

ODPRN Comprehensive Research Plan: Testosterone Replacement Therapy

Pharmacoeconomic Unit

April 29, 2014

Summary Pharmacoeconomic Proposal

Research Questions

- RQ1. What is the current evidence for the cost-effectiveness of testosterone replacement therapy in all clinical areas where it is indicated?
- RQ2. What is the economic impact of alternative policies for reimbursing testosterone replacement therapies?

Methods

RQ1 Systematic Review of Published Economic Evaluations

We will conduct a review of the available literature on the cost-effectiveness of testosterone replacement therapy in all clinical areas where it is indicated.

RQ2 Reimbursement Based Economic Assessment

We will develop a model which will identify the optimal policy relating to reimbursing testosterone replacement therapies. Analysis will identify the change in the forecasted drug budget for the next three years associated with different reimbursement policies and will be discussed in conjunction with any impact on clinical effectiveness.

Deliverables

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

Detailed Pharmacoeconomic Proposal

Research Questions

- RQ1. What is the current evidence for the cost-effectiveness of testosterone replacement therapy in all clinical areas where it is indicated?
- RQ2. What is the economic impact of alternative policies for reimbursing testosterone replacement therapies?

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 testosterone replacement therapy in all clinical areas where it is indicated.

A search of the medical literature from 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. 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 testosterone replacement therapy in all clinical areas where it is indicated.

De novo Economic Evaluation

Given the broad nature of the decision question, a traditional economic evaluation to assess the value for money for testosterone replacement therapy in all clinical areas where it is indicated is not feasible.

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 testosterone replacement therapy. This will be achieved through a three stage process.

1. Forecasting of testosterone replacement therapy expenditure for the next three years

We will obtain data on current usage of testosterone replacement therapy 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 testosterone replacement therapies available on the formulary as a potential independent variable to assess the impact of market expansion.

2. Identification of candidate reimbursement strategies

The second stage will involve identifying alternative approaches to reimbursement of testosterone replacement therapy. 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 testosterone replacement therapies (either currently covered only or all regardless of current coverage) – or specific – targeted at specific testosterone replacement therapies.

3. Assessment of budget impact of candidate strategies

Using the techniques adopted in step 1, we will forecast the budget expenditure on testosterone replacement therapies for each alternative reimbursement strategy.

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 detailing methods adopted, results, discussion and summary policy recommendations. The report will comprise of a two page executive summary followed by a detailed technical report. In addition, we will provide a fully executable excel based reimbursement economic model for the Ministry of Health should they require it. This should not however, be shared with industry representatives.

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 testosterone replacement therapy expenditures will be completed within 12 weeks of commencement to coincide with the completion of the clinical review. The reimbursement based economic assessment 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 testosterone replacement therapies are available. Any reanalyses and a revised final report will be available 4 weeks after receipt of stakeholder reviews.