

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

GUIDANCE EXECUTIVE (GE)

Consideration of consultation responses on review proposal

Review of TA117; Cinacalcet for the treatment of secondary hyperparathyroidism in patients with end-stage renal disease on maintenance dialysis therapy

This guidance was issued in January 2007. The review date for this guidance was deferred in 2010 until the results of the EVOLVE trial became available.

Background

At the GE meeting of 16 April 2013 it was agreed we would consult on the review plans for this guidance. A four week consultation has been conducted with consultees and commentators and the responses are presented below.

Proposal put to consultees:	TA117 should be transferred to the 'static guidance list'.
Rationale for selecting this proposal	The EVOLVE study did not show significant reductions in cardiovascular endpoints relative to placebo. This implies that recommendation 1.1 does not require review at the present time. With regard to the recommendations in 1.2 and 1.3, these were originally based on the Committee being persuaded that in this extreme situation, where patients are at very high risk of adverse events and have poor quality of life, the incremental cost effectiveness ratio was likely to be reduced to the extent that cinacalcet could be considered a cost-effective use of NHS resources. There was no robust data from a randomised controlled trial in this subgroup and this remains the case. Consequently there is no new evidence that would prompt a review of the guidance at this time.

GE is asked to consider the original proposal in the light of the comments received from consultees and commentators, together with any responses from the appraisal team. It is asked to agree on the final course of action for the review.

Recommendation post consultation:	TA117 should be transferred to the 'static guidance list'
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Respondent	Response to proposal	Details	Comment from Technology Appraisals
Society for Endocrinology	Agree	In view of the EVOLVE data being 'not positive', I think the stance of NICE on this is entirely appropriate in that the guidance remains 'static'.	Response noted.
Royal College of Physicians Renal Association	Agree	Having liaised with the Renal Association, we wish to support the proposal.	Comment noted.
Royal College of Nursing	Agree	The Royal College of Nursing notes the results of the EVOLVE study. We are not aware of any new evidence. In view of this, the RCN supports proposals to move this guidance to the static list. Prior to moving the guidance to the static list, we would like to enquire if there is a comprehensive review of all/any new data regarding Cinacalcet? It would be helpful if this list was made available.	Comment noted. As part of the review of the guidance, the Information Services at NICE updates the evidence base for the technology under review. This usually includes rerunning the search strategy used in the original assessment report, and carrying out a search for current clinical trials that are ongoing where the results may inform the review of the guidance. The new evidence, along with the implications for the review is then summarised in the proposal paper sent to stakeholders.

Respondent	Response to proposal	Details	Comment from Technology Appraisals
Medicines and Healthcare Products Regulatory Agency	No comment	We do not have any comment on the NICE proposal to place this appraisal guidance on its 'static list'.	Comment noted.
Amgen	Agree	Amgen supports NICE's proposed approach to transfer TA 117 to the 'static guidance list'. Amgen is not aware of any evidence which would warrant a review of TA 117.	Comment noted.

No response received from:

<p><u>Patient/carer groups</u></p> <ul style="list-style-type: none"> • Afiya Trust • Black Health Agency • British Kidney Patient Association • Equalities National Council • Independent Age • Kidney Alliance • Kidney Research UK • Muslim Council of Britain • Muslim Health Network • South Asian Health Foundation • Specialised Healthcare Alliance <p><u>Professional groups</u></p>	<p><u>General</u></p> <ul style="list-style-type: none"> • Allied Health Professionals Federation • Board of Community Health Councils in Wales • British National Formulary • Care Quality Commission • Commissioning Support Appraisals Service (CSAS) • Department of Health, Social Services and Public Safety for Northern Ireland • Healthcare Improvement Scotland • National Association of Primary Care • National Pharmacy Association • NHS Alliance • NHS Commercial Medicines Unit • NHS Confederation
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- Association of Anaesthetists of Great Britain and Ireland
- Association of Renal Industries
- Association of Renal Technologists
- Association of Surgeons of GB and Ireland
- British Association for Services to the Elderly (BASE)
- British Association of Endocrine And Thyroid Surgeons
- British Association of Urological Nurses
- British Geriatrics Society
- British Renal Society
- Royal College of Anaesthetists
- Royal College of General Practitioners
- Royal College of Pathologists
- Royal College of Surgeons
- Royal Pharmaceutical Society
- Royal Society of Medicine
- Society of DGH Nephrologists
- The Urology Foundation
- UK Renal Pharmacy Group
- United Kingdom Clinical Pharmacy Association

Others

- Department of Health
- NHS Cumbria CCG
- NHS England
- NHS Redditch & Bromsgrove CCG
- Welsh Government

- Public Health Wales NHS Trust
- Scottish Medicines Consortium
- Welsh Kidney Patients Association

Possible comparator manufacturers

- AbbVie (Paricalcitol)

Relevant research groups

- Cochrane Metabolic and Endocrine Disorders Group
- Cochrane Renal Group
- Health Research Authority
- MRC Clinical Trials Unit
- National Institute for Health Research
- Research Institute for the Care of Older People

Assessment Group

- Assessment Group tbc
- National Institute for Health Research Health Technology Assessment Programme

Associated Guideline Groups

- National Clinical Guidelines Centre
- National Collaborating Centre for Acute and Chronic Conditions

Associated Public Health Groups

- None

GE paper sign-off: Janet Robertson, Associate Director – Technology Appraisals Programme

Contributors to this paper:

Technical Lead: Ahmed Elsada

Project Manager: Andrew Kenyon

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