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

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ABC 81171 (04/2008)

Highlights of New Products Added

■ **BARACLUDE** (entecavir) (BMS) **0.5 mg tablet** is a guanosine nucleoside analogue used in the treatment of chronic hepatitis B virus (HBV) infection in adults. This product was originally reviewed via the Common Drug Review and recommended for listing with criteria and/or conditions. The Expert Committee recommended that this product be added to the AHWDBL via special authorization with the following criteria for coverage: *"For the treatment of chronic hepatitis B infection in patients with advanced fibrosis or cirrhosis documented on radiologic or histologic grounds and a HBV DNA concentration above 2,000 IU/mL. Entecavir will not be reimbursed in combination with other anti-viral therapy."* Please refer to the current *AHWDBL* for additional details.

■ **HEPSERA** (adefovir dipivoxil) (GIL) **10 mg tablet** is a prodrug of adefovir indicated for use in the treatment of chronic HBV in adults with compensated and decompensated liver disease with evidence of active viral replication and either evidence of histologically active disease or elevation in serum aminotransferases (ALT or AST). This product was originally reviewed by the Common Drug Review and recommended for listing with criteria and/or conditions. The Expert Committee recommended that this product be listed via special authorization. Please refer to the current *AHWDBL* for special authorization criteria.

■ **HYZAAR** (losartan potassium/hydrochlorothiazide) (MFC) **100 mg/12.5 mg tablet** is a line extension to the currently listed 50 mg/12.5 mg and 100 mg/25 mg strengths of HYZAAR. The manufacturer estimated that approximately 33% of current claims for the single entity products (Cozaar 100 mg and hydrochlorothiazide 12.5 mg) would be replaced by the addition of **HYZAAR** 100/12.5 to the AHWDBL. Accordingly, the Committee recommended that this product be added as it offered a therapeutic and cost advantage.

Highlights of Interchangeable Products Added February 1, 2008

■ **APO-PIOGLITAZONE, CO PIOGLITAZONE, GEN-PIOGLITAZONE, NOVO-PIOGLITAZONE, pms-PIOGLITAZONE, RATIO-PIOGLITAZONE AND SANDOZ PIOGLITAZONE** (pioglitazone hydrochloride) **15 mg, 30 mg and 45 mg tablets** have been added to the *AHWDBL* as first-entry generic products interchangeable with the innovator product, Actos (LIL). The addition of these products is expected to provide savings of over $1,950,500 to all government-sponsored drug programs in the first year of listing.

■ **RAN-RABEPRAZOLE** (rabeprazole sodium) (RAN) **10 mg and 20 mg tablets** have been added to the *AHWDBL* as first-entry generic products interchangeable with the innovator product, Pariet (JOI). The addition of these products is expected to provide savings of over $900,000 to all government-sponsored drug programs in the first year of listing.

Highlights of Products Not Added

■ **SEROQUEL XR** (quetiapine fumarate) (AZE) **50 mg, 100 mg, 200 mg, 300 mg and 400 mg extended release tablet** is a line extension of the product line, Seroquel. The XR formulation is dosed once daily and is indicated for the management of the manifestations of schizophrenia. The Committee indicated that submitted data did not clearly show that **SEROQUEL XR** offered a therapeutic advantage over the listed product, Seroquel. Further, the Committee expressed concern that the XR formulation possessed only one indication whereas; Seroquel is indicated for both schizophrenia and bipolar disorder - mania. Accordingly, **SEROQUEL XR** was not recommended for addition to the *AHWDBL*.

Highlights of Changes to Benefit Status

■ **LOSEC** (omeprazole magnesium) (AST) **10 mg sustained release tablet** has been changed to an unrestricted listing. During the review of a first entry interchangeable 10 mg product, the Expert Committee recalled that Losec 10 mg had originally been recommended for listing via special authorization due to cost concerns. Given the low utilization of this strength and the April 1, 2008 addition of **SANDOZ OMEPRAZOLE** (omeprazole) (SDZ) **10 mg capsule**, the Committee recommended that this product be changed from a special authorization listing to an unrestricted listing.