the DBL report

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An Official Accompaniment to the Alberta Health and Wellness Drug Benefit List (AHWDBL)

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

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Highlights of Products Added

■ **APO-OMEPRAZOLE** (omeprazole) (APX), a first-entry interchangeable product, was added to the *AHWDBL* on June 1, 2006**,** as the manufacturer provided direct evidence of comparative therapeutic efficacy between Apo-Omeprazole capsules and Losec tablets. Further, it was noted that this product is priced 43% less than the innovator and has the potential to offer savings of $10,900,000 in the first year of listing.

■ **CLARUS** (isotretinoin) (PRP) **10 mg and 40 mg capsules** have been recommended for addition to the *AHWDBL* in an interchangeable grouping with Accutane. Clarus is a first-entry interchangeable product offering 26% savings over the innovator product. As isotretinoin is a known teratogen, and in keeping with the commitment required of the innovator's manufacturer, Prempharm, was required to develop a risk management program. This program is entitled, CLEAR (Clinical Education and Awareness Resource) and is intended to assist physicians and pharmacists with counseling patients on effective use of contraception while taking these products.

■ **CO LEVETIRACETAM** (levetiracetam) (COB) **250 mg, 500 mg and 750 mg tablets** are indicated as adjunctive therapy in the management of patients with epilepsy who are not satisfactorily controlled by conventional therapy. Co Levetiracetam was recommended for addition to the *AHWDBL* via special authorization as it is a first-entry interchangeable product that offers 26% savings over Keppra.

■ **FLOMAX CR** (tamsulosin HCl) (BOE**) 0.4 mg controlled-release tablets** are a line extension of the currently listed, Flomax product. Flomax CR uses an Oral Controlled Absorption System (OCAS) that involves a controlled-release matrix, which reportedly provides a constant release of drug throughout the large intestine, regardless of whether it is taken with or without food. The manufacturer stressed that Flomax CR and the currently listed Flomax are not interchangeable. The Committee recommended that this product be added to the *AHWDBL* as an unrestricted benefit.

■ **PMS-CITALOPRAM** (citalopram hydrobromide) **10 mg tablets** and **PMS-MIRTAZAPINE** (mirtazapine) **15 mg tablets** (PMS) are line extensions of currently listed benefits on the *AHWDBL*. The manufacturer indicated that these products were introduced to allow patients to take lower doses of medication without the need to split tablets. The Expert Committee recommended the addition of **PMS-CITALOPRAM 10 mg and PMS-MIRTAZAPINE 15 mg tablets** because they offer a therapeutic advantage.

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Special Authorization Criteria Change for Duragesic Patches

Correspondence from an Alberta physician prompted the Expert Committee to review the current special authorization criteria for **DURAGESIC (fentanyl) 25 mcg, 50 mcg, 75 mcg and 100 mcg transdermal patches** (JOI). The Committee noted that the special authorization criteria were quite lenient in light of the safety concerns and abuse potential related to this agent. Accordingly, it was recommended that the special authorization criteria be revised to read:

"For the treatment of persistent, severe chronic pain in those patients who require continuous around-the-clock analgesia for an extended period of time in those patients who cannot swallow."

and

"For the treatment of persistent, severe chronic pain in those patients who require continuous around-the-clock analgesia for an extended period of time in those patients who require opioid therapy at a total daily dose of at least 60 mg/day oral morphine equivalents. Patients must have tried and not been able to tolerate at least two discrete courses of therapy with two of the following agents: morphine, hydromorphone and oxycodone, if not contraindicated."

At the direction of the Committee, "two discrete courses" are defined as separate courses of therapy containing one or more of the agents noted above. For example, a patient who reported only taking morphine and an oxycodone product concomitantly prior to requesting coverage for Duragesic would only be considered to have tried one discrete course of therapy and would not meet the criteria.

Change in Benefit Status of EENT Anti-Allergy Products

A comprehensive review of clinical evidence to support the efficacy of topical Eye, Ear, Nose and Throat (EENT) products used in the treatment of allergies was conducted. Following their review of the information obtained in the literature, as well as input from the manufacturers, the Committee recommended that the following EENT anti-allergy products be de-listed from the *AHWDBL* effective July 1, 2006: lodoxamide tromethamine (Alomide®), sodium cromoglycate (Apo-Cromolyn®, Cromolyn®, Opticrom®, Solu-Crom®), and levocabastine HCl (Livostin®).

Review of Benefit Status of Plavix

The Committee considered a resubmission from the manufacturer requesting that the length of authorization for the Limited Restricted Benefit (LRB) of Plavix be extended from 30 days to one year. In addition to the manufacturer's submission, an extensive literature review was conducted to examine the clinical evidence supporting an extension of coverage beyond 30 days post-stent placement. After considering the available information, the Committee concluded that the strongest evidence for the use of Plavix lies within the first 30 days after stent placement, regardless of whether the patient received a drug-eluting or bare metal stent. Accordingly, the Committee recommended that the benefit status of Plavix remain unchanged. Please refer to the *AHWDBL* for a detailed overview of the coverage criteria for Plavix.

Products Not Added to the AHWDBL

■ **PAMIDRONATE DISODIUM OMEGA** (pamidronate disodium) (OMG) was not recommended for addition to the *AHWDBL*. While the Committee indicated that the comparative data supported the interchangeability of this product with the innovator, Aredia, it was noted that there was a substantial price disparity between the price of Pamidronate Disodium Omega and other currently listed interchangeable products. Accordingly, the Committee recommended that this product not be added as it fails to offer a cost advantage.

■ **PREVACID FASTABS** (lansoprazole) (ABB) **30 mg delayed-release tablets** disintegrate on the tongue into enteric-coated microgranules that are swallowed with saliva. The manufacturer stated that this product would offer an advantage for patients with dysphagia or who are being fed via nasogastric tube. The Committee noted that the currently listed product, Prevacid, allows for dosing of such patients. Therefore, it was recommended this product not be added as it fails to offer a therapeutic advantage over currently listed products.

Removal of Interchangeability Designation of Novo-Bupropion SR 150 mg Tablets

Effective June 1, 2006, the interchangeability designation of Novo-Bupropion SR 150 mg with Wellbutrin SR 150 mg has been removed. Following reports of stability issues associated with the Novopharm product, the Expert Committee completed additional investigation. The Committee concluded that stability issues preclude the ability to blister-pack or compliance-pack the medication. Accordingly, the Committee concluded that it was not appropriate to continue to have Novo-Bupropion SR 150 mg designated as interchangeable with Wellbutrin SR 150 mg on the *AHWDBL*.