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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ABC 81171 (04/2006)

Highlights of New Products Added

■ **ACLASTA** (zoledronic acid) (NOV) is indicated as a single-dose infusion for the treatment of Paget's disease of bone in patients with elevations in serum alkaline phosphatase of at least two times the upper limit of the age-specific normal reference range, or who are symptomatic, or those at risk for complications from their disease. The **5 mg/100 mL** injection is available via special authorization with the following criteria for reimbursement: *"For the treatment of Paget's disease. Special authorization for this criterion may be granted for one dose per 12-month period. Coverage cannot be provided for two or more medications used in the treatment of Paget's disease when these medications are intended for use in combination or when therapy with two or more medications overlap."*

■ **FUCITHALMIC** (fusidic acid) (LEO) **1% viscous ophthalmic drops (unpreserved)** have been recommended for addition to the *AHWDBL*, via special authorization, as a preservative-free alternative to other currently listed ophthalmic antibiotics. The criteria for coverage will be as follows: *"For the treatment of ophthalmic infections in patients with documented sensitivity to preservatives."*

■ **SAIZEN** (somatropin) (SRO) is now indicated for replacement therapy in adult patients with acquired or idiopathic growth hormone deficiency. In addition, this product is less expensive than the currently listed somatropin product, HUMATROPE. [Please note: These products are not interchangeable.] Accordingly, the Expert Committee recommended the **3.3 mg & 5 mg vials for injection** be listed on the *AHWDBL* with the following criteria for coverage: *"For replacement of endogenous growth hormone in adults with severe growth hormone deficiency. Information is required regarding the results of a diagnostic insulin tolerance test. Growth hormone values less than 3 mcg/litre during hypoglycemia are indicative of severe growth hormone deficiency."*

■ **TWINJECT** (epinephrine) (PAL) **0.15 mg auto-injector** is a line-extension to the currently listed 0.3 mg strength. The **0.15 mg** strength is indicated for use in children and adults weighing 15 – 30 Kg, while the 0.3 mg strength is for patients > 30 Kg. **TWINJECT** is a single-use, auto-injection device that once activated will administer one dose, with a second dose available by manual administration. The Committee felt the second dose may offer a clinical advantage in situations where patients require additional dosing of epinephrine following an anaphylactic episode. Accordingly, the Committee recommended this product be added to the *AHWDBL* as a single source product.

Special Authorization Criteria Change for Alzheimer's Drugs

The Committee considered the issue of combination use of agents for the treatment of Alzheimer's disease (AD). It was noted that there are currently no published studies available to evaluate such use of these products. As a result, the Committee indicated that special authorization coverage of agents used in the treatment of AD should not be considered when intended for use in combination. Therefore, the following will be added to special authorization criteria for coverage of Alzheimer's agents currently listed on the *AHWDBL*:

"*Coverage cannot be provided for two or more medications used in the treatment of Alzheimer's disease (donepezil, rivastigmine, galantamine) when these agents are intended for use in combination.*"

Affected products include the following:

- **ARICEPT** (donepezil hydrochloride) (PFI) 5 mg & 10 mg tablets
- **EXELON** (rivastigmine hydrogen tartrate) (NOV) 1.5 mg, 3 mg, 4.5 mg & 6 mg capsules and 2 mg/mL oral solution
- **REMINYL** (galantamine hydrobromide) (JOI) 4 mg, 8 mg & 12 mg tablets
- **REMINYL ER** (galantamine hydrobromide) (JOI) 8 mg, 16 mg & 24 mg extended-release capsules

Highlights of Interchangeable Products Added

- **APO-METHYLPHENIDATE SR** (methylphenidate hydrochloride) (APX) **20 mg extended-release tablet** is a first-entry generic product that was deemed interchangeable with the innovator, RITALIN SR 20 mg. The Committee recommended this product be added to the *AHWDBL* as it provides a 39% savings over the innovator product.

- **CO AZITHROMYCIN** (azithromycin monohydrate) (COB) **250 mg tablet** is a first-entry generic product that has been deemed interchangeable with ZITHROMAX 250 mg tablet. This product qualified for fast-track addition to the *AHWDBL* by virtue of the savings offered to the government-sponsored programs. As a result, this product was added **effective March 1, 2006**.

In addition, **APO-AZITHROMYCIN** (APX), **NOVO-AZITHROMYCIN** (NOP) and **SANDOZ AZITHROMYCIN** (SDZ) (azithromycin monohydrate) **250 mg tablets** were added, **effective April 1, 2006**.

- **SANDOZ DILTIAZEM T** (diltiazem hydrochloride) (SDZ) **120 mg, 180 mg, 240 mg, 300 mg & 360 mg extended-release capsules** have been deemed interchangeable with the respective strengths of the innovator, TIAZAC extended-release capsules. As a result of the substantial savings offered, this first-entry generic product also met fast-track criteria for addition to the *AHWDBL*. Accordingly, **SANDOZ DILTIAZEM T** was added in an interchangeable grouping with TIAZAC, **effective March 1, 2006**.

Highlights of Products Not Added

- **BIAXIN XL** (clarithromycin) (ABB) is a **500 mg extended-release tablet** formulation of the currently listed BIAXIN BID. This product is dosed as 1000 mg (i.e. 2 tablets) every 24 hours. Overall, the Committee indicated that no new information had been provided to warrant a change in their previous recommendation not to list this product.

- **DIOVAN** (valsartan) (NOV) **40 mg tablet** is a line extension to the currently listed 80 mg & 160 mg tablets. This new, lower strength has been introduced to support dose titration for the new indication to reduce cardiovascular mortality in clinically stable patients with signs or symptoms of left ventricular dysfunction in conjunction with acute MI when the use of an ACE inhibitor is inappropriate. The Committee indicated that it was likely the 40 mg strength would be used during a patient's hospital stay post-MI and therefore not largely used by the outpatient population. The Committee recommended that this product should not be added, as it does not offer a therapeutic and/or cost advantage over other available therapies.

New Criterion for Optional Special Authorization of Select Quinolones

Please note, the following will be added to the Optional Special Authorization (OSA) criteria for the quinolone antibiotics currently available via OSA:

"*For use in other current Health Canada approved indications when prescribed by a specialist in Infectious Diseases.*"

Please refer to section 3A of the current *AHWDBL* for a full listing of products and criteria.