Cost-effectiveness of omalizumab in adults with severe asthma: results from the Asthma Policy Model

Wu A C, Paltiel A D, Kaniz K M, Weiss S T, Fuhlbrigge A L

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
The objective was to assess the cost-effectiveness of omalizumab for the treatment of moderate-to-severe allergic asthma. The authors concluded that omalizumab was not cost-effective for most patients with severe asthma, unless the price of omalizumab was under $200. The study was generally well conducted and, despite some limited reporting of the economic data, the authors’ conclusions appear to be valid.

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

Study objective
The objective was to assess the cost-effectiveness of omalizumab for the treatment of severe persistent allergic asthma in order to determine whether the high cost of omalizumab might be justified by improved clinical outcomes.

Interventions
The two strategies were omalizumab added to inhaled corticosteroids (ICS) and quick relievers when needed, compared with ICS and quick relievers. Dosing for omalizumab was based on both immunoglobulin E (IgE) level and weight (0.016mg/kg IgE).

Location/setting
USA/primary and secondary care.

Methods
Analytical approach:
This economic evaluation was based on the published Asthma Policy Model, which was a Markov state-transition model simulation of the natural history and treatment of asthma. The time horizon of the analysis was 10 years and the authors stated that the perspective was societal.

Effectiveness data:
The clinical data were derived from a selection of known, relevant studies and the authors’ opinions. The details of the published sources, for some inputs, were given. For example, some data on the treatment effects of omalizumab plus ICS compared with ICS alone came from a published randomised controlled trial (RCT) and a systematic review. The efficacy of the ICS therapy was based on authors’ opinions and on a published study, and it was pointed out that this assumption deliberately favoured omalizumab. The key clinical outcome was the reduction in exacerbation rate and improvement in the forced expiratory volume in one second (FEV$_1$).

Monetary benefit and utility valuations:
The utility valuations were derived from an author’s previous work which elicited patients’ preferences using the time trade-off approach and other preference measures. The relationship between the predicted FEV$_1$ and the preference scores was estimated using ordinary least-squares regression.

Measure of benefit:
Quality-adjusted life-years (QALYs) and symptom-free days (SFDs) were used as the summary benefit measures. QALYs were discounted at an annual rate of 3%.
Cost data:
The analysis included the costs of drugs, office visits, laboratory testing, emergency department visits, and hospitalisations. The cost of omalizumab was based on IgE level and weight. The resource consumption was based on published studies, which were also used to derive the disease-related costs. The wholesale price was used for omalizumab. All costs were in US dollars ($) and the price year was 2005. Future costs were discounted at an annual rate of 3%.

Analysis of uncertainty:
A deterministic univariate sensitivity analysis was used to determine whether the cost-utility ratios were robust to variations in the model inputs, over plausible ranges.

Results
Over a 10-year time horizon, the expected quality-adjusted months were 80.01 with omalizumab plus ICS and 78.33 with ICS alone. The expected costs were $131,000 with omalizumab plus ICS and $16,000 with ICS alone. Thus, the incremental cost per QALY gained with omalizumab was $821,000, and the incremental cost per SFD gained was $120.

In patients with more severe asthma, defined as a baseline acute event rate of five times the base-case rate, the incremental cost per QALY was $491,000.

The sensitivity analysis identified the monthly cost of omalizumab and the improvement in quality of life as the most influential model inputs. The most interesting finding was that only at a drug price of less than $200 per month (the price was $1,300 in the base-case), did the incremental cost per QALY gained fall below the threshold of $100,000 per QALY.

Authors' conclusions
The authors concluded that omalizumab was not cost-effective for most patients with severe asthma, unless the price of omalizumab was under $200.

CRD commentary
Interventions:
The rationale for the selection of ICS as the comparator was appropriate because it represented the usual strategy for the management of patients with severe asthma.

Effectiveness/benefits:
The clinical estimates were selected from published sources, which were presumably chosen as the most appropriate evidence for the model. The design of some of these sources (RCTs and meta-analyses) should ensure the validity of the clinical inputs. The authors' assumptions were based on other published evidence and were justified. Given the uncertainty underlying some of these inputs, they were varied in the sensitivity analyses. The authors described the method used to derive patients' preferences for asthma-related conditions. They demonstrated that the values they used were consistent with those reported in published studies. QALYs are a validated and generalisable benefit measure.

Costs:
Although the authors stated that the perspective was societal, the categories of costs appear to reflect the perspective of the health care system. The costs and quantities were derived from published sources, the details of which were not given, except for drug consumption patterns. This lack of detail reduces the transparency of the economic analysis and limits its ability to be transferred to other settings. The cost results were broken down into key cost categories. The price year and the use of discounting were reported and the economic data were treated deterministically. Variations in the cost estimates were investigated in the sensitivity analyses.

Analysis and results:
The costs and benefits were appropriately synthesised. The issue of uncertainty was addressed using a deterministic approach, which focused on individual model inputs. This approach may appear to be weak (especially in comparison with a more comprehensive multivariate methodology), but it is effective in determining whether the base-case findings are robust. The authors noted some limitations of their analysis relating to the use of modelling and the choice of the
FEV\textsubscript{1} as a clinical outcome.

**Concluding remarks:**
The study was generally well conducted and, despite some limited reporting of the economic data, the authors’ conclusions appear to be valid.

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