

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

GUIDANCE EXECUTIVE (GE)

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.

Recommendation

- A review of the guidance should be deferred until the completion of the EVOLVE trial. That we consult on the proposal.

Consideration of options for recommendation:

Options	Comment
A review of the guidance should be planned into the appraisal work programme.	There is currently no new evidence to warrant updating the guidance.
The decision to review the guidance should be deferred until results of the EVOLVE trial are available.	There may be new evidence available after the completion of the EVOLVE study. Therefore, the decision to review the guidance should be deferred until the results of the trial are published.
A review of the guidance should be combined with a review of a related technology and conducted at the scheduled time for the review of the related technology.	There is currently no new evidence and therefore it is not an option to combine with a related technology review.
A review of the guidance should be combined with a new appraisal that has recently been referred to the Institute.	There is currently no new evidence and therefore it is not an option to combine with a new appraisal.
A review of the guidance should be incorporated into an on-going clinical guideline.	There is currently no new evidence and therefore it is not an option to incorporate with an on-going guideline.
A review of the guidance should be updated into an on-going clinical guideline.	There is currently no new evidence and therefore it is not an option to incorporate into an on-going guideline.
A review of the guidance should be transferred to the 'static guidance list'.	There may be new evidence available on completion of EVOLVE Study and therefore it is not an option to transfer to the 'static guidance list'.

Original remit

To appraise the clinical and cost effectiveness of cinacalcet hydrochloride for the treatment of secondary hyperparathyroidism in patients with end stage renal disease on maintenance dialysis therapy.

Current guidance

1. Cinacalcet is not recommended for the routine treatment of secondary hyperparathyroidism in patients with end-stage renal disease on maintenance dialysis therapy.

2. Cinacalcet is recommended for the treatment of refractory secondary hyperparathyroidism in patients with end-stage renal disease (including those with calciphylaxis) only in those:

- who have 'very uncontrolled' plasma levels of intact parathyroid hormone (defined as greater than 85 pmol/litre [800 pg/ml]) that are refractory to standard therapy, and a normal or high adjusted serum calcium level, **and**
- in whom surgical parathyroidectomy is contraindicated, in that the risks of surgery are considered to outweigh the benefits.

3. Response to treatment should be monitored regularly and treatment should be continued only if a reduction in the plasma levels of intact parathyroid hormone of 30% or more is seen within 4 months of treatment, including dose escalation as appropriate.

Relevant Institute work

Published

TA48 Renal failure - home versus hospital haemodialysis. December 2004. Placed on the static list.

CG73 Chronic kidney disease. September 2008. Expected review date: September 2011.

In topic selection

Safety information

None

Details of new indications

None

Details of new products

None

On-going trials

<p>EVOLVE</p> <p>EValuation Of Cinacalcet HCl Therapy to Lower CardioVascular Events</p>	<p>Estimated Study Completion Date: November 2010</p> <p>Estimated Primary Completion Date: August 2010 (Final data collection date for primary outcome measure)</p> <p></p> <p>EVOLVE is a global study carried out in approximately 500 sites in 22 countries.</p>
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New evidence

The search strategy from the original assessment report was re-run on the Cochrane Library, Medline, Medline(R) In-Process and Embase. References from 2007 onwards were reviewed.

Implementation

A submission from Implementation is attached at the end of this paper.

Equality and diversity issues

In the UK, there is an increased risk of end-stage renal disease among individuals from ethnic communities (particularly Indo Asians and black people). There is also similar evidence in the U.S., where the incidence rate of end-stage renal disease among African Americans is at least 3.5 times greater than whites, and there are likely to be higher incidences of end-stage renal disease among Mexican Americans and Native Americans than among whites.

There is currently no indication as to whether the EVOLVE study will look at subgroup analysis across different ethnic groups or if the study findings will be used to inform equality and diversity issues.

