Cost-effectiveness of cinacalcet in secondary hyperparathyroidism in the United States
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Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

CRD summary
This study assessed the cost-effectiveness of cinacalcet plus low-dose vitamin D for the treatment of secondary hyperparathyroidism in dialysis patients. The authors concluded that cinacalcet plus vitamin D treatment was cost-effective. The quality of the study methodology was good, and the methods and results were generally well presented. However, the conclusion that cinacalcet was cost-effective was based on using a willingness-to-pay threshold of $100,000, which some might consider as too high.

Type of economic evaluation
Cost-effectiveness analysis, cost-utility analysis

Study objective
The study assessed the cost-effectiveness of cinacalcet and low-dose vitamin D for the treatment of secondary hyperparathyroidism in dialysis patients.

Interventions
The calcimimetic cinacalcet plus vitamin D was compared with vitamin D alone.

Location/setting
USA/outpatient secondary care.

Methods
Analytical approach:
A patient-level simulation model was developed to estimate the long-term health effects and costs associated with treatment of secondary hyperparathyroidism in dialysis patients. The time horizon of the study was the lifetime of the patient. The authors stated that the US public healthcare system (Medicare) perspective was used.

Effectiveness data:
Clinical and effectiveness estimates came from previously published studies. The main measure of effectiveness was the impact of the interventions on levels of parathyroid hormone, calcium, and phosphorus. These estimates came from a clinical trial (ADVANCE trial, Floege et al. 2010, see Other Publications of Related Interest). The impact of these biomarkers on mortality, cardiovascular events, fractures and parathyroidectomy were estimated from three different published sources: Block model (Block et al. 2004 , see Other Publications of Related Interest), an observational study; Cunningham model (Cunningham et al, 2005, see Other Publications of Related Interest), a combined analysis of four randomised trials of cinacalcet; and Danese model (Danese et al. 2008, see Other Publications of Related Interest), a study investigating the effect of duration in recommended targets.

Monetary benefit and utility valuations:
Utility estimates were obtained from previously published studies.

Measure of benefit:
Quality-adjusted life-years (QALYs) and life-years gained. Future benefits were discounted using an annual rate of 3%.

Cost data:
The direct costs included drug costs, treatment of cardiovascular events, treatment of hospitalised fractures, and
parathyroidectomy procedures. Costs of drugs were obtained from the Centre for Medical Services or average wholesale prices published in the Red Book. Other medical costs were obtained from Medicare data claims, US diagnostic-related group tariffs, published studies, and the Healthcare Cost and Utilization project. The price year was 2009, with costs inflated using the medical component of the US Consumer Price Index. All costs were reported in US$. Future costs were discounted using an annual rate of 3%.

Analysis of uncertainty:
One-way sensitivity analyses were undertaken by varying the values for the model inputs. A probabilistic sensitivity analysis was undertaken by fitting probability distributions to all the model variables. The results were presented in a cost-effectiveness acceptability curve.

Results
The average QALYs gained with cinacalcet plus vitamin D were: 3.82 (Block model), 3.47 (Danese model), and 3.64 (Cunningham model). The average costs for cinacalcet plus vitamin D were: $112,040 (Block model), $99,118 (Danese model), and $82,331 (Cunningham model).

The average QALYs gained using vitamin D alone were: 3.24 (Block model), 3.20 (Danese model), and 3.24 (Cunningham model). The average costs using vitamin D alone were: $80,332 (Block model), $79,685 (Danese model), and $80,332 (Cunningham model).

Costs and benefits were combined using an incremental cost-utility ratio (the additional cost per QALY gained).

When compared with vitamin D alone, cinacalcet plus vitamin D was associated with an incremental cost per QALY of $54,560 (Block model), $72,456 (Danese model), and $5,064 (Cunningham model).

Results of the probabilistic sensitivity analyses showed that the probability that cinacalcet plus vitamin D was cost-effective at a willingness-to-pay threshold of $100,000 per QALY gained was 98% when using the Block and Cunningham models.

Authors’ conclusions
The authors concluded that cinacalcet plus vitamin D treatment was cost-effective for treatment of secondary hyperparathyroidism.

CRD commentary
Interventions:
The interventions under study were reported adequately. The comparator was appropriate as it reflected standard treatment in the authors’ setting.

Effectiveness/benefits:
Clinical and effectiveness data came from previously published studies. The authors did not report how published studies were identified and whether a systematic review of the literature was undertaken. As a result, it was not clear if all the relevant clinical and effectiveness data were considered for inclusion into the model. However, the main measures of effectiveness were obtained from a clinical trial, so it was likely that the main measures used in the model were internally valid.

Costs:
The perspective adopted was explicitly reported to be that of Medicare; it would appear that all relevant major cost categories and costs were included for this perspective. The sources from which costs were derived were adequately reported. The price year, time horizon, discount rate used, inflationary exercises and currency details were all reported.

Analysis and results:
An individual patient simulation model was used to synthesise cost and outcome information. Adequate details of the model structure were provided with a diagram of the model. Uncertainty in the results was adequately tested using one-way and probabilistic sensitivity analyses. As limitation to their study, the authors reported that some of the data assessing the impact of biomarkers on clinical outcomes was obtained from non-randomised evidence.
Concluding remarks:
The quality of the study methodology was good, and the methods and results were generally well presented. However, the conclusion that cinacalcet was cost-effective was based on using a willingness-to-pay threshold of $100,000, which some might consider as too high.

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