

# ODPRN Comprehensive Research Plan: Testosterone Replacement Therapy

Environmental Scan

April 29, 2014

## ODPRN Drug Class Review Proposal: Environmental Scan

### Study Title: Testosterone Replacement Therapies (TRT)

- Objectives:**
1. To summarize the pharmacy benefit programs for TRT in Ontario, across Canada and in select international jurisdictions
  2. To determine the impact of different drug reimbursement schemes for TRT (e.g., restricted access) on patient access, patient satisfaction, quality of life and/or utilization and costs
  3. To summarize the guidelines for management of hypogonadism, in particular the role of testosterone replacement therapies

- Study Questions:** In patients with hypogonadism:
1. How are testosterone replacement therapies currently being accessed in publicly funded programs across Canada as well as internationally?
  2. What is the impact of different drug reimbursement schemes for TRT (e.g., restricted access) on patient access, patient satisfaction, quality of life and/or utilization and costs?
  3. Does sex, gender or socioeconomic status play an important role in any of the analyses described?

### Objective 1: Pharmacy Benefit Programs in Ontario, across Canada and internationally

**Study Design:** Design: summary of available information available through the Internet; interviews with individuals at the government agencies responsible for the public drug plan  
Data sources: Internet, direct contact with individuals

- Study Population:**
- Canada: provincial/territorial public plans
  - England, Wales, Northern Ireland, Scotland: NICE (National Institute for Health and Care Excellence)
  - Australia: Pharmaceutical Benefits Scheme
  - United States: Medicare, Veterans Affairs
  - New Zealand: PHARMAC (Pharmaceutical Management Agency)

- Intervention:**
- Testosterone replacement therapies:
    - Oral: testosterone undecanoate (Andriol)
    - Injectable: testosterone cypionate (Depo-testosterone), testosterone enanthate (Delatestryl)
    - Topical: Androderm, Testim, Androgel, Axiron

<b>Outcome(s) of Interest:</b>	Drug Reimbursement Criteria and Policies: <ul style="list-style-type: none"> <li>• Restricted Access vs. General Benefit</li> <li>• Specific restriction criteria</li> </ul>
<b>Objective 2: Impact of different drug reimbursement schemes for Testosterone Replacement Therapies</b>	
<b>Study Design:</b>	<u>Design:</u> Literature review <u>Data sources:</u> Medline, EMBASE, Cochrane Collection, Grey literature
<b>Study Population:</b>	Testosterone Replacement Therapies for hypogonadism
<b>Intervention:</b>	Various drug reimbursement schemes, including general benefits, step therapy, special authorization
<b>Outcome(s) of Interest:</b>	Indirect/direct measurements of clinical outcomes, patient satisfaction, quality of life, utilization and/or costs
<b>Objective 3: Guidelines for management of hypogonadism</b>	
<b>Study Design:</b>	<u>Design:</u> Literature review <u>Data sources:</u> Medline, EMBASE, Cochrane Collection, Grey literature
<b>Study Population:</b>	Patients with hypogonadism
<b>Intervention:</b>	Guidelines/recommendations for the management of patients with hypogonadism
<b>Outcome(s) of Interest:</b>	Published guidelines by various organizations Endocrine Society Guideline (2010), European Association of Urology (2012)