

LONG-ACTING MEDICATIONS FOR ATTENTION DEFICIT HYPERACTIVITY DISORDER

The Ontario Public Drug Programs and its expert advisory committee, the Committee to Evaluate Drugs (CED), recently re-evaluated the funding of long-acting medications for the management of Attention Deficit Hyperactivity Disorder (ADHD). Treatments evaluated in this review include:

- ◆ Adderall XR® (extended-release mixed amphetamine salts)
- ◆ Biphentin® (extended-release methylphenidate)
- ◆ Concerta® (extended-release methylphenidate)
- ◆ Strattera® (atomoxetine)

Key Findings

- ◆ **Randomized controlled studies on long-acting ADHD medications have shown that they are effective at improving measures of behaviour, attention and performance, but suggest that they are similar to short-acting agents in terms of efficacy and safety.**
- ◆ **There is a lack of good quality, direct comparison studies to assess the relative efficacy and safety of long-acting ADHD medications compared with short-acting agents. Although long-acting agents are dosed once daily, there is no evidence that this added convenience translates into improved treatment adherence or other important clinical outcomes.**
- ◆ **Long-acting ADHD medications cost two to three time more than short-acting agents. Because long-acting products have not been shown to be therapeutically superior, they are funded only in patients who cannot be adequately managed with short-acting treatments. These include patients who do not receive sufficient symptom control or experience side effects from short-acting agents.**
- ◆ **Long-acting treatments can also be considered in situations where there are administrative or societal barriers associated with short-acting products, such as the inability of a child to receive ADHD medications at school or where there is a risk of abuse of short-acting products.**
- ◆ **To ensure that long-acting agents are used in the clinical settings where they are most likely to be cost-effective and to obtain better value for money, the Ontario Public Drug Programs pursued listing agreements with the manufacturers of long-acting ADHD medications.**
- ◆ **Based on listing agreements that address appropriate utilization and cost, Adderall XR (extended-release mixed amphetamine salts), Concerta (extended-release methylphenidate), and Biphentin (extended-release methylphenidate) are now listed on the Ontario Drug Benefit Formulary with therapeutic notes. (For details, please see "FUNDING STATUS OF LONG-ACTING ADHD MEDICATIONS" on page 2.)**
- ◆ **As a listing agreement has not been reached, Strattera (atomoxetine) will continue to be funded through the Exceptional Access Program according to the previous criteria. (For details, please see "FUNDING STATUS OF LONG-ACTING ADHD MEDICATIONS" on page 3.)**

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Background

Attention Deficit Hyperactivity Disorder (ADHD) is the most commonly diagnosed behavioral disorder of childhood, affecting an estimated 3-5% of school aged children. It is diagnosed much more often in boys than in girls. Symptoms include an inability to concentrate, hyperactivity, and impulsiveness. ADHD is a long-term, chronic condition. About half of the children with ADHD will continue to have symptoms of inattention or impulsivity as adults. ADHD can affect progress in school, social skills development, and job performance.

Treatments for ADHD often include behavioural interventions (e.g. setting clear goals, rewarding positive behaviour, etc.) as well as drug therapy.

Dexedrine (immediate-release dexamphetamine) and several brands of immediate- and slow-release methylphenidate (Ritalin, Ritalin SR and generics) are funded as General Benefit products on the Ontario Drug Benefit Formulary. Some patients may require several doses per day of these products to control their symptoms. Adderall XR (extended-release mixed amphetamine salts), Biphentin (extended-release methylphenidate), Concerta (extended-release methylphenidate) and Strattera (atomoxetine) are long-acting treatments that offer the convenience of once-daily dosing.

Funding Status of Long-Acting ADHD Medications

Adderall XR, Biphentin, Concerta

**Listed on the Ontario Drug Benefit Formulary with the following therapeutic note
(which outlines the clinical setting where these agents are most likely to be cost-effective):**

Patients ≥ six years of age diagnosed with ADHD according to Diagnostic and Statistical Manual of Mental Disorders (DSM)-IV criteria and where symptoms are not due to other medical conditions which affect concentration, and who require 12-hour continuous coverage due to academic and/or psychosocial needs, and who meet all of the following:

- 1) *The patient demonstrates significant and problematic disruptive behaviour or has problems with inattention that interfere with learning; AND*
- 2) *The medication is prescribed by or in consultation with a specialist in pediatric psychiatry, pediatrics or a general practitioner with expertise in ADHD; AND*
- 3) *The patient has been tried on methylphenidate immediate-release or methylphenidate slow-release or Dexedrine IR or Dexedrine Spansules, and has experienced unsatisfactory results due to poor symptom control, side effects, administrative barriers, or societal barriers.*

Administrative barriers include:

- *inability of a school to dose the child at lunch;*
- *the school lunch hour does not coincide with the dosing schedule;*
- *poor compliance with noon or afternoon doses;*
- *the patient is unable to swallow tablets.*

Societal barriers include:

- *the patient or patient's caregiver(s) has (have) a history of substance abuse or diversion of listed immediate-release alternatives;*
- *the patient or patient's caregiver(s) is/are at risk of substance abuse or diversion of listed immediate-release alternatives.*

LONG-ACTING MEDICATIONS FOR ATTENTION DEFICIT HYPERACTIVITY DISORDER**Funding Status of Long-Acting ADHD Medications****Strattera****Funded through the Exceptional Access Program (EAP) according to the following clinical criteria:**

Patients \geq six years of age diagnosed with ADHD according to Diagnostic and Statistical Manual of Mental Disorders (DSM)-IV criteria and where symptoms are not due to other medical conditions which affect concentration, and who require 12-hour continuous coverage due to academic and/or psychosocial needs, and who meet all of the following:

- 1) *The patient demonstrates significant and problematic disruptive behaviour or has problems with inattention that interfere with learning; AND*
- 2) *The medication is prescribed by or in consultation with a specialist in pediatric psychiatry, pediatrics or a general practitioner with expertise in ADHD; AND*
- 3) *The patient has been tried on methylphenidate immediate-release or methylphenidate slow-release or Dexedrine IR or Dexedrine Spansules, and has experienced unsatisfactory results due to poor symptom control or side effects; AND*
- 4) *Evidence of benefit from a one month trial with Strattera.*

Health Canada Advisory

Health Canada issued an advisory cautioning against the use of ADHD drugs in patients who have high blood pressure, heart disease or abnormalities, hardening of the arteries or an overactive thyroid gland. All ADHD drugs stimulate the heart and blood vessels (cardiovascular system). The effects are usually mild or moderate, but in some patients, this stimulation may, in rare cases, result in cardiac arrests, strokes or sudden death. Patients taking ADHD drugs should consult with their physician if they have any questions or concerns.

Committee to Evaluate Drugs

The Committee to Evaluate Drugs (CED) is an expert advisory group that makes recommendations to the Executive Officer of the Ontario Public Drug Programs. The CED's recommendations are based on an evaluation of the therapeutic value and cost-effectiveness of the drug relative to available alternatives. Membership on the CED includes practicing physicians, pharmacists, health economics experts, and patients.

For more information about the Ontario Public Drug Programs and the Committee to Evaluate Drugs, please visit:

www.health.gov.on.ca/english/providers/program/drugs/drugs_program_mn.html