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 (2008/01)

Highlights of New Products Added

■ **EPREX** (epoetin alfa) (JOI) **20,000 unit/syringe injection syringe** is a line extension to the **EPREX** products currently available via special authorization on the *AHWDBL*. The Expert Committee recommended the **20,000 unit/syringe** be added as a benefit, subject to coverage under special authorization. Please refer to the current *AHWDBL* for a full listing of available strengths, special authorization criteria and applicable special authorization request forms.

■ **PMS-AMIODARONE** (amiodarone hydrochloride) (PMS) **100 mg tablet** was reviewed as a line extension to the **PMS-AMIODARONE** 200 mg strength currently listed on the *AHWDBL*. The Committee reviewed the manufacturer's product submission and recommended inclusion as an unrestricted benefit after noting that the availability of a lower strength of amiodarone may offer a therapeutic advantage in select patients, and that the price of the 100 mg tablet is half the cost of a 200 mg tablet.

■ **PMS-PAROXETINE** (paroxetine hydrochloride) (PMS) **40 mg tablet** is a line extension to the currently listed 20 mg & 30 mg strengths of **PMS-PAROXETINE**. Paroxetine is indicated in the treatment of a number of conditions where the recommended daily dose is 40 mg, and where the maximum daily dosage recommendation may exceed 40 mg (up to 60 mg/day). It was also noted that the cost of the 40 mg tablet is at parity with the price of two 20 mg tablets. Accordingly, the Committee recommended **PMS-PAROXETINE 40 mg tablet** be added to the list as it offered a therapeutic advantage for certain conditions.

Highlights of Interchangeable Products Added

■ . **APO-METOPROLOL SR** (metoprolol tartrate) (APX) **100 mg & 200 mg sustained-release tablets** will be listed in interchangeable groupings with LOPRESOR SR 100 mg & 200 mg sustained-release tablets, respectively.

■ **PORTIA 21 & 28** (levonorgestrel/ethinyl estradiol) (APX) **150 mcg/30 mcg oral tablet** is a first-entry generic product that has been added as interchangeable with MIN-OVRAL 21 & 28.

■ **RATIO-VENLAFAXINE XR** (venlafaxine hydrochloride) (RPH) **37.5 mg, 75 mg & 150 mg extended-release capsules** have been added as subsequent-entry generic products interchangeable with the currently listed venlafaxine XR products. The addition of **RATIO-VENLAFAXINE XR** to the *AHWDBL* is expected to provide savings of over $780,000 to all government-sponsored drug programs in the first year of listing and therefore, these products were added to the list **effective November 1, 2007**.

Highlights of Products Not Added

■ . **ACTONEL** (risedronate sodium) (PGA) **75 mg tablet** was reviewed as a line extension to the currently listed **ACTONEL** products. This new strength is approved for treatment of post-menopausal osteoporosis, dosed as one tablet daily for two consecutive days each month. Due to concerns regarding patient compliance issues, it was not recommended for addition to the AHWDBL.

■ **MEZAVANT** (mesalamine) (SHB) **1.2 g delayed and extended release tablet** is indicated for the induction of remission (clinical and endoscopic) in patients with active, mild to moderate ulcerative colitis. Upon review, the Committee indicated this product fails to offer a therapeutic and/or cost advantage. Accordingly, this product was not recommended for addition to the *AHWDBL*.

Special Authorization Criteria Change: Ketek

The Expert Committee considered recent Health Canada-endorsed safety information from the manufacturer of **KETEK** (telithromycin) (SAV) **400 mg tablet**, indicating that **KETEK** is no longer approved for the treatment of bronchitis, sinusitis or tonsillitis/pharyngitis. As a result, the current special authorization (SA) criteria is revised to the following:

"For the treatment of community acquired pneumonia after failure of first line therapy, as defined by clinical deterioration after 72 hours of antibiotic therapy or lack of improvement after completion of antibiotic therapy."

In order to comply with the above criterion, information is required regarding the type of infection and organisms involved, previous antibiotic therapy that has been utilized and the patient's response to therapy. Information is also required regarding the first line agents the organism is resistant to or why other first-line therapies cannot be used in this patient.