**THE IMPACT OF HEALTHCARE POLICY BASED ON DRUG PLAN PERSPECTIVE VERSUS THE MINISTRY OF HEALTH PERSPECTIVE: A CASE STUDY OF THE ODPRN RECOMMENDATIONS OF RestrictING REIMBURSEMENT OF TESTOSTERONE REPLACEMENT THERAPY FOR HYPOGONADISM IN ONTARIO, CANADA**

**ABSTRACT**

OBJECTIVES: The Ontario Drug Policy Research Network (ODPRN) published recommendations to restrict reimbursement and coverage criteria of testosterone replacement therapy (TRT) in Ontario to the Exceptional Access Program (EAP). The ODPRN’s budget impact analysis (BIA) evaluated the following 4 reimbursement scenarios: no reimbursement change (option A), restricting coverage of all forms of TRT to the EAP (option B), restricting oral and topical forms only (option C), or restricting topical forms only (option D). The analysis assumed exponential growth of TRT expenditures and inappropriate use in 76.4% of patients and took into consideration drug prescription costs alone, resulting in forecasted savings ranging from $7.16 million over a 3-year period. JSS Medical Research performed the BIA from the Ministry of Health perspective.

METHODS: Our hybrid epidemiological and claims-based BIA considered both the costs of TRT and key cost drivers associated with reimbursement and utilization. The study assumed a hybrid model of top-down and bottom-up approach for drug expenditures based on claims data, as well as published literature and expert opinion. TRT utilization was assessed using ODPRN scenarios with and without inappropriate use TRT use over a 3-year period.

RESULTS: Based on the JSS assumption that all patients currently qualify for TRT and taking into consideration key cost drivers, option B would cost $1.01 million; option C, $766,000; and option D $525,000. A sensitivity analysis was undertaken under various assumptions of inappropriate use, in which JSS Medical Research forecasted savings of $573,000-$13.4 million as opposed to savings of $7.16 million forecasted by the ODPRN. CONCLUSIONS: ODPRN savings exclude key cost drivers and assume a greater magnitude of inappropriate use. The burden of the policy change could completely offset savings and generate costs of up to $1 million to the healthcare budget. Healthcare policy recommendations based on drug costs alone understate the true cost to the Ministry of Health, shifting, and in this case creating additional costs to other areas of the healthcare system.

**BACKGROUND**

• Hypogonadism is a clinical and biochemical syndrome resulting in testosterone deficiency (TD).

• Guidelines recommend offering testosterone replacement therapy (TRT) to patients with hypogonadism in order to achieve and maintain serum T levels between 10.4 and 17.5 mmol/L.

• Currently, available formulations of TRT in Canada include injectable, oral and topical agents. Each formulation represents a unique risk profile.

• Recently, the Ontario Drug Policy Research Network (ODPRN) released recommendations to limit TRT reimbursement to the Exceptional Access Program (EAP), and has suggested changing in coverage inuitus policy criteria requiring documented TD diagnosis, as well as two confirmitory low serum testosterone tests. This was performed to control access to TRT over the past year.

• The ODPRN conducted a budget impact analysis (BIA) to evaluate the proposed change in TRT coverage criteria. However, the BIA did not assess the cost of changing current TRT drug utilization, laboratory testing, physician visits and EAP evaluation and processing. These elements would be important by the policy.

**OBJECTIVES**

As to perform a BIA encompassing all costs to the Ministry of Health that are associated with coverage inclusion criteria change, for each reimbursement option:

- Guide decision-makers on the proposed changes to the TRT reimbursement policy, and its impact on the healthcare system.

**METHODS**

• A hybrid epidemiological and claims-based approach was used to forecast the proportion of patients with testosterone deficiency (TD) in Ontario. (Table 1)

• The BIA included costs of TRTs and the key cost drivers of physician visits, administering injectable TRT, testosterone level testing and EAP evaluation and processing. TRT drug costs consisted of average year expenditures claimed (IMS Health data).

• JSS Medical Research conducted the ODPRN scenarios with and without inappropriate use TRT use over a 3-year period. Option A assumed the status quo where no change was applied to the current coverage criteria while option B restricted all forms of TRT to the EAP, option C restricted oral and topical forms of TRT only, and option D restricted topical forms of TRT only. Due to unsubstantiated evidence of inappropriate use, the base case analysis relied on expert opinion, and assumed all users of TRT would qualify. The sensitivity analysis replicated the ODPRN assumptions of inappropriate use, terminating coverage of 46%, 15% and 7% of patients in options B, C, and D, respectively.

• Historical claims made by Ontario beneficiaries during 2008-2014 were used to forecast market growth. (Figure 1)

**RESULTS**

- Option A represented the status-quo and evaluated the costs of no change to current coverage criteria. Expenditures to the Ministry of Health were forecasted at $9.9 million, $10.2 million and $10.5 million in 2016, 2017 and 2018, respectively.

- When compared to the current forecast (option A – Table 2), option B results in incremental costs to the Ministry of Health of $7.16 million over 3 years. (Table 3)

**CONCLUSIONS**

- The results of this analysis suggest that the reimbursement restriction proposed by the ODPRN would generate additional costs to other areas of the healthcare system.

- The burden of the policy change could completely offset savings and generate costs of up to $1 million to the healthcare budget.

- No chart review or formal assessment was conducted to demonstrate or quantify inappropriate use of TRT, therefore the conclusion of cost savings forecasted by the ODPRN is open to caution.

- Healthcare policy recommendations based on drug costs alone underestimate the true cost of the Ministry of Health.

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