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Original Article

# Projected economic impact of clinical findings of generic entry of topiramate on G4 European countries

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## ABSTRACT

**Objectives:** To explore the effects of generic substitution of the antiepileptic drug (AED) topiramate (Topamax in Canada; to convert observed Canadian costs into the settings of France, Germany, Italy, and the United Kingdom (UK); and to forecast the economic impact of generic topiramate entry in these four European countries.

† Topamax is a registered trade name of Ortho-McNeil Neurologics, Inc., Titusville, NJ, USA

**Research design and methods:** Health claims from Régie de l'assurance maladie du Québec (RAMQ) plan (1/2006–9/2008) and IMS Health data (1998–2008) were used.

Patients with epilepsy and  $\geq 2$  topiramate dispensings were selected. An open-cohort design was used to classify observation into mutually-exclusive periods of branded versus generic use of topiramate. Canadian healthcare utilization and costs (2007 CAN\$/person-year) were compared between periods using multivariate models. Annualized per-patient costs (2007€ or 2007£/person-year) were converted using Canadian utilization rates, European prices and service-use ratios. Non-parametric bootstrap served to assess statistical significance of cost differences. Topiramate market was forecasted following generic entry (09/2009–09/2010) using autoregressive models based on the European experience. The economic impact of generic topiramate entry was estimated for each country.

Results: A total of 1164 patients (mean age: 39.8 years, 61.7% female) were observed for 2.6 years on average. After covariates adjustment, generic-use periods were associated with increased pharmacy dispensings (other AEDs: +0.95/person-year, non-AEDs: +12.28/person-year,  $p < 0.001$ ), hospitalizations (+ 0.08/person-year,  $p = 0.015$ ), and lengths of hospital stays (+0.51 days/person-year,  $p < 0.001$ ). Adjusted costs, excluding topiramate, were CAN\$1060/person-year higher during generic use ( $p = 0.005$ ). Converted per-patient costs excluding topiramate were significantly higher for generic relative to brand periods in all European countries (adjusted cost differences per person-year: €706–815,  $p < 0.001$  for all comparisons). System-wide costs would increase from 3.5 to 24.4% one year after generic entry.

Limitations: Study limitations include the absence of indirect costs, possible claim inaccuracies, and IMS data limitations.

Conclusions: Higher health costs were projected for G4 European countries from the Canadian experience following the generic entry of topiramate.

Key words: :

Antiepileptic drugs

Budget impact

Cost conversion

Generic substitution

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Transparency

Declaration of funding

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## Declaration of financial/other relationships

M.G. has disclosed that she is an employee of Janssen-Cilag EMEA. All other co-authors disclosed that they are employees of Analysis Group, Inc., which has received research grants to conduct this study from Janssen-Cilag EMEA.

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## Notes

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