ODPRN ONTARIO DRUG POLICY RESEARCH NETWORK

Comprehensive Research Plan:

Atypical Antipsychotic Use for the Behavioural and Psychological Symptoms of Dementia in the Elderly

Pharmacoeconomic Unit

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Research Questions

RQ1. What is the current evidence for the cost-effectiveness of atypical antipsychotics versus typical antipsychotics and antidepressants in the management of behavioural and psychological symptoms of dementia in the elderly?

RQ2. Based on a de novo economic model, what is the cost-effectiveness of atypical antipsychotics versus typical antipsychotics and antidepressants in the management of behavioural and psychological symptoms of dementia in the elderly?

RQ3. What is the economic impact of alternative policies for reimbursing atypical antipsychotics versus typical antipsychotics and antidepressants in the management of behavioural and psychological symptoms of dementia in the elderly?

Methods

Systematic Review of Published Economic Evaluations

To address RQ1 we will conduct a systematic review of the available literature on the cost-effectiveness of atypical antipsychotics versus typical antipsychotics and antidepressants in the management of behavioural and psychological symptoms of dementia in the elderly.

A search of the medical literature will be conducted in Medline (indexed, in-process and other non-indexed from 1948 to present), Embase, NHS EED and Tufts CEA registry in order to capture all relevant literature based on the NHS EED recommended search strategy. A standard search strategy for identification of economic studies will be linked to the clinical search terms adopted by the clinical review. In addition, the reference lists of retrieved studies will be hand searched.

Two reviewers will first review the abstracts of studies identified by the initial literature search literature searches in order to identify potential articles for inclusion within the critical appraisal. Any disagreements will be resolved through consensus with erring on the side of caution through inclusion.

Extracted studies will then be further reviewed with studies excluded for lack of context or for not being full economic evaluations.

The critical review will identify common methodological issues within studies. Each study will be assessed through a three step process: initial assessment for validity, assessment of study quality, assessment of study's pertinence to the decision question.

Focus will be on the strength and quality of evidence addressing the cost-effectiveness of atypical antipsychotics versus typical antipsychotics and antidepressants in the management of behavioural and psychological symptoms of dementia in the elderly.

De novo Economic Evaluation

We will develop a de novo economic model to assess the cost effectiveness of alternative reimbursement strategies for atypical antipsychotics in the management of behavioural and psychological symptoms of dementia in the elderly. The economic model will build on previous analyses. We will construct a Markov model which will model disease progression. Natural history data relating to disease progression will be combined with treatment effectiveness and adverse event data from the clinical review conducted as part of this class review. Costs and utilities associated with disease severity will be derived from the literature. Analysis will be conducted from the perspective of the Ministry of Health with results presented as incremental cost per quality adjusted life years gained. Detailed deterministic sensitivity analysis will be conducted along with Monte Carlo simulation methods to determine decision uncertainty.

Reimbursement Based Economic Assessment

The focus for this component of the proposal is to develop an applied, policy-oriented economic model which will help facilitate the reimbursement decision. Focus will be on identifying the optimal reimbursement criteria through considering both budget impact and clinical effectiveness as criteria with a focus on reimbursement scenarios not just interventions. Analysis will identify the budget impact of alternative approaches to the current reimbursement status of atypical antipsychotics. This will be achieved through a three stage process.

1. Forecasting of current expenditure for atypical antipsychotics, typical antipsychotics and antidepressants.

   We will obtain data on current usage of drug treatments in the management of behavioural and psychological symptoms of dementia in the elderly to allow identification of the number of claims, number of claimants, total costs and drug unit costs in a given year (broken down quarterly).

2. Identification of candidate reimbursement scenarios

   The second stage will involve identifying alternative approaches to reimbursement of combination therapies. This will rely heavily on strategies identified during the scoping assessment along with further consultation with OPDP. Strategies could include coverage of therapies either as general benefit or more restricted access. Strategies could be general – applied to all products– or specific – targeted at specific products.

3. Assessment of budget impact of candidate scenarios

   Using the techniques adopted in step 1 we will forecast the budget expenditure for each alternative reimbursement scenario.

   Results will be presented in terms of budget impact and cost effectiveness using the de novo economic model.

Deliverables

We will provide a written report detailing methods adopted, results, discussion and summary policy recommendations. The report will comprise a two page executive summary followed by a detailed technical report.

Timelines

On acceptance of this proposal, work will commence. The review of economic evaluations will be completed within 6 weeks of the commencement. The de novo economic model will be developed and populated within 12 weeks of commencement. The forecasting of drug expenditures will be completed within 12 weeks of commencement. Both of these components are timed to coincide with the completion of the clinical review. The reimbursement based economic modeling will be completed between 12 and 16 weeks to allow delivery of an aligned final report at 16 weeks. Any reanalyses and a revised final report will be available 4 weeks after receipt of stakeholder reviews.