Cost effectiveness of lacosamide in the adjunctive treatment of patients with refractory focal epilepsy in Belgium

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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
The objective was to examine the cost-effectiveness of lacosamide, added to standard anti-epileptic drug therapy, for patients with refractory focal epilepsy. The authors concluded that the addition of lacosamide appeared to be cost-effective, for patients with difficult-to-treat epilepsy, in Belgium. The methods were good and the presentation was satisfactory. The authors’ conclusions appear to be appropriate.

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

Study objective
The objective was to examine the cost-effectiveness of lacosamide, added to standard anti-epileptic drug therapy, for patients with refractory focal epilepsy.

Interventions
Lacosamide 300mg once daily, plus standard anti-epileptic medication, was compared with standard anti-epileptic drugs alone. Treatment was given for up to two years.

Location/setting
Belgium/out-patient care.

Methods
Analytical approach:
A decision analytic model was used to compare the cost-effectiveness of the two treatments, in a hypothetical cohort of 1,000 patients. The time horizon was two years. The authors stated that the perspective of the third-party payer was adopted.

Effectiveness data:
The estimates of treatment effectiveness were from two pivotal multicentre, randomised controlled trials of lacosamide versus placebo. The primary outcome was the proportion of patients with a reduction in seizure frequency, of at least 50%, compared with baseline seizure frequency. Adverse events were not included due to their low incidence with anti-epileptic drugs.

Monetary benefit and utility valuations:
The utility values were from an Italian study, which used the time trade-off technique to elicit utility values, from 81 patients with diagnosed uncontrolled epilepsy.

Measure of benefit:
The number of seizures avoided and quality-adjusted life-years (QALYs) were the summary benefit measures. Future QALYs were discounted at an annual rate of 1.5%.

Cost data:
The economic analysis considered the costs of drugs, practice nurse, general practitioner and out-patient department visits, in-patient and emergency department admissions, electroencephalograms, and laboratory tests.
was the opinions of experienced neurologists in Belgium, collected using the Delphi panel technique. The costs were from Belgian national sources. They were in Euros (EUR) and discounted at an annual rate of 3%. The price year was 2008.

Analysis of uncertainty:
A deterministic univariate sensitivity analysis was undertaken on the key model inputs. These inputs were varied by ±10%, ±20% or ±30% from their initial values. A probabilistic sensitivity analysis, based on 1,000 Monte Carlo simulations, was performed. The types of probabilistic distribution were described. The results were displayed in a tornado diagram, and an incremental cost-effectiveness scatter plot.

Results
Over 24 months, the number of seizures was 112.7 with lacosamide plus anti-epileptic drug therapy and 119.6 with drug therapy alone. The QALYs were 1.240 with lacosamide and 1.202 without. The total costs were EUR 76,941 with lacosamide and EUR 80,560 without.

The addition of lacosamide was found to be dominant over anti-epileptic drug therapy alone, as it was more effective and less costly.

The sensitivity analysis indicated that lacosamide was 100% cost-effective, at two years, at a willingness-to-pay threshold of EUR 30,000 per QALY gained.

Authors' conclusions
The authors concluded that the addition of lacosamide appeared to be cost-effective, for patients with difficult-to-treat epilepsy, in Belgium.

CRD commentary
Interventions:
The selection of the comparators was appropriate. The efficacy and safety of lacosamide for epilepsy had been demonstrated in clinical trials. The standard care was included.

Effectiveness/benefits:
The authors did not report a systematic literature review to identify the primary sources for the clinical data. Treatment efficacy was from randomised controlled trials, which are generally considered to be valid sources. They did report a systematic review for the utility values, and they justified their choice of the data from one study, but the details of the review were not reported. QALYs are a validated benefit measure, and they are comparable with the benefits of other health care interventions. They overcome the difficulties associated with a disease-specific measure, such as the number of seizures avoided.

Costs:
The categories of costs were consistent with the authors' stated perspective. The sources for these costs and the resources quantities were reported clearly. These sources reflected the Belgian health care system. The unit costs were presented for all items, but the reporting of the quantities of resources was limited. Discounting was appropriate, and the price year was stated, allowing reflation exercises.

Analysis and results:
The costs and benefits were appropriately synthesised. The incremental cost-effectiveness ratio was not necessary, as one strategy dominated the other. The uncertainty was satisfactorily addressed in deterministic and probabilistic sensitivity analyses. The methods and results of the main analysis and the sensitivity analyses were clearly presented. In their discussion, the authors highlighted the limitations of their study, including the fact that their results might not account for factors, such as patient adherence to therapy, and the reliance on expert opinion for resource use estimates.

Concluding remarks:
The methods were good and the presentation was satisfactory. The authors' conclusions appear to be appropriate.
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