ODPRN ONTARIO DRUG POLICY RESEARCH NETWORK

Drug Class Review:

Testosterone Replacement Therapy

Responses to Comments on Comprehensive Research Plan

June 6, 2014

30 Bond Street, Toronto ON, M5B 1W8 www.odprn.ca info@odprn.ca

Patient and Healthcare Professional Perspective - Qualitative Study

Comment: When determining the feasibility and acceptability of recommendations, how will human resources/capacity concerns be considered when determining the acceptability of a LU recommendation versus EAP?

Response: The human resources/capacity concerns will primarily be considered from a cost perspective - even if this is not formally considered in the cost analysis, it will likely come up as a point of discussion in the Citizen's Panel meeting and open-ended questions of the surveys. For example, in our last DCR, the Citizen's Panel and stakeholders that completed the social acceptability surveys discussed and considered physician time required to apply to EAP, Ministry time to process applications, etc. as considerations in the overall "cost" of a policy option.

Systematic Literature Review and Network Meta-Analyses – Systematic Review Unit

Comment: Number and/or level of comorbidities may impact efficacy and safety. Suggest to include comorbidities as a planned subgroup.

Response: We have added comorbidities to RQ2 (Does the efficiacy or safety of testosterone replacement therapy depend on: age, duration, dose, comorbidity.

Comment: How is androgen deficiency being defined? Androgen deficiency can be determined by a diagnosis of hypogonadism (hypothalamic, pituitary, or testicular disorder or age-related or idiopathic hypogonadism) by their physicians.

Response: Androgen deficiency is being defined as either diagnosed hypogonadism (low testosterone level plus sign/symptoms) or low testosterone level alone. This should capture both diagnosed androgen deficiency syndrome and age-related testosterone decline.

Comment: Suggest to include change in prostate-specific antigen (PSA) levels as a safety outcome. PSA levels are commonly reported as adverse events in TRT trials.

Response: Although we had previously discussed adding PSA levels to the safety outcomes, a decision was made to focus on hard outcomes and to avoid using lab readings (except for testosterone readings).

Pharmacoepidemiology Unit

Comment: Patient level data can be requested from RAMQ. Suggest to include Quebec data where topical preparations have general benefit listings. Inclusion of Quebec data will also increase sample size for the planned analyses.

Response: Unfortunately, given time constraints, accessing a new source of data will not be feasible for this review. However - we will be capturing overall prescription volumes of testosterone products through IMS for Quebec, and will stratify this by payer (public/private). This will give us an estimate as to whether broader coverage of topical formulations in Quebec has impacted overall TRT rates in that province. We may also have the ability to stratify this analysis by formulation, which would allow us to conduct an analysis that estimated overall prescribing rates of topical formulations reimbursed by public drug programs among each province in Canada. We will investigate this possibility and will include in the final report if feasible.

Reimbursement-based Economics – Pharmacoeconomics Program

Comment: Does the ODPRN plan on conducting an economic evaluation for a specific clinical area if no information is obtained from the literature?
Response: No – there are no plans to create de-novo economic evaluation

Comment: How will new product entrants be considered in the economic model/budget impacts?
Response: We will model the increase in TRT prescribing based on new entrants to the market. Therefore, we can assess the potential expansion of budget through coverage of further products. As we are not doing a de novo economic evaluation, we will not be assessing the cost effectiveness of new products – we will include however any published literature relating to these products.