CANADIAN COORDINATING OFFICE FOR HEALTH TECHNOLOGY ASSESSMENT

OFFICE CANADIEN DE COORDINATION DE L'ÉVALUATION DES TECHNOLOGIES DE LA SANTÉ

CEDAC FINAL RECOMMENDATION on RECONSIDERATION and REASONS for RECOMMENDATION

MIXED AMPHETAMINE SALTS EXTENDED RELEASE CAPSULES
(Adderall XR™ – Shire BioChem Inc)

Description:
Adderall XR™ is an extended-release capsule containing *d*- and *l*-isomers of mixed amphetamine salts. The capsule contains two types of pellets in a 1:1 ratio, an immediate release pellet and a delayed release enteric coated form. Adderall XR™ is indicated for the treatment of attention deficit hyperactivity disorder (ADHD).

Recommendation:
The Canadian Expert Drug Advisory Committee recommends that mixed amphetamine salts extended release capsules not be listed.

Reasons for the Recommendation:

1. No head-to-head randomized controlled trials are available that compare mixed amphetamine salts extended release capsules with stimulants licensed in Canada – i.e. regular and sustained release formulations of methylphenidate, and dextroamphetamine. Therefore, the relative efficacy of mixed amphetamine salts extended release capsules compared to currently available stimulants cannot be determined.

2. No evidence from trials with an active comparator is available to show that compliance with mixed amphetamine salts extended release capsules is better than with other stimulants. (The longest parallel-group randomized placebo-controlled trial followed patients for 3 weeks. Fifty-two per cent of patients were prematurely withdrawn from a 2-year uncontrolled, observational study.)

3. The cost of mixed amphetamine salts extended release capsules is higher than the cost of comparators.

4. Mixed amphetamine salts extended release capsules has not been shown to be cost effective.

Of Note:

1. Mixed amphetamine salts immediate release (Adderall IR), which was used as a comparator in trials of Adderall XR, is not licensed in Canada.

2. Both published and unpublished data were reviewed and taken into consideration in making this recommendation.