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)

produced by Alberta Blue Cross

In this issue:

Highlights of:

ABC 81171 (10/2006)

Highlights of Products Added

■ **APO-FENO-SUPER** (fenofibrate) (APX), **100 mg and 160 mg tablets** were added to the *AHWDBL* on August 1, 2006 in an interchangeable grouping with Lipidil Supra. This product is priced over 30% less than the innovator and is expected to offer savings of approximately $712,000 to the government-sponsored programs in the first year of listing.

■ **METADOL** (methadone hydrochloride) (PMS) **1 mg/mL oral solution** is a line extension of the currently listed Metadol product line. This product reportedly offers an advantage to clinicians and patients by decreasing the dilutions needed to achieve required dosing, thereby decreasing dispensing errors. The Committee agreed that the availability of the 1 mg/mL strength may decrease the complexity associated with dispensing methadone in many instances. Accordingly, they recommended that **METADOL** be added to the *AHWDBL* as it offered a therapeutic advantage.

■ **NOVO-ONDANSETRON** (NOP), **PMS-ONDANSETRON** (PMS), **RATIO-ONDANSETRON** (RPH) **AND SANDOZ-ONDANSETRON** (SDZ) (ondansetron HCl dihydrate) **4 mg and 8 mg tablets** were added to the *AHWDBL* effective August 1, 2006. These products offer between 30% and 40% savings over the cost of the innovator product, Zofran, and a potential savings for the government-sponsored drug programs of $868,000 in the first year of listing.

■ **RAN-RISPERIDONE** (risperidone) (RAN) **0.25 mg, 0.5 mg, 1 mg, 2 mg, 3 mg and 4 mg tablets** are first-entry interchangeable products for Risperdal. **RAN-RISPERIDONE** is cross-licensed with Risperdal and is priced over 30% less than the innovator. The Committee recommended that this product be added effective August 1, 2006 as it has the potential to offer greater than $3,000,000 to the government-sponsored drug programs in the first year of listing.

Highlights of Changes to Special Authorization Criteria

■ The special authorization criteria for **PEGASYS** (peginterferon alfa-2a) (HLR) **180 mcg/mL vial and 180 mcg/0.5 mL pre-filled syringe** were changed to include the indication of treatment of chronic hepatitis B as the product was deemed to offer a therapeutic advantage over presently available therapies. Please refer to the *AHWDBL* for complete listing of the special authorization criteria for **PEGASYS**.

Special Authorization Criteria Change for Drugs Used in the Treatment of Alzheimer's Disease

The Expert Committee was advised that the accreditation for the Mainpro-C dementia course had lapsed on March 31, 2006. The Committee recalled that designated prescribers are able to apply for coverage for patients initiating therapy with MMSE scores between 10 and 13. Prescribers may be deemed to be designated by virtue of their specialty or by completing the Mainpro-C dementia course or the care of the Elderly Six-month/One-year Fellowship Program. The Committee reviewed available continuing education courses in order to determine whether there was a course available that could replace the Mainpro-C course. After their review of several courses, Committee members recommended that the criteria for **ARICEPT** (donepezil) (PFI), **EXELON** (rivastigmine) (NOV) and **REMINYL ER** (galantamine) (JOI) be revised to include the following:

"Specialists in Geriatric Medicine, Neurology, and Psychiatry are deemed designated prescribers by virtue of their specialty in medical practice. All other practitioners will be added to the list of designated prescribers if they have successfully completed Mainpro-C credits through the College of Family Practice (Physicians) [prior to March 31, 2006], the Care of the Elderly Six-month/One-year Fellowship program through the department of Medicine or the Mainpro-M1 course entitled, "Module 2: Advanced Alzheimer's Disease."

Highlights of Products Added via Special Authorization

- **EPREX** (epoetin alfa) (JOI) **40,000 IU/mL pre-filled syringe** has been recommended for listing on the *AHWDBL* via special authorization for the treatment of anemia of cancer in patients with non-myeloid malignancies. The Committee has recommended that patients be allowed a maximum dosage of 40,000 IU per week when an authorization is granted for this product presentation. Please refer to the *AHWDBL* for a complete listing of the special authorization criteria.

- **NORPROLAC** (quinagolide hydrochloride) (FEI) **0.075 mg and 0.150 mg tablets** are indicated for the treatment of hyperprolactinemia. This product was originally reviewed via the Common Drug Review (CDR) Process and recommended for listing for patients with hyperprolactinemia who have failed or are intolerant to bromocriptine. The manufacturer had since requested that **NORPROLAC** be granted an unrestricted listing; hence, the product was placed before the Expert Committee for consideration. After reviewing the CDR recommendations and additional material, the Committee concurred with the CDR's recommendation and indicated that this product should be listed via special authorization. Please refer to the *AHWDBL* for a full listing of the coverage criteria.

Highlights of Products Not Added

- **ADVICOR** (niacin/lovastatin) (ORY) **500 mg/20 mg and 1000 mg/20 mg extended-release tablets** were not recommended for addition to the *AHWDBL*. This product was originally reviewed via the CDR process and recommended for listing. However, **ADVICOR** was placed before the Expert Committee because one of its components, extended-release niacin, was previously not recommended for listing via the *AHWDBL*. The Committee concluded that since the niacin component of the product was not currently listed on the *AHWDBL*, **ADVICOR** should remain unlisted as it fails to offer a cost and/or therapeutic advantage.

- **ARICEPT RDT** (donepezil hydrochloride) (PFI) **5 mg and 10 mg rapid dissolving tablet** is reported to offer a therapeutic advantage in select patient groups because it rapidly dissolves into a paste once in the mouth, at which time it may be swallowed with water. The Committee questioned the need for such a dosage form in the Aricept product line given that the original tablets are quite small. In addition, Committee members indicated that patients with Alzheimer's Disease often require compliance packaging. Unfortunately, **ARICEPT RDT** must remain in the original package until administration; therefore, it would be difficult to maintain tablet integrity when compliance aids are used. Accordingly, the Committee recommended that this product not be added as it fails to offer a therapeutic advantage.

- **RISPERDAL CONSTA** (risperidone) (JOI) **25 mg/vial, 50 mg/vial and 75 mg/vial powder for injectable prolonged-release suspension** was not recommended for listing as it failed to offer a cost and/or therapeutic advantage. The Committee concluded that the manufacturer had not provided any information that would merit a change in their previous recommendation.