

# GH Submission to ODBP

## Objectives:

### Primary:

- Inclusion of PWS on the Special Drugs Program for Growth Hormone Therapy
  - Elimination of Stimulation Testing as a requirement for funding (not required to show evidence of GH deficiency)



Ontario  
MINISTRY OF HEALTH AND LONG-TERM CARE

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### Ontario Public Drug Programs

Public Information

- What programs does Ontario offer?
- New Eligibility Requirements for The Low-Income Seniors Co-Payment Drug Program
- Get Naloxone Kits for Free
- Questions and Answers
- Application Forms
- Which drugs do the programs pay for?
- How are drugs in Ontario approved?
- The Trillium Drug Program
- Requests for Accommodation
- What is Ontario doing to improve our drug programs?
- Are you taking more than two medications?
- How is Ontario supporting the proper use of narcotics?
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### The Special Drugs Program (SDP)

#### What does the program cover?

The Special Drugs Program (SDP) covers the full cost of certain outpatient drugs used to treat a number of serious conditions. These include:

- cystic fibrosis (a lung disease)
- thalassaemia (a blood disease)
- Zidovudine and pentamidine for HIV infection (a disease of the immune system)
- Erythropoietin for anemia due to end stage kidney disease
- Children with a solid organ or bone marrow transplant
- children with growth failure**
- medications for sickle cell anemia
- Gaucher's disease (a genetic disorder).

The drugs covered must be prescribed by a doctor, and must be obtained from a designated treatment centre. To learn more, see the [Health Insurance Act, Regulation 552 Section 8 \(2\)](#).

#### Am I eligible?

Talk to your doctor to find out if you may be covered under SDP and where you can get treatment. To qualify, all of these statements must apply to you:

- I live in Ontario and have a valid health card which shows that I am entitled to health care services paid for by QHIP, and
- I am a patient with one of the diseases or conditions covered, and
- I am under the care of an Ontario doctor at a designated treatment centre for this disease or condition, and
- the doctor has confirmed that my condition needs the drug(s) covered by the SDP.

#### What costs will I pay?

If you qualify, SDP will pay 100% of the cost of your treatments.

#### For More Information

Call **ServiceOntario**, INFOline at 1-866-532-3161  
In Toronto, 416-314-5518  
TTY 1-800-387-5559  
In Toronto, TTY 416-327-4282  
Hours of operation : 8:30am - 5:00pm

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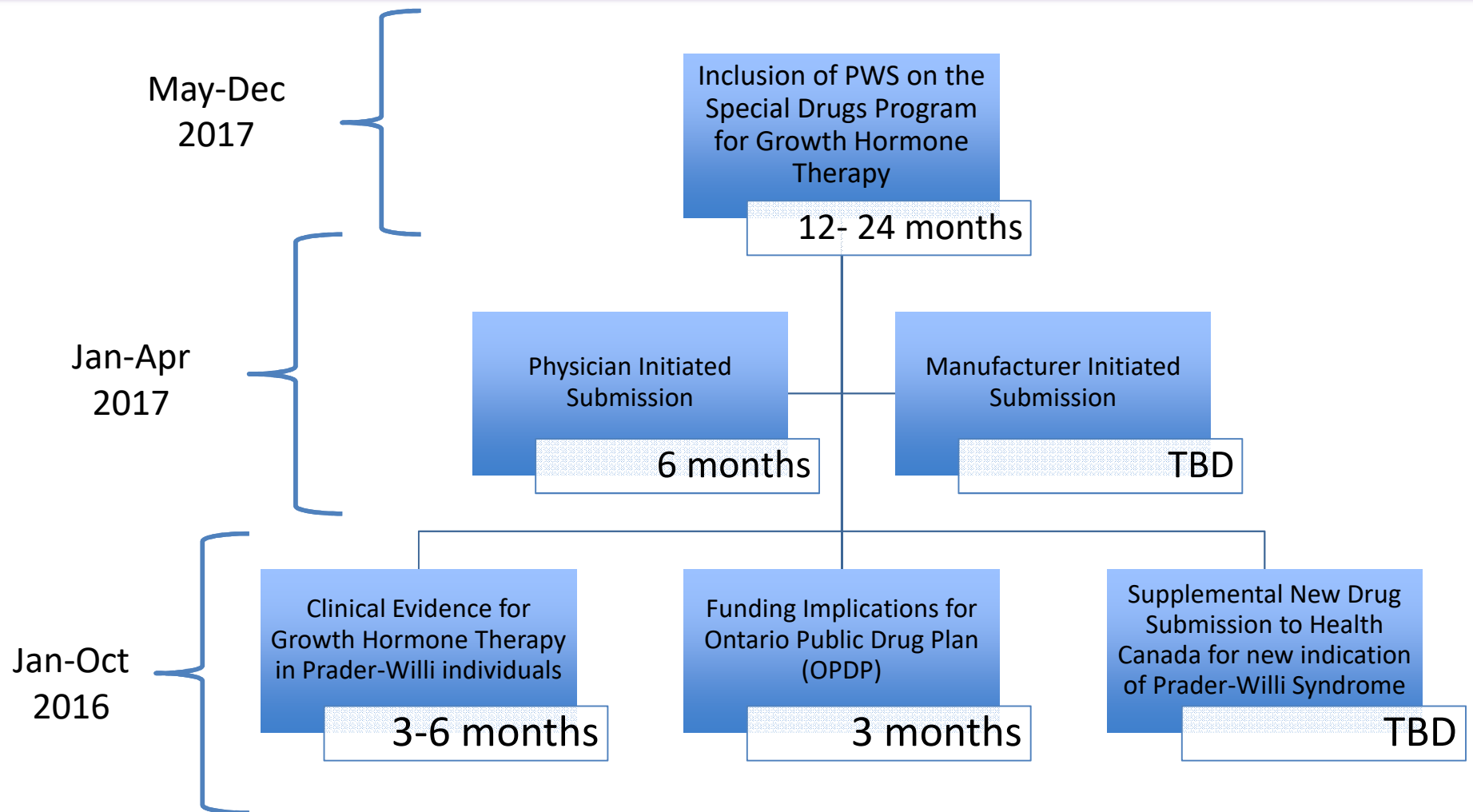
# Factors to Drive Strategy

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## Challenges to overcome:

- Currently in Canada no manufacturer has label claim for PWS
- Product Monograph for Growth Hormone manufacturers (somatropin) contains contraindications for PWS
- No regulatory pathway for manufacturers to file SNDS with Health Canada for new indication
  - Lacking the required clinical data to show efficacy and safety of this drug in the intended patient population
- Provincial Formularies (ODBP/SDP) require manufacturers to possess Notice of Compliance (label claim)
  - and many, many more specific requirements

# Project Plan GH Access



## Physician Initiated Submission

AxSource Consulting:  
\*Cover Letter  
\*Executive Summary  
\*Pharmacoeconomic Perspective  
\*Clinical Evidence  
\*Total budget impact on ODPD  
\*Safety Database

## Main Application Components

Funding Implications for Ontario Public Drug Plan (OPDP)

Clinical Evidence for Growth Hormone Therapy in Prader-Willi individuals

## Preliminary Work

Caregiver questionnaire to FRPWR Canada members via survey monkey

Non-proprietary statistics from Sick Kids, McMaster, London HS & Children's Hospital in Ottawa

Systematic review of all clinical and published evidence

