Clinical and economic evaluation of exenatide for formulary decisions

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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 evaluated the cost-effectiveness of Byetta (exenatide) in the treatment of patients with Type 2 diabetes mellitus (DM) and determined the potential impact of adding Byetta to the formulary of a hypothetical health plan. The authors concluded that exenatide treatment would not be cost-effective for the majority of individuals with Type 2 DM. Limitations in the study methodology, especially in relation to the data used in the analysis, mean that the authors’ conclusions should be considered with a degree of caution.

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

Study objective
The study evaluated the cost-effectiveness of Byetta (exenatide) in the treatment of patients with Type 2 diabetes mellitus (DM) and determined the potential impact of adding Byetta to the formulary of a hypothetical health plan.

Interventions
The use of Byetta was compared with placebo for the assessment of long-term health outcomes. For the assessment of the budgetary impact, the alternative medications were thiazolidinedione, insulin glargine, and insulin glargine plus a bolus dose of a rapid-acting insulin analogue.

Location/setting
USA/outpatient care.

Methods
Analytical approach:
A published model, the Centre for Outcomes Research (CORE) Diabetes model, was used in the analysis (Palmer et al. 2004, see ‘Other Publications of Related Interest’ for bibliographic details). The CORE model was based on a series of secondary (Markov) models with Monte Carlo simulations. The time horizon of the study was 50 years. The authors also modelled the economic impact of adding exenatide to the health plan formulary over a 5-year period. The perspective of the study was not reported.

Effectiveness data:
The epidemiologic and clinical data used in the study were obtained from clinical studies. The main clinical effectiveness estimates used in the model were life expectancy, changes in glycated haemoglobin A1c (HbA1c) and weight loss, and their impact on morbidity and mortality.

Monetary benefit and utility valuations:
Not reported.

Measure of benefit:
The two summary measures of benefit derived were the quality-adjusted life expectancy (QALEs) and quality-adjusted life-years (QALYs) gained. Future health benefits were discounted at an annual rate of 3%.

Cost data:
The costs included in the analysis were those in the CORE model, as well as the costs of exenatide and alternative drugs. These were obtained from the Drug Topics Red Book (November 2006). Future health costs were discounted at
an annual rate of 3%. The costs were reported in US dollars ($).

Analysis of uncertainty:
A series of one-way sensitivity analyses was performed by varying the discount rate and HbA1C level in the CORE model. A one-way sensitivity analysis was performed on the budget impact model by changing compliance, percentage of patients expected to be on exenatide, the price of exenatide and the prevalence of Type 2 DM.

Results
CORE Diabetes model.
At 5 years, the incremental life expectancy was 0.02 years, the incremental QALE was 0.07 years and the incremental cost was $6,986. The incremental cost-effectiveness ratios (ICERs) were $104,697 per QALY and $359,757 per QALE.

At 50 years, the incremental life expectancy was 0.35 years, the incremental QALE was 0.32 years and the incremental cost was $15,477. The ICERs were $48,921 per QALY and $43,814 per QALE.

The results were sensitive to HbA1C levels and variations in the discount rate.

Budget impact model.
The compliance-adjusted total costs ranged from $655,032 to $2,292,611 from years 1 to 5. These results were sensitive to changes in compliance and to the percentage of individuals expected to be on exenatide.

Authors’ conclusions
The authors concluded that exenatide treatment would not be cost-effective for the majority of individuals with Type 2 DM.

CRD commentary
Interventions:
The interventions were reported clearly but there was no explicit justification for the comparator used (placebo) in the CORE model.

Effectiveness/Benefits:
The authors used a published model for their analysis and provided no details of the methods. The effectiveness data were derived from published studies, but no systematic search of the literature was reported. Although the sources of the literature were given, neither the methods used to identify primary studies nor the inclusion criteria applied were reported. The utility values used in the model and their sources were unclear and there were no details of the methods of utility measurement. It is therefore not possible to assess the validity of these values without recourse to the referenced studies. Consequently, it is not possible to judge whether the best available evidence was used to derive effectiveness.

Costs:
As with the effectiveness data, the authors provided no details of the costing methodology used in the CORE model. Therefore, it is unclear whether all the relevant cost categories and costs were included. The price year was not reported, which will hamper reflation exercises to other time periods.

Results and Analysis:
The authors did not provide a full explanation of the model structure. The results, however, were reported in detail, as were the results of the one-way sensitivity analyses performed. The sensitivity analysis conducted was not very thorough, with only three model parameters being varied. In addition, probabilistic sensitivity analysis is a more thorough way to fully capture parameter uncertainty. Overall, although the authors referred readers to published literature for more details of the methods used, more information should have been reported.
Concluding remarks:
Limitations in the study methodology, especially in relation to the data used in the analysis, mean that the authors’ conclusions should be considered with a degree of caution.

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None stated.

Bibliographic details

Other publications of related interest


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