Wales

20,000 on dialysis

10,000 patients on dialysis have PTH or phosphate levels outside the recommended range

The serious effect of secondary hyperparathyroidism on our patient members

- An operation is sometimes needed to remove the parathyroid glands
- Bone disease and fractures
- Further damage to the kidneys themselves

- Calcification of tissue and blood vessels leading in some cases to heart disease and death
- Patients need to take a cocktail of medicines in order to create balance amongst PTH – Calcium – Phosphorus – Vitamin D. This medicinal burden is on top of the burden that dialysis itself causes renal patients to endure.
- Fear – patients are a community of patients, they are not patients in isolation. It is very obvious to a renal patient that heart disease, possibly caused by calcification, is likely to be the eventual cause of their death – not the failure of their kidneys.
- Pain and itching
- Nausea, vomiting or constipation
- Heartburn
- Tiredness and depression (caused by anaemia)

Current treatments

Current medicinal treatments are unsatisfactory as evidenced by the frequent need to operate to remove the parathyroid glands (parathyroidectomy). Frequent very close monitoring is needed of phosphate, PTH and calcium levels. Renal patients continue to die as a direct result of raised calcium levels.

What is needed

Renal patients need a better solution that enables better control of the mineral balance in the body – they look for a gold standard treatment that reduces the threat to their life and improves their day to day quality of life – already low through dialysis.

Patients themselves cannot as a group know whether calcimimetics are that gold standard treatment – that is an issue for the institute (NICE) to determine. However the NKF has received testimonials from patients put onto calcimimetics that appear highly promising. In particular patients report an improvement in pain (caused by bone disease) and in their ability to walk. Less muscle spasms have been reported and sleep patterns improved.

We ask that NICE give calcimimetics the opportunity to prove their worth (or otherwise) and Nephrologists the freedom to prescribe the drug so that real evidence of the drugs value can be obtained. Patients need something better than the current treatment options.

Timothy F Statham OBE
 Chief Executive
 National Kidney Federation
 10.11.05