Appendix C

National Institute for Clinical Excellence

Comment 1: the draft remit

Section	Consultees	Comments	Action
Remit size	NHS Quality Improvement Scotland	The remit may need to be restricted to patients with renal failure undergoing dialysis who have secondary hyperparathyroidism rather than patients with renal failure not on dialysis - unless the licence will cover all renal failure patients	
	Renal Association	Satisfactory	No action
Licensing Issues	No comments on this section received.		No action
Wording	NHS Quality Improvement Scotland	Yes [in answer to the question "*Does the wording of the remit reflect the issue(s) of clinical and cost effectiveness about this technology that NICE should consider?*"]	No action
Timing Issues	NHS Quality Improvement Scotland	Existing medical treatment for secondary hyperparathyroidism is suboptimal and so there is great interest in using calcimimetics and avoiding surgery. An early review by NICE would be appropriate to avoid postcode prescribing.	No action
	Renal Association	This unique product is likely to be requested to be used in all renal units when licensed. Therefore to avoid inappropriate use and postcode prescribing early guidance would be of considerable benefit.	No action
	Welsh Kidney Patients' Association	Not urgent	No action
Additional comments on the draft remit	None received		No action

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Comment 2: the draft scope

Section	Consultees	Comments	Action
Background information	NHS Quality Improvement Scotland	I think it would be more accurate to say that disturbances of phosphate/calcium in renal failure result in metastatic calcification and secondary hyperparathyroidism. The role of 2y hyperpara in calcification is uncertain.	Background information amended (shortened)
	Renal Association	Expansion on the early development of changes (CKD stage 3) in calcium and phosphate metabolism and stimulation of the parathyroid glands would be useful background, as would comment on skeletal resistance to PTH. Mention should be made of soft tissue calcification and calciphylaxisis. Tendon rupture is very rare and found in patients with longstanding poorly controlled hyperparathyoidism. I see one possible use of cinacalcet will be in renal transplant patients with ongoing hyperparathyroidism and again background here would be useful. Current treatment should be expanded to include non-calcium phosphate binders.	Background information is usually brief and does not usually cover specific issues in detail. Tendon rupture removed. Cinacalcet will be reviewed within its licensed indications so cannot include renal transplant patients at present. Calcium and non calcium phosphate binders mentioned
The technology/ intervention	Amgen	Although the brand name for cinacalcet HCl is Sensipar in the US, it will be Mimpara in the UK (and Europe)	Changed brand name in scope
	NHS Quality Improvement Scotland	I think so. [In answer to the question "*Is the description of the technology accurate?*"]	No action
	Renal Association	Yes [In answer to the question "*Is the description of the technology accurate?*"]	No action
Population	NHS Quality Improvement Scotland	See comments above. I think the existing studies may mean that the population is limited to those on dialysis.	No action
	Renal Association	Consider 3 groups; predialysis (CKD 3-5); Dialysis CKD 5 and renal transplants (CKD 3 -5)	Will only be able to consider within the licensed indications
Comparators	NHS Quality Improvement Scotland	Yes [In answer to the question "*Is this (are these) the standard treatment(s) currently used in the NHS with which the technology should be compared?*"]	No action

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	Renal Association	There is evidence that the standard treatment will be modified, therefore compared as an addition to treatment will underestimate cost benefit. Especially if Sevelemar HCL is used as the phosphate binder to achieve Renal Association Standards of phosphate control. Other standard management strategies to consider should include earlier parathyroidectomy and daily dialysis.	Discussed at consultee information meeting. Phosphate binders are not direct comparators, any impact on their usage should be taken into account in the economic analysis. If the evidence allows, parathyroidectomy will be included
Outcomes	NHS Quality Improvement Scotland	morbidity - I do not think that "cardiovascular events related to v calcification" are measurable and in any case v calcification is related more to treatment of hyperphosphataemia (eg sevalamer) rather than hyperpara (see above). - the "need for parathyroidectomy" varies from clinician to clinician and is a poor comparator for this reason.	Discussed at the consultee information meeting. Cardiovascular events remain as an outcome, but the scope no longer states that these are related to vascular calcification. Parathyroidectomy as an outcome as well as a comparator was discussed at the scoping workshop.
	Renal Association	The practice of modern nephrology is" Prevention." Fracture rate/tendon rupture are all late events.Cardiovascular disease is related to both Calcium, Phosphate and the Calcium phosphate product.The "standards" for these parameters are set. Achievement of these standards will be important. Outcome should include the need for parathyroidectomy as stated but this is one of the comparators that may be more effective than giving cinacalcet.	Achievement of Renal Association standards added as an outcome.
Economic analysis	Renal Association	It is likely that the time duration will be for life or until the patient receives a renal transplant. It would be useful to obtain background information on the use of sevelemar HCL around the country. The average cost of this drug is around £4.00 per day and it is likely that its use will be significantly reduced when cinacalcet is introduced.	For consideration by assessment group when developing economic model
Other considerations	NHS Quality Improvement Scotland	Bone histology changes should be included as an outcome.	Discussed at scoping workshop. Bone histology is unlikely to be assessed in clinical practice. No action

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	Royal College of Physicians	We are disappointed that the appraisal will not be looking at the indications of inoperable primary hyperparathyroidsim and parathyroid carcinoma but understand that this may be because the manufacturers have not sought a licence for those indications in the UK	Cinacalcet will be licensed for parathyroid carcinoma (see CHMP opinion) but this indication is outside the current remit.
	Renal Association	Comparison should be considered against optimal current treatment . At present treatment varies across the country, numbers of dieticians for example very considerably from unit to unit. It would be useful to consider the implication of these wider issues	No action
Additional comments on the draft scope.	Royal College of Nursing	The Chair of the RCN Nephrology Nursing Forum reviewed the draft scope of the proposed appraisal on behalf of the RCN and is happy with it. We do not have any additional comment to make at this stage.	No action

The following consultees/commentators indicated that they had no comments on the draft remit and/or the draft scope

The Association of Renal Technologists
British Kidney Patients Association
British Thyroid Association
British Thyroid Foundation
National Public Health Service for Wales
Royal College of Pathologists
Royal Pharmaceutical Society of Great Britain
Welsh Assembly Government

Comment 3: provisional matrix of consultees and commentators

Consultees	Suggestion	Action
NHS Quality Improvement Scotland	Professional Group consultees should include the Society for Endocrinology and (for endocrine surgeons) the Royal College of Surgeons.	