the AHWDBL 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 (04/2005)

Cancidas Added via Special Authorization

■ **CANCIDAS** (caspofungin) (MFC) is the first in a new class of antifungal agents called glucan synthesis inhibitors, which have a distinct mechanism of action unlike currently available antifungals. **CANCIDAS** acts to target the fungal cell wall and has shown activity (in vitro) against various pathogenic fungi of the *Aspergillus* species. The Expert Committee recommended that **CANCIDAS** be added to the *AHWDBL* via special authorization with the following criteria for coverage:

"For esophageal candidiasis in patients who are intolerant to fluconazole and itraconazole, or who have failed both agents as evidenced by significant clinical deterioration due to the fungal infection during a course of therapy or no resolution after a full course of therapy."

Highlights of New Products Added

■ **CESAMET** (nabilone) (VCL) is indicated in adults for the management of severe nausea and vomiting associated with cancer chemotherapy. The **0.5 mg capsule** is a line extension to the currently listed 1 mg tablet. According to the manufacturer, the 0.5 mg strength will offer dose flexibility and assist with the safety profile of nabilone. The Committee indicated that there may be a potential therapeutic advantage if the 0.5 mg strength is used and less adverse events are experienced by patients. In addition, while both strengths are priced at parity on a per mg basis, the Committee indicated that there may also be a potential cost advantage if the 0.5 mg strength is used in place of the 1 mg strength. Accordingly, it was recommended that **CESAMET 0.5 mg capsule** be added to the *AHWDBL*.

■ **PEGETRON** (peginterferon alfa-2b/ribavirin) (SCH) injection kits, previously only available with the peginterferon alfa-2b component in a vial of lyophylized powder requiring reconstitution, are now available in kits containing **REDIPEN** pre-filled injection syringes in the following strengths: 80 mcg/0.5 mL, 100 mcg/0.5 mL, 120 mcg/0.5 mL and 150 mcg/0.5 mL. The new format is intended to ensure convenient and accurate dosing. The Committee agreed that the availability of pre-filled syringes for the peginterferon alfa-2b component may provide a therapeutic advantage. Therefore, **PEGETRON REDIPEN** kits have been recommended for addition to the *AHWDBL* subject to the same special authorization criteria and testing requirements applied to the currently listed **PEGETRON** kits. (Please refer to the current *AHWDBL* for a full listing of special authorization criteria.)

Bacid Removed from the AHWDBL

■ **BACID** (lactobacillus acidophilus) (ERF) capsules – A comprehensive review of the medical literature for therapeutic efficacy of *Lactobacillus acidophilus* in the treatment of irritable bowel syndrome was conducted as a component of the Review of Benefit Status (ROBS) process. The Expert Committee gave due consideration to the information available, as well as a response submitted by the manufacturer in support of maintaining this product on the *AHWDBL*. Nonetheless, it was noted that there does not appear to be good literature evidence to support the use of *Lactobacillus acidophilus*. Accordingly the Expert Committee has recommended that **BACID** be removed from the *AHWDBL*, **effective April 1, 2005**, in order to enable broader coverage of higher priority products, classes or categories of drugs on the *AHWDBL*. A transition period will apply to this product, and therefore claims will be honored for processing until June 15, 2005. More detailed information on the ROBS process, including ROBS criteria, can be found in the currently published *AHWDBL*.

Highlights of Products Not Added

■ **CONCERTA** (methylphenidate HCl) (JOI) 18 mg, 36 mg & 54 mg extended release tablets – The Expert Committee gave due consideration to a resubmission for this product. The Committee had previously recommended against listing **CONCERTA** as the information provided failed to demonstrate a therapeutic and/or cost advantage over other presently accepted therapies. After reviewing the information provided within the resubmission, the Committee remained unconvinced that the addition of this agent would merit the incremental costs. The Committee indicated that no new information had been provided that would warrant a change in their previous recommendation not to add **CONCERTA** to the *AHWDBL*.

■ **CUTIVATE** (fluticasone propionate) (GKC) 0.05% cream is indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses. Upon review, the Committee advised that Cutivate does not appear to provide any therapeutic advantage vis-à-vis currently available less costly alternatives (e.g. betamethasone, hydrocortisone). Therefore, it was recommended that this product not be added to the *AHWDBL*.

■ **GENTLAX-S** (bisacodyl/docusate sodium) (PUR) is an enteric-coated combination product consisting of a stimulant laxative (bisacodyl) with a stool softener (docusate). Cathartics and laxatives are not currently listed as benefits on the *AHWDBL*; however, there are a number of products included in the *Palliative Care Drug Benefit Supplement*. The Committee gave due consideration to the submitted information and indicated that, as the individual agents are currently available, and given the nominal potential for savings, this product does not offer a therapeutic and/or cost advantage over other presently listed therapies. Accordingly, the Committee recommended that **GENTLAX-S** not be added.

Selective COX-2 Inhibitors: Emerging Safety Concerns

On December 22, 2004, Health Canada issued an Advisory that states accumulating evidence indicates the use of selective Cox-2 inhibitors, in certain individuals, to be associated with an increased risk of heart attack or stroke, and recommended that, until further information becomes available, one should consider that there is a strong possibility of an increased risk of cardiovascular events when using selective COX-2 inhibitors.

Subsequently, on April 7, 2005, an additional Advisory was issued regarding a request from Health Canada to Pfizer Canada Inc. to voluntarily discontinue sales of Bextra (valdecoxib) due to ongoing review of information with regard to serious, potentially life-threatening skin reactions. In the April 2005 Advisory, Health Canada also informed Canadians of new restrictions on the use of Celebrex (celecoxib). For more information, please log onto the Health Canada website at http://www.hc-sc.gc.ca, and follow the links through Health Protection to the Advisories/Warnings section.