

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

The response of North Eastern Derbyshire PCT to the NICE second Appraisal Consultation Document (July 2006)

i) *Whether you consider that all the evidence has been taken into account.*

We felt that the first Appraisal Consultation Document (ACD) was very thorough and agreed with the conclusions. It was consistent with work that we had done locally to consider applications for funding of Cinacalcet, which were based on the available evidence and the principles stated in the NICE 'Social Value Judgements' document. It was also consistent with a similar review carried out by NORCOM on behalf of the North Trent PCTs and with the conclusions of the Scottish Medicines Consortium.

We do not believe that the preliminary recommendation for the use of Cinacalcet for patients with refractory secondary hyperparathyroidism (1.2) is consistent with the evidence base and NICE Social Value Judgements. These recommendations contradict the findings noted in points 4.3.5, 4.3.6 and 4.3.7 of the original appraisal document. On reviewing the responses to the first consultation, they appear to be strongly influenced by the fact that there is no other specific treatment available to these patients, and therefore the NHS should be required to fund Cinacalcet.

The ACD does not show Cinacalcet to be cost effective. Funding Cinacalcet would therefore reduce resources available for cost effective interventions for other patients

ii) *Whether you consider that the summaries of clinical and cost effectiveness are reasonable interpretations of the evidence and that the preliminary views on the resource impact and implications for the NHS are appropriate*

We felt the views expressed in the first ACD were reasonable, and disagree with the change to recommend Cinacalcet for the subgroup of patients with refractory disease.

We have received a small number of requests to commission Cinacalcet. All requests to date would meet the preliminary recommendations for funding. These are patients with very high PTH, in whom the estimated annual treatment cost would be up to £9 000 per year and the cost per QALY in the region of £48 000.

To recommend Cinacalcet in this sub-group of patients may be inconsistent with principle 5 of the NICE's 'Social Value Judgements,' and could require PCTs to direct resources away from other treatments.

iii) *In whom surgical parathyroidectomy is contraindicated*

We would expect that patients with renal failure would often have absolute or relative contraindications to surgery. If Cinacalcet is recommended for these patients, it would be appropriate to have clarity on how 'contraindications for surgery' would be interpreted.

The prevalence of the sub-group of patients that would meet the criteria for the preliminary recommendation in 1.2 is not stated

In our limited experience of applications for Cinacalcet, one patient, appeared to have absolute contraindications to parathyroidectomy, in others, there were relative contraindications to surgery. We consider that there is a potential for significant costs for the NHS if Cinacalcet is recommended by clinicians in preference to surgery, with its associated increased risks in this 'higher risk' patient group.

We agreed with the points discussed in paragraphs 4.3.6 and 4.3.7 from the first ACD, which concluded that there was insufficient clinical evidence for this subgroup and no evidence available on the clinical effectiveness of Cinacalcet compared with surgical parathyroidectomy, and is therefore not consistent with a recommendation for its use

iv) *Whether you consider that the provisional recommendations of the Appraisal Committee are sound and constitute a suitable basis for the preparation of guidance to the NHS*

We are concerned that to proceed with 'Provisional Recommendation 1.2', to recommend Cinacalcet Hydrochloride for patients with refractory secondary hyperparathyroidism, would be inappropriate and would represent divergence from the key principles used in allocating NHS resources.

- Cinacalcet has not been demonstrated as cost effective
- Clinical effectiveness of Cinacalcet for this patient subgroup is unclear
- Contraindications to parathyroidectomy are not made clear and therefore open to interpretation
- The recommendation may be inconsistent with NICE Social Value Judgements
- Implementation of the recommendation could divert resources away from cost effective interventions for other patients

## Conclusion

The PCT view is that Cinacalcet Hydrochloride should not be recommended for the treatment of secondary hyperparathyroidism in patients with end-stage renal disease on maintenance dialysis therapy

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