ODPRN Drug Class Review:

Triptans for the treatment of migraines in adults

Detailed Pharmacoeconomic Proposal

Research Questions

RQ1.   What is the current evidence for the cost-effectiveness of triptans (alone or in combination with other drugs) for acute treatment of migraines compared to: other triptans, acetaminophen, antiemetics, acetylsalicylic acid (ASA) and ergots?

RQ2.   What is the economic impact of alternatives reimbursement statuses for triptans (e.g. restricted vs. more open access)?

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 triptans (alone or in combination with other drugs) for acute treatment of migraines compared to: other triptans, acetaminophen, antiemetics, acetylsalicylic acid (ASA) and ergots.

A search of the medical literature will be conducted 1948 to present in Medline (indexed, in-process and other non-indexed), Embase, Cochrane database, NHS EED and Tufts CEA registry will be conducted in order to capture all relevant literature based on the NHS EED recommended search strategy. Key economic search words will include, "economics", "costs", "cost", "costly", "price", "pricing", "pharmacoeconomics", "expenditure", "value", "budget". These 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

triptans (alone or in combination with other drugs) for acute treatment of migraines compared to: other triptans, acetaminophen, antiemetics, acetylsalicylic acid (ASA) and ergots.

De novo Economic Evaluation

Given the nature of the decision question and the consistent cost of triptans, there is no requirement for a traditional economic evaluation to assess the value for money for each of the candidate treatments. Evidence on differential clinical effectiveness will be sufficient to consider selective reimbursement strategies within the reimbursement based economic assessment.

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 strategies not just interventions. Analysis will identify the budget impact of alternative approaches to the current reimbursement status of triptans. This will be achieved through a three stage process.

1. Forecasting of triptan expenditure for the next three years

    We will obtain data on current usage of triptans from OPDP to allow identification of the number of claims, number of claimants, total costs and drug unit costs in a given year (broken down monthly) as well as data on claims per claimant. We will first standardize drug costs to the current year drug costs.

    We will use time series analyses to forecast the drug costs for the next three years adopting three approaches: simple linear interpolation (naïve approach), linear regression and polynomial regression. For regression methods we will include the number of triptans available on the formulary as a potential independent variable to assess the impact of market expansion.

    Similar analyses will be conducted for alternative therapies such as ergots.

2. Identification of candidate reimbursement strategies

    The second stage will involve identifying alternative approaches to reimbursement of triptans. This will rely heavily on strategies identified during the scoping assessment along with further consultation with OPDP. Strategies could include more open access through

general benefit and quantity caps. Strategies could be general – applied to all triptans (either currently covered only or all regardless of current coverage) – or specific – targeted at specific triptans.

3. Assessment of budget impact of candidate strategies

Using the techniques adopted in step 1 we will forecast the budget expenditure on triptans and ergots for each alternative reimbursement strategy. Three data sources will assist in this process: findings from the qualitative review, EAP information relating to triptans and historical evidence of market growth associated with opening access to a drug class.

The qualitative review will inform the likely market growth for triptans by focussing on qualitative evidence regarding access to triptans.

Data on EAP requests for triptans can similarly inform potential market growth. This will include the number of EAP request by triptan, the proportion of requests that are successful, the proportion of requests that are unsuccessful and the use opf ergots by those who were unsuccessful in their request,

Historical evidence of market growth associated with opening access to a drug class will allow evidence on the likely hemorrhaging of the market for other alternative therapies – i.e.ergots. This requires the willingness of OPDP to provide any data relating to similar reimbursement scenarios. Such analyses will facilitate further analyses pertinent to other drug classes.

Results will be presented in terms of budget impact as well as incorporating a discussion on the impact on clinical effectiveness.

Deliverables

We will provide a written report detaining methods adopted, results, discussion and summary policy recommendations. The report will comprise a two page executive summary followed by a detailed technical report. In addition, we will provide a fully executable excel based reimbursement economic model.

Timelines

On acceptance of this proposal, work will commence. The review of economic evaluations will be completed within 6 weeks of the commencement. The forecasting of triptan expenditures will be completed within 12 weeks of commencement to coincide with the completion of the clinical review. The reimbursement based economic modelling will be completed between 12 and 16 weeks to allow delivery of an aligned final report at 16 weeks, once information on the relative clinical effectiveness of triptans are available. Any reanalyses and a revised final report will be available 4 weeks after receipt of stakeholder reviews.