the DBL report

Issue #13, October 1999

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

We would like to bring to your attention the similarity in brand names between the new anti-inflammatory **CELEBREX** (celecoxib) and the antidepressant **CELEXA** (citalopram hydrobromide).

Highlights of New Products 'Fast-Tracked'

A number of products met Alberta Health and Wellness (AHW) criteria for fast-track and were added either July 1 or August 1, 1999:

■ **CELEBREX** (celecoxib) (SEA) is the first of a new category of NSAIDS — the COX-II inhibitors. At therapeutic doses COX-II inhibitors affect proinflammatory prostaglandins but not COX-I mediated prostaglandins which are responsible for homeostatic effects. Data have shown that the GI safety profile of Celebrex is superior to that of other NSAIDs. It does not inhibit platelet aggregation and does appear to cause clinically important renal changes in patients with normal renal function; potential effects in patients with severe renal insufficiency have yet to be determined. This product had received "Priority Review" status by the Therapeutic Products Programme (TPP) of Health Canada and was listed as an unrestricted benefit effective August 1, 1999.

■ **REBETRON** (ribavirin/ interferon alfa-2b) (SCH) for the treatment of hepatitis C received "Priority Review" status by TPP and was made available by Special Authorization effective August 1, 1999 to allow patients that were receiving ribavirin through the TPP Special Access Program (SAP) to complete 48 weeks of treatment. The SAP program was discontinued for ribavirin on April 30, 1999. Further review is necessary to determine coverage for the use of this combination therapy in the general hepatitis C population.

■ **SANDOSTATIN LAR** (ocreotide acetate) (NOV) received "Priority Review" status by TPP and has been added to the AHWDBL effective July 1, 1999 "for the treatment of acromegaly". The new indications of diarrhea associated with carcinoid tumours and VIP-omas are currently under reveiw. This product is administered by intramuscular injection once a month whereas Sandostatin SC is administered subcutaneously three times a day. The impact of the "LAR" formulation on patient acceptability and compliance will be substantial.

Highlights of New Products Added

■ **ACCOLATE** (zafirlukast) (ZEN) was added as an unrestricted benefit for individuals 12 to 18 years of age ONLY. Leukotriene receptor antagonists (LTRA) offer therapeutic advantage for children due to the potential to reduce dosage of steroids which may impact on bone development. Coverage of LTRA for the management of adult asthma remains under review.

■ **ATACAND** (candesartan cilexetil) (AST) and **AVAPRO** (irbesartan) (BMS) were added. These new Angiotensin II AT_1 Receptor Blockers (ARBs) at $1.08 day offer therapeutic advantage compared to **COZAAR** (losartan at $1.10-2.20/day)

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Highlights of New Products Added

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in terms of pharmacokinetic profile and 24 hour blood pressure control. It appears that antihypertensive control is satisfactorily obtained with QD administration while at times, BID administration of losartan is required. **DIOVAN** (valsartan) at $1.05/day is also covered. It should be noted that clinical data comparing the new ARBs to losartan are available; however, only pharmacodynamic studies have directly compared the new ARBs.

■ **CELEXA** (citalopram hydrobromide) (VLH) is a highly selective and potent SSRI with minimal effects on norepinephrine and dopamine reuptake. Citalopram exhibits weak or no inhibition of the isozymes of the cytochrome P450; as a consequence it has a low potential for drug interactions. It is less expensive than the current market leader antidepressants (i.e. **ZOLOFT** and **PAXIL**).

■ **HEPTOVIR** (lamivudine) (GLA) has expanded criteria for coverage via Special Authorization which are "To prevent hepatitis B re-infection in post-liver transplant patients".

Change in Benefit Status

Effective October 1, 1999, Special Authorization will no longer be required for **FORADIL** (formoterol fumarate) 12 mcg/dose inhalation capsule, **OXEZE** (formoterol fumarate dihydrate) 12 mcg/dose aerosol and **SEREVENT** (salmeterol xinafoate) 25 mcg/dose aerosol, 50 mcg/dose inhalation disk and 50 mcg/dose metered inhalation powder. These products are now unrestricted benefits.

New LCA Products Added

New interchangeable groupings have been established with the inclusion of additional first entry generic products on July 1, August 1 and October 1, 1999. Some products were fast-tracked because of the substantial savings they will bring to the government-sponsored programs.

Drug	Generic Brand	Innovator Brand	Date Added
Amiodarone	Alti-Amiodarone	Cordarone	August 1, 1999
Divalproex sodium	Apo-Divalproex, Novo-Divalproex, Nu-Divalproex	Epival	July 1, 1999
Enalapril maleate	Nu-Enalapril	Vasotec	July 1, 1999
Fenofibrate	Apo-Feno-Micro, PMS-Fenofibrate	Lipidil Micro	July 1, 1999
Fenofibrate	Gen-Fenofibrate	Lipidil Micro	August 1, 1999
Gentamicin (ophthalmic ointment)	Gentamicin Ophthalmic Ointment	Garamycin	October 1, 1999
Ipratropium (nasal spray)	PMS-Ipratropium	Atrovent	October 1, 1999
Tobramycin (ophthalmic solution)	Tomycine PMS-Tobramycin	Tobrex	October 1, 1999

Note: a 60-day transition period will apply to all new LCA categories.

Highlights of Products Not Added

■ **ARICEPT** (donepezil hydrochloride) (PFI) remains *deferred* as discussions with the manufacturer are on-going in order to define a way of making the drug available to an appropriate population of patients that would benefit from this treatment.

■ **INHIBACE PLUS** (cilaprazil/hydrochlorothiazide) (HLR) is a 'fixed combination' product. The recommendation not to add this product to the AHWDBL is consistent with the fact that fixed ratio/poly pharmacy dosage forms do not offer the flexibility of dose titration necessary for optimal treatment of hypertension and are not the agents of choice in clinical practice.

■ **EVISTA** (raloxifene hydrochloride) (LIL) remains *deferred* for further discussion since no new data have been provided to support efficacy in terms of a significant impact on hip fractures, cardiovascular and breast/uterine cancer outcomes.

■ **PLAVIX** (clopidogrel bisulfate) (WIN) which is indicated for the secondary prevention of vascular ischemic events in patients with a history of symptomatic atherosclerotic disease, remains a *deferred* product. AHW and the manufacturer are working towards ensuring appropriate use of clopidogrel if it is covered on the government sponsored drug programs. Additional information has been requested pertaining to the use of clopidogrel 'post-stent'.

ABC 80103 / 40359 99/08