Appraisals comment and summary:

Cinacalcet is not recommended for the routine treatment of secondary hyperparathyroidism in patients with end-stage renal disease on maintenance dialysis therapy. The evidence available would not lead to a change in the recommendations. Upon completion of the EVOLVE study the results will be considered and the decision to update this guidance revisited in light of those results.

GE paper sign off:

Nina Pinwill, Associate Director, CHTE
15 December 2009

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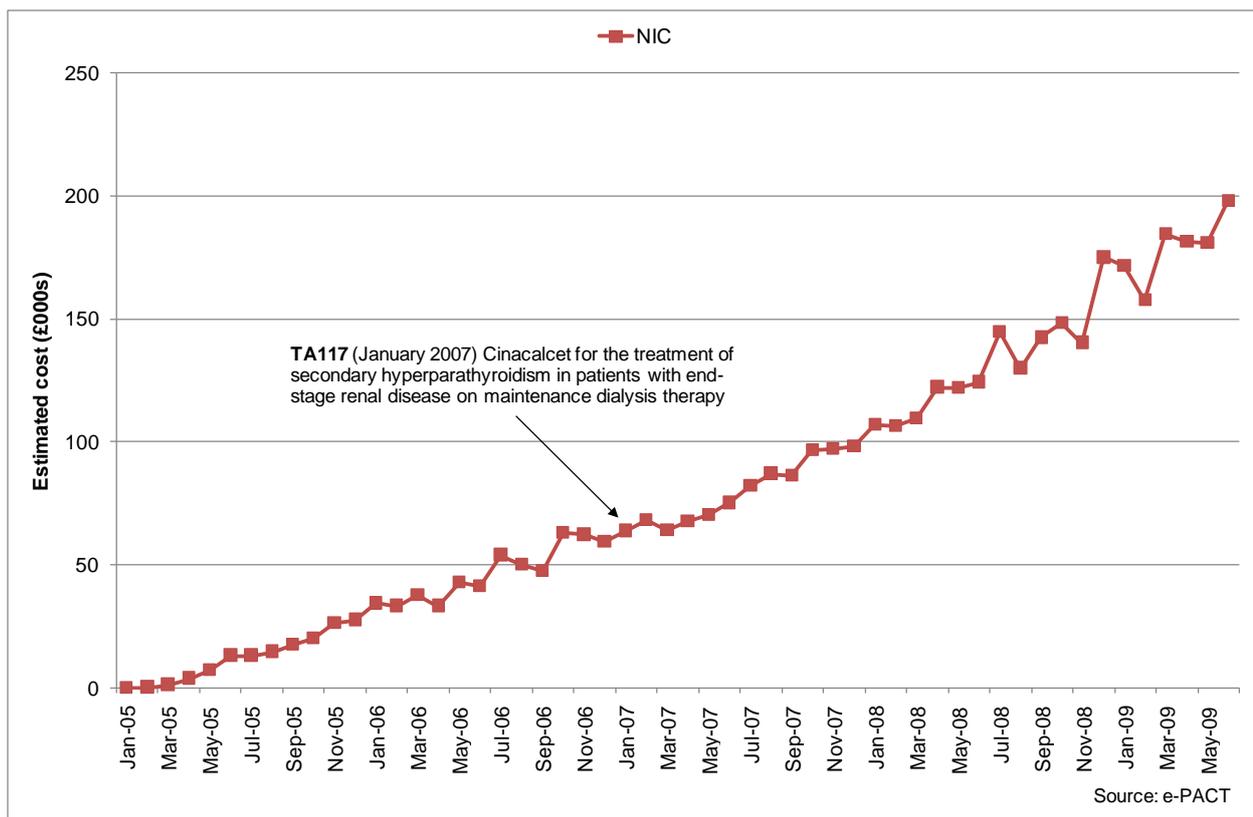
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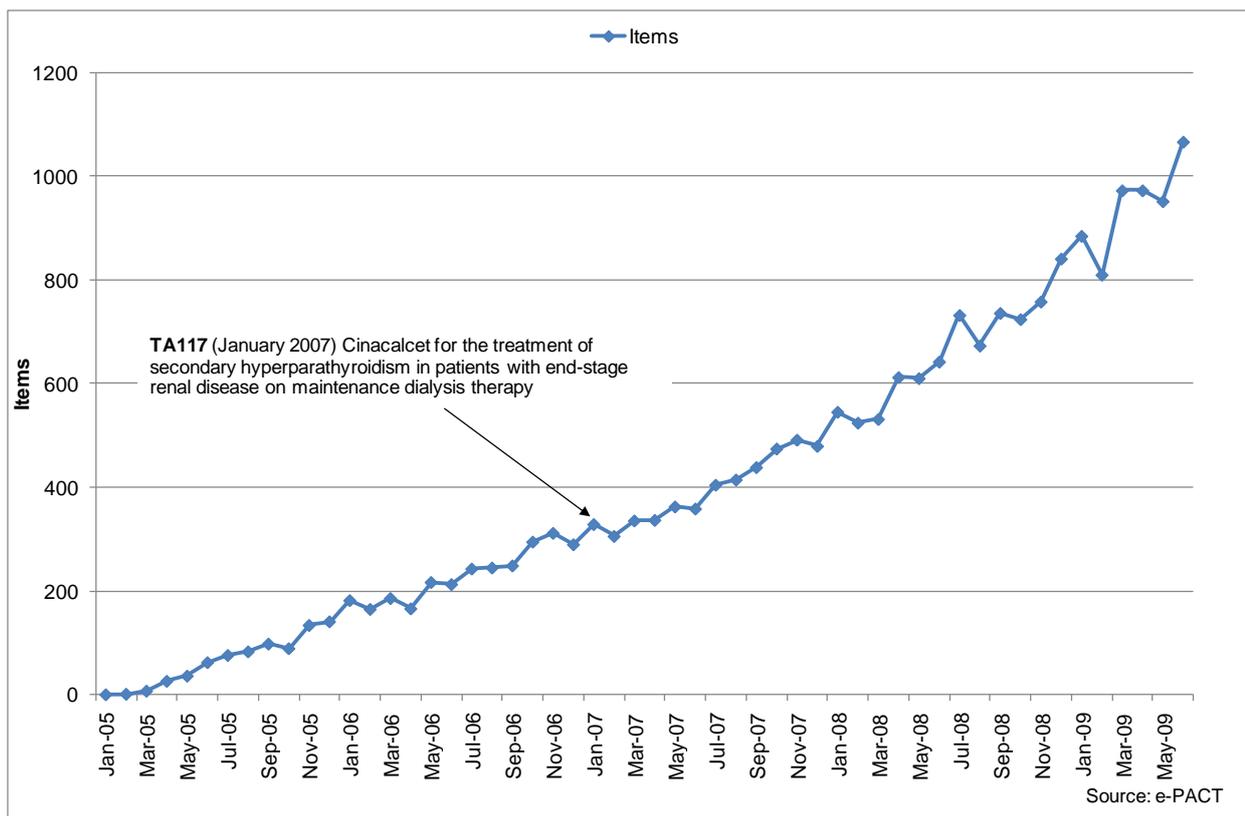
Guidance Executive Review

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

1. National Prescribing Data (primary care)

Data showing trends in prescribing costs and volume are presented below. Unfortunately this data does not link to diagnosis so needs to be treated cautiously in relation to the specific recommendations of the guidance.





2. External literature

A literature search was carried out using the following databases:

- Evaluation and review of NICE implementation evidence (ERNIE)
- Cinahl (EBSCO Host)
- Embase (Ovid)
- HMIC (Search 2)
- Medline (Ovid)
- Medline in Process (Ovid)

The search found no results that linked directly to the uptake of this piece of guidance.