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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In this issue:

Highlights of New Products Added

■ **ACCOLATE** (zafirlukast) (ZEN) and **SINGULAIR** (montelukast sodium) (MSD) have been added via Special Authorization (SA) for individuals > 18 years for the prophylaxis and chronic treatment of asthma as an alternative to increased doses of inhaled glucocorticosteroids. Patients must be unable to use long-acting β_2 agonists or have demonstrated persistent symptoms despite use of long-acting β_2 agonists. These criteria are based upon the recently published Canadian Asthma Consensus Report [CMAJ 1999; 161 (11 Suppl)]. There is Level I evidence for use of long-acting β_2 agonists as add-on therapy to moderate or higher doses of inhaled glucocorticosteroids, whereas the use of Leukotriene-Receptor Antagonists (LTRAs) as add-on therapy is supported only by Level II evidence. As a result, long-acting β_2 agonists should be the primary treatment choice.

■ **ADVAIR** (combination of salmeterol and fluticasone) (GLA), which is indicated only for patients with reversible obstructive airways disease >12 years of age, was added as an unrestricted benefit. Advair has been shown to be superior to monotherapy with the single agents. According to the 1999 Canadian Asthma Consensus Report, inhaled long-acting β_2 agonists should be used as add-on therapy to moderate or higher doses of inhaled glucocorticosteroids to achieve control of persistent asthma symptoms (Level I).

■ **ALERTEC** (modafinil) (DAX) is the only drug approved in Canada, to date, specifically for the treatment of narcolepsy. This condition is estimated to affect approximately 1,500 Albertans. Alertec will be available to patients via SA according to the following: "For the treatment of documented narcolepsy when initially prescribed by a sleep specialist affiliated with a recognized level 1 lab or a general neurologist or a psychiatrist."

■ **MONUROL** (fosfomycin tromethamine) (PFR) is a single dose treatment for uncomplicated urinary tract infections (UTI). It has been shown to be comparable in efficacy to 7-10 days of fluoroquinolone therapy. Monurol is more costly than treatment of UTI with older agents or 3-day fluoroquinolone regimens; however, it is cost-effective when compared with 7-10 days of fluoroquinolones. Patient compliance is likely to improve with the single dose treatment.

■ **PLAVIX** (clopidogrel bisulfate) (WIN) has been available on the AHWDBL via SA since January 15, 2000 for the prevention of thrombosis post intravascular stent placement. SA criteria have now been broadened and Plavix will be covered for the prevention of cardiovascular events according to the following: "For those patients who are not able to take ASA either due to a contraindication to ASA or have recurrent events while on ASA."

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Clarification on Aricept Special Authorization (SA) Criteria

ARICEPT (donepezil hydrochloride) (PFI) was added to the AHWDBL via SA on December 1, 1999. The SA criteria for **ARICEPT** were developed and refined on the basis of "best practice" principles in order to provide reimbursement for patients with a MMSE (Mini-Mental State Examination) score between 10 to 26. As a point of clarification, SA reimbursement will be considered and continuously provided for those patients whose MMSE score rises above 26 while on **ARICEPT,** providing that their MMSE score at the time of starting **ARICEPT** was <26.

Products removed from the AHWDBL

Following a review of vaccines covered on the AHWDBL, the Alberta Health and Wellness Disease Control and Prevention Branch has recommended that Hepatitis B Immune Globulin (**BAYHEP**) and Tetanus Immune Globulin (**BAYTET)** be removed from the AHWDBL effective April 1, 2000. These products are recommended in post-exposure situations only on the advice of the Medical Officer of Health and will be supplied free of charge through regional public health. In addition, Influenza Virus Vaccine (**FLUVIRAL)** and Pneumococcal Vaccine (Polyvalent) (**PNEUMOVAX 23)** have also been removed and will be provided free of charge to individuals at risk. Additional information on availability can be obtained from regional public health.

