THE ROYAL COLLEGE OF PATHOLOGISTS

Re : NICE Appraisal Consultation Document.
Cinacalcet hydrochloride for the treatment of secondary hyperparathyroidism in patients with end-stage renal disease on maintenance dialysis therapy.

Submission from Dr Graham H Beastall

Having previously commented on the Health Technology Appraisal report on this topic I am pleased to be able to review the feedback from various sources and the Appraisal Consultation Document (ACD) that has been produced from that feedback. I thank the Appraisal Committee for the detailed and clear content of the ACD.

Overall I accept the main recommendation in the ACD that based on current evidence 'Cinacalcet hydrochloride is not recommended for the routine treatment of secondary hyperparathyroidism in patients with end-stage renal disease on maintenance dialysis therapy.'

The scientific basis for Cinacalcet hydrochloride action is well founded and there is universal agreement that it is an effective drug for reducing plasma PTH in this group of patients, and that it may also have a beneficial effect on other biochemical parameters, including plasma phosphate. It is also clear that the use of Cinacalcet hydrochloride is preferred by patients and that it offers less chance of adverse effects in comparison to some conventional therapy. The 'stumbling block' for Cinacalcet hydrochloride is that at this point in time the strength of evidence to support its introduction into routine practice is very weak. There is currently only poor quality evidence that the undoubted biochemical improvement from use of the drug translates into reduced mortality and morbidity and an improved quality of life. As the ACD makes clear further evidence in these areas is urgently required. I believe that if that evidence is forthcoming then the case for the introduction of Cinacalcet hydrochloride into routine practice will be strong.

The ACD contains a detailed assessment of the cost effectiveness of Cinacalcet hydrochloride and it puts forward data to support a variety of models. In all cases, however, the cost effectiveness looks poor because the data to support the clinical effectiveness is currently missing. It would be misleading if the main message from the ACD is about an 'expensive' drug – the main message is that we have a drug that has yet to be proven to be clinically effective.

While waiting for better quality evidence there remains the question about the non-routine use of Cinacalcet hydrochloride in individual patients with severe and/or complex secondary hyperparathyroidism. Although it is not strongly evidence-based I am persuaded by the expert view that a case can be made for short-term use of the drug in individual patients who are awaiting surgical hyperparathyroidism or for longer-term use in individual patients who are considered high risk for surgery for parathyroidectomy.

Evidence on the clinical effectiveness of Cinacalet hydrochloride should be kept under regular review.

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