

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL 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 with a review date of December 2009.

Background

At the GE meeting on 8 December 2009 it was agreed the review plans for this guidance would be deferred until the completion of the EVOLVE trial. A four-week consultation was conducted with consultees and commentators. The responses are presented below.

Proposal put to consultees:	A review of the guidance should be deferred until the completion of the EVOLVE trial. That we consult on the proposal.
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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:	A review of the guidance should be deferred until the completion of the EVOLVE trial.
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Respondent	Response to proposal	Details	Comment from Technology Appraisal
Genzyme Therapeutics (sevelamer)	Agree	<p>We are aware of two ongoing studies of relevance to this guideline:</p> <ul style="list-style-type: none"> • EVOLVE Trial: Evaluation Of Cinacalcet HCl Therapy to Lower CardioVascular Events. • ADVANCE: Study to Evaluate Cinacalcet Plus Low Dose Vitamin D on Vascular Calcification in Subjects with Chronic Kidney Disease Receiving Hemodialysis. <p>We would also highlight the recently published Kidney Disease Improving Global Outcomes (KDIGO) clinical guidelines for the Diagnosis, Evaluation, Prevention, and Treatment of Chronic Kidney Disease-Mineral and Bone Disorder (CKD-MBD) which position cinacalcet for raised PTH.</p>	<p>The EVOLVE trial is ongoing and will complete in November 2010. Once the EVOLVE trial has been completed the results will be considered and the decision to update this guidance revisited in light of those results.</p> <p>The review proposal will incorporate all new evidence that has been generated since the publication of TA117 which will include the ADVANCE study.</p>
Medicines and Healthcare products Regulatory Agency	Agree	The MHRA is not aware of any evidence that impinges on NICE's proposal to postpone the review.	Noted.
Department of Health	Agree	The matrix of consultees and commentators there is a mention of the "National Kidney Confederation". We believe that this should read "National Kidney Federation".	This has been corrected.
NHS Quality Improvement Scotland	No comment	-	Noted.
Royal College of Nursing	Agree	-	
Welsh Assembly Government	No comment	-	Noted.
Society for Endocrinology	Agree	-	

No response received from the following consultees and commentators:

Manufacturers/sponsors

- Amgen (cinacalcet)

Patient/carer groups

- Afiya Trust
- Black Health Agency
- British Kidney Patient Association
- British Thyroid Foundation
- Chinese National Healthy Living Centre
- Counsel and Care
- Equalities National Council
- Kidney Alliance
- Kidney Research UK
- Muslim Council of Great Britain
- Muslim Health Network
- National Kidney Federation
- Polycystic Kidney Disease Charity
- South Asian Health Foundation
- Specialised Healthcare Alliance

Professional groups

- Association of Renal Industries
- Association of Renal Technologists
- British Association for Services to the Elderly (BASE)
- British Association of Urological Nurses
- British Dietetic Association
- British Geriatrics Society
- British Renal Society
- British Thyroid Association
- British Urological Foundation

General

- Board of Community Health Councils in Wales
- British National Formulary
- Commissioning Support Appraisals Service (CSAS)
- Department of Health, Social Services and Public Safety for Northern Ireland
- Medicines and Healthcare products Regulatory Agency
- National Association of Primary Care
- Public Health Wales NHS Trust
- NHS Alliance
- NHS Confederation
- NHS Purchasing and Supply Agency
- Scottish Medicines Consortium
- Welsh Kidney Patients Association

Comparator manufacturers

- 3M (aluminium hydroxide)
- Abbott (calcitriol, paricalcitol)
- LEO Pharma (alfacalcidol)
- ProStrakan (calcium carbonate)
- Roche (calcitriol)
- Shire Pharmaceuticals (calcium carbonate, lanthanum carbonate)
- Vitaline Pharma (calcium acetate)

Relevant research groups

- MRC Clinical Trials Unit
- National Institute for Health Research
- Policy Research Institute on Ageing and Ethnicity
- Research Institute for the Care of Older People

<ul style="list-style-type: none"> • Renal Association • Royal College of General Practitioners • Royal College of Pathologists (kidney, liver, cancer) • Royal College of Physicians • Royal Pharmaceutical Society • Royal Society of Medicine – Intellectual Disabilities Forum • Society for DGH Nephrologists • UK Renal Pharmacy Group • United Kingdom Clinical Pharmacy Association <p><u>Others</u></p> <ul style="list-style-type: none"> • NHS Knowsley • Surrey PCT 	<p><u>Evidence Review Group/ Assessment Group</u></p> <ul style="list-style-type: none"> • National Institute for Health Research Health Technology Assessment • tbc <p><u>Associated Guideline Groups</u></p> <ul style="list-style-type: none"> • National Clinical Guidelines Centre for Acute and Chronic Conditions <p><u>Associated Public Health Groups</u></p> <ul style="list-style-type: none"> • none
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GE paper sign-off:

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