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:

Changes in Special Authorization Criteria

Special Authorization for Cerezyme

Highlights of New Products Added

Expert Committee Profiles: Dr. Stephen C. Newman

Highlights of Deferred Products

Changes in Special Authorization Criteria

■ Special Authorization criteria for **ACCOLATE** (zafirlukast) (AZC) and **SINGULAIR** (montelukast) (MFC) have been revised. These products will now be available "for the prophylaxis and chronic treatment of asthma in patients over the age of 18 who meet one of the following criteria: a) when used as adjunctive therapy in patients who do not respond adequately to high doses of inhaled glucocortico-steroids and long-acting β_2-agonists. Patients must be unable to use long-acting β_2-agonists or have demonstrated persistent symptoms while on long-acting β_2-agonists, OR b) cannot operate inhaler devices. For the prophylaxis of exercise-induced bronchoconstriction in patients over the age of 18 where tachyphylaxis exists for long acting β_2-agonists." SINGULAIR remains an unrestricted benefit for patients 6 to 18 years of age whereas ACCOLATE is unrestricted for patients 12 to 18 years of age.

■ Special Authorization criteria regarding the use of **NEORAL** (cyclosporine) (NOV) for the treatment of rheumatoid arthritis have also been modified: cyclosporine will now be available "for the treatment of severe rheumatoid arthritis in patients who are unable to tolerate or have failed an adequate trial of methotrexate. This drug product must be prescribed by a specialist in Rheumatology".

Special Authorization for Cerezyme

■ **CEREZYME** (imiglucerase) (GZM) was added to the AHWDBL effective May 1, 2000, by Special Authorization for the management of Gaucher Disease. Gaucher Disease is a rare genetic disorder that requires enzyme replacement therapy. Physicians who have patients who may benefit from imiglucerase are required to submit medical information to Alberta Blue Cross. The information will be reviewed for eligibility according to established guidelines.

Highlights of New Products Added

■ **Fixed-dose Combination Antihypertensive Agents -** the therapeutic value of fixed-dose combination products (e.g. ACE inhibitor/diuretic and ARB/diuretic) for the treatment of hypertension has been recently recognized in several reports (e.g. 1999 WHO International Society of Hypertension Guidelines and Adherence to Management of High Blood Pressure: Recommendations of the Canadian Coalition for High Blood Pressure Prevention and Control - 1998). While these products are not indicated for initial therapy and should be used only in patients already titrated to the optimal dose of the two components, the

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Highlights of Deferred Products

■ **AVANDIA** (rosiglitazone maleate) (SMJ) is the first "glitazone" to be brought to market in Canada and is the first agent to be indicated for the treatment of insulin resistance. Efficacy of AVANDIA, alone or in combination with metformin or sulphonylurea drugs, has been demonstrated in Type II diabetic patients not controlled by diet and exercise. Significant reductions in glycemic parameters were accompanied by a decrease in levels of insulin and insulin precursors; however, the long term impact on hard clinical endpoints remains unclear. Because of the high cost of this drug, further discussions are in progress to determine the appropriate use of AVANDIA and to define the population of patients that would be expected to benefit the most from treatment with this product.

■ **VISUDYNE** (verteporfin) (CBV) is a drug used for age-related macular degeneration (AMD) in "Visudyne Therapy," a two-stage process requiring intravenous administration of verteporfin and irradiation of the macula with non-thermal laser red light. Results of the clinical investigation in patients with predominantly classic subfoveal choroidal neovascularization show significant efficacy in preventing degeneration of visual acuity parameters; however, it appears that patients will likely require multiple treatments and the long term benefit in terms of prevention of blindness remains to be clarified. Discussions with expert retinal ophthalmologists in the province and the manufacturer are necessary to gather further information regarding the incidence of AMD in Alberta and the expected long-term benefit of this high cost treatment.

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appropriate use of these agents provides therapeutic benefit over concomitant therapy in terms of improved compliance, particularly in the elderly. The following products have been added to the AHWDBL effective October 1, 2000: **AVALIDE** (irbesartan/hydrochlorothiazide) (WIN), **DIOVAN HCT** (valsartan/hydrochlorothiazide) (NOV), **HYZAAR DS** (losartan/hydrochlorothiazide) (MFC), **INHIBACE PLUS** (cilazapril/hydrochlorothiazide) (HLR), **PRINZIDE** (lisinopril/hydrochlorothiazide) (MFC), **ZESTORETIC** (lisinopril/hydrochlorothiazide) (AZC).

Please note that although Prinivil and Zestril have been designated as interchangeable, no data to support the interchangeability of Prinzide and Zestoretic have been reviewed, therefore these products are considered non-interchangeable.

■ **QVAR** (beclomethasone dipropionate) (MMH) is a CFC-free MDI that uses hydrofluoroalkane-13a (HFA) as a propellant. Lung deposition of beclomethasone is enhanced and oropharyngeal deposition is reduced due to smaller particle size when delivered via QVAR compared to the CFC-containing formulation of beclomethasone. Clinical trials have shown that approximately 2.6 times the dose of CFC-beclomethasone is required to produce the same effect on lung function as QVAR.

Expert Committee Profiles: Dr. Stephen C. Newman

Dr. Stephen C. Newman joined the Expert Committee in May 1999. He obtained his BSc (mathematics) and M.A. (mathematics) from Dalhousie University (Halifax, NS), and received his M.D. and MSc (epidemiology) from the University of Toronto. Dr. Newman is a professor in the Department of Psychiatry at the University of Alberta and holds a cross-appointment with the Department of Public Health Sciences and the Department of Family Medicine. He has been the recipient of the Alberta Heritage Foundation for Medical Research (AHFMR) Scholar Award and has served on numerous scientific advisory committees, most recently on the Scientific Review Committee for the Alberta Mental Health Research Fund, the Alberta Health Collaboration Advisory Committee for the Health Research Fund (Alberta Health and AHFMR) and the Research Ethics Board at the Faculty of Medicine (U of A). Dr. Newman is a member of various professional associations including the Canadian Society of Epidemiology and Biostatistics, the Society for Epidemiologic Research and the American Psychopathological Association. Furthermore, he teaches in the areas of statistics, epidemiology and critical appraisal of medical literature; his research interests include the study of prevalence of psychiatric disorders, in particular, geriatric depression and the incidence of suicide attempts.

Dr. Newman's vision of the Alberta government-sponsored drug programs is that they should ensure that Albertans have access to the best drug therapies available that are consistent with scientifically demonstrated efficacy.

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