the DBL report

Issue #14, January 2000

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

In this issue:

Note:

A reduced version of the DBL report will accompany each issue of the updates to the AHWDBL. This publication provides an opportunity for communication between the Expert Committee and Alberta physicians and pharmacists. Questions and suggestions on issues of interest are welcome.

Highlights of New Products Added

■ **ACCURETIC (quinapril hydrochloride/hydrochlorothiazide**) (PDA) the Expert Committee has revisited the issue of fixed-ratio combination products in the treatment of hypertension and has come to the conclusion that after the patient is titrated to the appropriate dose with the single agents, the use of the combination product can be of therapeutic value, particularly for the management of seniors with hypertension already on multidrug regimens. The two available strengths of Accuretic allow the dose of quinapril to be increased while the hydrochlorothiazide dose remains constant.

■ **ARICEPT (donepezil hydrochloride)** (PFI) has become available via Special Authorization (SA) effective December 1, 1999. SA criteria for Aricept have been developed and refined on the basis of "best practice" principles following review of the literature and consultation with specialists. Existing patients with a MMSE (Mini-Mental State Examination) score of 10 to 26 are eligible for coverage and any prescriber in Alberta may submit SA requests for such patients. All physicians can initiate therapy with Aricept for new patients with a MMSE score of 14 to 26. Only physicians with recognized expertise in the management of dementia disorders can initiate therapy in new patients with a MMSE score of 10 to 13. Once initiated, therapy with Aricept can be continuously reimbursed for all patients with a score of 10 to 26.

■ **COSOPT (dorzolamide hydrochloride and timolol maleate)** (MSD) this combination product for the control of ocular hypertension and open-angle glaucoma was added, since it provides cost savings compared to the administration of single agents and can potentially improve compliance in the treatment of conditions that often require combination therapy.

■ **HUMATROPE (somatropin)** (LIL) is now available via SA for the replacement of endogenous growth hormone (GH) in adults with severe GH deficiency. Information is required regarding the results of a diagnostic insulin tolerance test. GH values < 3 mcg/L during hypoglycemia are indicative of severe GH deficiency.

Highlights of Deferred Products

■ **GLUCONORM (repaglinide)** (NNA) is a short-acting insulin secretagogue that offers a short onset of action, a short half-life, and less risk of hypoglycemia if a patient misses a meal. Since it is more expensive than the listed Least Cost Alternative (LCA) products, glyburide and gliclazide, further discussion is required to determine if it is cost-effective.

■ **TOBI (tobramycin sulfate)** (PGC) this preservative-free formulation of tobramycin sulfate for inhalation received "Priority Review" by the Therapeu-

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Why are drug products under review not eligible for special authorization or made available on an exception basis?

Physicians and Pharmacists often ask why drug products under review are not eligible for special authorization, or made available on an exception basis?

The Expert Committee on Drug Evaluation and Therapeutics was established by the Minister of Health and Wellness to consider the scientific, therapeutic, clinical, and socio-economic merits of drug products. This was done to ensure therapeutic advantage and cost-effectiveness of new drug products added to the *Alberta Health & Wellness Drug Benefit List (AHWDBL).* If a drug product were made available before it was actually reviewed by the Committee, this would circumvent the purpose of the drug review process and the mandate of the Expert Committee.

In addition, it would be unethical to provide coverage for a drug product prior to the review being completed, in the event that the outcome of the review is a decision not to add the drug product to the *AHWDBL*. Please note that the Minister of Health and Wellness makes final decisions after reviewing the recommendations of the Expert Committee and Alberta Health and Wellness.

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tic Products Programme (TPP) of Health Canada. Data showed efficacy versus placebo; however, therapeutic advantage over the use of the parenteral solution as inhalation therapy has not been shown in clinical trials. Tobi is significantly more expensive than the parenteral solution. Consultations with infectious diseases and cystic fibrosis specialists are on-going.

Expert Committee profiles: Dr. James Silvius

Dr. James Silvius joined the Expert Committee in May 1999. Prior to this, he obtained his MD degree from the University of Alberta and has undertaken clinical training in internal medicine and geriatrics in Edmonton and Halifax. Dr. Silvius obtained the Royal College Certificate of Special Competence in Geriatric Medicine in 1990. He is currently Clinical Associate Professor in the Division of Geriatric Medicine at the University of Calgary (U of C) and Deputy Chief of the Regional Division of Geriatric Medicine, U of C. His research interests are in the management of dementia. Dr. Silvius is a member of both the Canadian and Alberta Medical Associations, the Canadian Society of Geriatric Medicine and the AMA-APhA Joint Communications Advisory Committee for Drug Use in the Elderly. He is a consultant geriatrician for the David Thompson Health Region and the Site Leader for Seniors' Health (Acute Care) at the Peter Lougheed Centre in Calgary. Dr. Silvius chairs the Pharmacy and Therapeutics Committee (Continuing Care) of the Calgary Regional Health Authority.

Dr Silvius sees the programs sponsored by AH&W as having a vital role to play in medical management of patients in Alberta. As new therapies become available for conditions where there have not been therapies or where they provide decided advantages over traditional agents, a mechanism must be in place to allow these new products to be affordable for those who would most benefit from them. In Dr. Silvius' opinion, the Expert Committee assists with recommendations on these therapies. Questions continually arise as to appropriate roles for new agents. Unrestricted and potentially inappropriate use, with costs borne by society, is not in the best interest of society. Failure to recommend agents for appropriate coverage is not in the best interest of the patient. According to Dr. Silvius, the role of the Committee increasingly is to attempt to make recommendations that balance the competing demands of the need for agents to be made expeditiously available, with an awareness of societal costs associated with their use. "It is a difficult task, and not an exact science!"

ABC 80103 / 40359 99/11