Highlights of Deferred Products

■ **INHIBACE PLUS** (cilazapril and hydrochlorothiazide) (HLR) is deferred pending further review and discussion by the Expert Committee on the clinical value and cost-effectiveness of combination antihypertensive products in light of the recently published International Society of Hypertension Guidelines for the Management of Hypertension.

■ **XENICAL** (orlistat) (HLR) has been shown to have significant effects on weight loss, weight regain and improvement in metabolic profile of obese individuals. These outcomes, including an effect on glycemic control, may be of particular benefit to Type II diabetics; however, this must be explored further. As a result, Xenical has been deferred for further review to allow consultation with the manufacturer and Alberta diabetologists regarding these benefits and impact upon long-term health outcomes. Furthermore, additional information is required regarding guidance on when patients should discontinue Xenical.

Highlights of Products Not Added

■ **ALDARA** (imiquimod) (MMH), which is indicated for the treatment of external genital and perianal warts/condyloma acuminata in adults, was not added. A less expensive alternate therapy, WARTEC (podophyllotoxin) (PMS), is available on the AHWDBL and is also a patient-applied therapy.

■ **RELENZA** (zanamivir) (GLA) is indicated for the treatment of uncomplicated acute illness due to influenza virus in patients 12 years and older who have been symptomatic for no more than 2 days. The primary endpoint in clinical trials was the median time to alleviation of major signs and symptoms of influenza. Results showed a statistically significant reduction of 1 day in this endpoint; however, no data have been provided which show a significant impact of Relenza on major complications of influenza or on mortality and morbidity endpoints. Furthermore, there is insufficient evidence for efficacy in high risk patients (e.g. elderly or patients with underlying respiratory disease).

■ **TOBI** (tobramycin sulfate) (PGC), a preservative-free formulation of tobramycin sulfate for inhalation, was not added to the AHWDBL. Consultations with infectious diseases and cystic fibrosis specialists indicated that the theoretical risk of lung damage due to the preservative has not been seen clinically. It appears that the compounding of preservative-free tobramycin solution for inhalation can be done relatively easily and at lower cost. Therefore there is no incentive for adding this expensive formulation to the AHWDBL

■ **VIAGRA** (sildenafil citrate) (PFI), which is indicated for the treatment of erectile dysfunction (ED), has not been added. Following consultation with Alberta experts, there was no strong support for addition of this product to the AHWDBL. Products for the treatment of ED have historically not been covered on Alberta government-sponsored drug programs.

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Expert Committee profiles: Dr. Judith Baker

Dr. Judith Baker joined the Expert Committee in May 1999. She obtained her BSP (Pharmacy), M.Sc. (Pharmaceutics) and Ph.D. in Biological Psychiatry from the University of Saskatchewan. Dr. Baker is a member of numerous professional associations including the Alberta Pharmaceutical Association (APhA) of which she was President in 1990, the Canadian Pharmacists Association (CPhA), the Canadian College of Clinical Pharmacy, the Capital Health Region (CHR) Pharmacists Association and the Canadian College of Neuropsychopharmacology. Dr. Baker has been a member of and has chaired many committees including the APhA Regulatory Affairs Committee, the APhA Drug Schedules Committee, and the CHR Pharmacists Long-term Care Committee. Dr. Baker has also held teaching appointments at the University of Alberta and the University of Aston (UK). In addition to practicing as a part-time community pharmacist, Dr. Baker is currently involved in many projects related to pharmacy practice through her consulting roles for the Alberta Wellnet Pharmacy Information Network, APhA, AMA, CPhA, Health Outcome Pharmacies, and Capital Health Authority. Dr. Baker currently chairs the APhA Practice Review Committee and is a member of the AMA Cognitive Impairment Clinical Practice working group and a member of the Alberta Wellnet Pharmacy Network Project Team. Dr. Baker's vision of the Alberta government-sponsored drug programs is that they should be comprehensive in terms of the range of drug therapies offered but must be administered in a fiscally responsible manner. Solutions will have to be found to the questions such as "Who will benefit most from treatment?" and "How can we afford to pay for the drug treatment?" that are posed by the new and extremely expensive "biotechnology" drugs.