the Rx 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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Highlights of New Products Added

■ **SALOFALK** (5-aminosalicylic acid) (AXC) rectal suppositories are indicated in the management of ulcerative proctitis and as adjunctive therapy in more extensive distal ulcerative colitis. The Committee had previously reviewed the **1000 mg suppository** (a line extension to the currently listed enteric-coated oral tablet, rectal enema and the 500 mg suppository) in 2000 and 2001. On both occasions, they had recommended that it not be listed, as the data provided by the manufacturer did not convince the Committee that the release characteristics of the **1000 mg suppository** were comparable to that of the 250 mg and 500 mg suppositories. The Committee recently reviewed a resubmission for this product, and based on clinical evidence provided they concluded that therapeutically, the **1000 mg suppositories** administered daily and 500 mg suppositories administered BID are comparable. The Committee commented that they were impressed that the manufacturer undertook the initiative to conduct a clinical trial in support of listing this product. Accordingly, it was recommended that **SALOFALK 1000 mg rectal suppository** be added to the *AHWDBL* as it provides a therapeutic and cost advantage.

■ **TRI-CYCLEN LO** (norgestimate/ ethinyl estradiol) (JOI) is a new oral contraceptive, and the only low estrogen triphasic product on the market to date. The Committee acknowledged that current clinical practice guidelines advocate the use of the lowest estrogen dose possible for oral contraceptives. This product is priced comparably with other currently listed oral contraceptives. Accordingly, **TRI-CYCLEN LO** has been recommended for addition to the *AHWDBL*.

■ **ZOMIG** (zolmitriptan) (AZC) **5 mg nasal spray** is a line extension to the currently listed 2.5 mg oral tablet and 2.5 mg Rapimelt tablet. The Committee acknowledged the parity pricing vis-à-vis the 2.5 mg tablet and recommended adding this product to the *AWHDBL* at parity with the other Zomig formulations. Accordingly, **ZOMIG 5 mg nasal spray** has been recommended for addition to the *AHWDBL* as a restricted benefit for patients 18 to 64 years of age, and via special authorization for patients 65 years of age and older. (Please refer to the current *AHWDBL* for a full listing of restricted benefit and special authorization criteria.)

Common Drug Review

The Common Drug Review (CDR) is a national process for reviewing new drugs and new combination products and providing formulary listing recommendations to participating publicly-funded federal, provincial and territorial (F/P/T) drug benefit plans in Canada. To find out more about the CDR or to view recommendations for products evaluated through the CDR, log onto the Canadian Coordinating Office for Health Technology Assessment website at www.ccohta.ca.

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The Review of Benefit Status (ROBS) Process

The Review of Benefit Status (ROBS) is a process by which the current *AHWDBL* products may be reviewed for continued value and appropriateness. In addition, Alberta Health and Wellness and/or the Expert Committee on Drug Evaluation and Therapeutics may at any time recommend that the benefit status of an individual product, class or category of drug products on the *AHWDBL* be reviewed. Developed in response to feedback from the Auditor General of Alberta, the ROBS process serves to assess the continued value of products after they have been added to the *AHWDBL*, thereby assisting with the sustainability of the government-sponsored drug programs.

As with the review of any product by the Committee, recommendations are made by considering the potential benefit to all patients covered by the government-sponsored drug programs. Following a ROBS review, the listing status of a product may remain unchanged, or could be revised or discontinued if one or more of the ROBS criteria, published in Section 1 of the *AHWDBL*, are met. If a change in benefit status is deemed to be warranted, manufacturers of the affected products are notified and provided with an opportunity to make a submission to the Committee prior to a final recommendation being made. The Expert Committee is the advisory committee to the Minister of Health and Wellness on matters pertaining to the coverage of products on the *AHWDBL*.

Highlights of Special Authorization Criteria Changes

■ **ARANESP*** (darbepoetin alfa) (AMG) was recently approved for the treatment of anemia in patients with non-myeloid malignancies, where anemia is due to the effect of concomitantly administered chemotherapy. The Expert Committee received a resubmission from the manufacturer to add this new indication to the current special authorization criteria. After careful consideration, the Committee recommended that the criteria for **ARANESP** be revised to include the following criterion: "For the treatment of anemia in patients with non-myeloid malignancies with low hemoglobin (<100 g/L) in whom blood transfusions are not possible due to transfusion reactions, cross-matching difficulties or iron overload. If hemoglobin is rising by more than 20 g/L per month, the dose of Aranesp should be reduced by about 25%. If hemoglobin exceeds 120 g/L, therapy should be discontinued until hemoglobin falls below 100 g/L, at which time Aranesp should be reinstituted at a dose 25% below the previous dose." Please refer to the current *AHWDBL* for a full listing of **ARANESP** special authorization criteria.

■ **IMITREX DF*** (sumatriptan succinate) (GSK) **50 mg tablet** will now be listed at parity with IMITREX DF 100 mg tablet. Previously available only for patients unable to tolerate the 100 mg tablet, the **50 mg tablet** will now be listed as a restricted benefit for patients 18 to 64 years of age inclusive for the treatment of acute migraine attacks in patients where other standard therapy has failed, and via special authorization with criteria for patients 65 years of age and older.

■ **PEGASYS RBV*** (peginterferon alfa-2a/ribavirin) (HLR), **PEGETRON*** (peginterferon alfa-2b/ribavirin) (SCH), and **PEGETRON REDIPEN*** (peginterferon alfa-2b/ribavirin) (SCH) have also had changes to their special authorization criteria. In response to feedback from, and in consultation with, physicians treating patients with chronic hepatitis C (HCV), the Committee has recommended the following changes:

- Patients with HCV genotype 2 or 3 and HIV co-infection will now be eligible for up to 48 weeks of treatment; however, these patients will be subject to the same testing requirements as required for patients with HCV genotype 1 (e.g. beginning with a stored baseline serum sample).
- Patients with HCV genotype 1 and who are post liver transplant will no longer be required to undergo HCV-RNA testing at the 12th week of treatment; however, these patients will still be required to meet requirements for testing at week 24.

***For a full listing of available formulations, restricted benefit and/or special authorization criteria, please refer to the current AHWDBL.**

Highlights of Interchangeable Products Added

■ **NOVO-BUPROPION SR** (bupropion hydrochloride) (NOP) 150 mg tablet is a first-entry generic product that was deemed interchangeable with the innovator, WELLBUTRIN SR 150 mg. At a savings of 32% over the innovator, the addition of this product to the *AHWDBL* could offer potential savings of over $290,000 to the Alberta Health and Wellness-sponsored drug programs in the first year of listing. Accordingly, it has been added to the *AHWDBL* in an interchangeable grouping **effective July 1, 2005**.

■ **NOVO-CILAZAPRIL** (cilazapril) (NOP) 1 mg, 2.5 mg & 5 mg tablets have been deemed interchangeable with the innovator, INHIBACE 1 mg, 2.5 mg & 5 mg tablets. The Committee recommended this first-entry generic product be added to the *AHWDBL* as it offers 37% savings over INHIBACE and anticipated savings of over $450,000 to the Alberta Health and Wellness-sponsored drug programs in the first year of listing, meeting criteria for FAST-TRACK addition. This product was added **effective May 1, 2005**.