the DBL report

**Issue #55, April 2010**

*An Official Accompaniment to the Alberta Health and Wellness Drug Benefit List (AHWDBL) produced by Alberta Blue Cross*

*The Expert Committee on Drug Evaluation and Therapeutics (ECDET)*



## In this issue:



***Highlights of recent changes to the AHWDBL and other topics of general interest***

# *Highlights of New Products Added*

■ **ATACAND PLUS** (candesartan cilexetil/hydrochlorothiazide) (AZC) **32 mg/12.5 mg & 32 mg/25 mg tablets** are angiotensin receptor blocker and diuretic combination products indicated for the treatment of essential hypertension. These line extensions to currently listed ATACAND and **ATACAND PLUS** products were added to the *AHWDBL* for providing a therapeutic and/or cost advantage.

■ **COVERSYL PLUS HD** (perindopril erbumine/indapamide hemihydrate) (SEV) **8 mg/2.5 tablet**, a combination angiotensin converting enzyme inhibitor and diuretic, is a line extension to currently listed COVERSYL and COVERSYL PLUS products. This product provides a therapeutic and/or cost advantage and has been added to the *AHWDBL* accordingly.

■ **PHL-AMLODIPINE** (amlodipine besylate) (PHH) **2.5 mg tablet** and **PMS-AMLODIPINE** (amlodipine besylate) (PMS) **2.5 mg tablet** are line extensions to **PHL-AMLODIPINE** and **PMS-AMLODIPINE** 5 mg & 10 mg tablets, respectively. This lower strength is supported in the dosage recommendations of the product monograph, for use in children and patients with reduced liver function. In addition, this strength was seen as a useful tool for dosage titration. Accordingly, the Committee recommended these products be added to the *AHWDBL*.

■ **VESICARE** (solifenacin succinate) (ASP) **5 mg & 10 mg tablets** have been added to the *AHWDBL* via step therapy/special authorization. This product, originally reviewed via the CDR, is indicated for treatment of overactive bladder, and will be available for patients who are intolerant to oxybutynin.

# *Change to Botox Unit of Issue*

Please be aware that the Unit of Issue for the **BOTOX** (botulinum toxin type A) (ALL) vial injection (DIN 01981501) has changed from vial to UNIT. **BOTOX** is available in 100 unit and 200 unit vials.

***A complete list of changes, as well as the full AHWDBL may be accessed at https://www.ab.bluecross.ca/dbl/publications.html.***

****Please refer to the current AHWDBL for explanations of coverage, full coverage details of products and listing of coverage criteria (where applicable).****

ABC 81171 (4/2010)

## *Highlights of Coverage Criteria Changes*

■ Changes to criteria for coverage were made for the following products:

- **ARANESP** (darbepoetin) (AMG) and **EPREX** (epoetin alfa) (JOI) for the indication of anemia of chronic renal failure
- **EXJADE** (deferasirox) (NOV)
- **EZETROL** (ezetimibe) (MFC)
- **HUMIRA** (adalimumab) (ABB) for the indication of Crohn's Disease

■ Criteria were also revised for the following biologic agents regarding the treatment of Rheumatoid Arthritis:

- **ENBREL** (etanercept) (AMG)
- **HUMIRA** (adalimumab) (ABB)
- **KINERET** (anakinra) (BVM)
- **ORENCIA** (abatacept) (BMS)
- **REMICADE** (infliximab) (SCH)
- **RITUXAN** (rituximab) (HLR)

**For full details regarding SA criteria changes please refer to the current *AHWDBL*.**

## *Reinstatement of Premarin Tablets*

■ **PREMARIN** (conjugated estrogens) (WAY) **0.3 mg, 0.625 mg & 1.25 mg tablets** had previously been removed from the *AHWDBL* due to a significant increase in price (with claims to be honored until March 31, 2010). Subsequent to notification in January 2010 of a substantial price decrease, these products will be reinstated on the *AHWDBL*, as regular benefits.

## *Orencia for Juvenile Idiopathic Arthritis*

■ **ORENCIA** (abatacept) (BMS) **250 mg/vial (base) injection** was originally reviewed via the CDR process for the new indication of **Juvenile Idiopathic Arthritis (JIA)**. The Canadian Expert Drug Advisory Committee (CEDAC) recommended **ORENCIA** be listed for JIA in children who are intolerant to, or have not had an adequate response to ENBREL (etanercept). Following consultation regarding coverage criteria with Alberta rheumatologists, including pediatric specialists, the Expert Committee has recommended this product be listed via special authorization. Stemming from the discussion of **ORENCIA**, the criteria for ENBREL in Juvenile Rheumatoid Arthritis have also been revised.

## *ROBS Reviews of Insulins and Oral Anti-Diabetic Agents*

As part of the Review of Benefit Status (ROBS) process, comprehensive clinical reviews of insulin and oral anti-diabetic agents were undertaken. The Expert Committee gave due consideration to the information available and recommended the following changes to the listing of specific products:

■ **APO-CHLORPROPAMIDE** (chlorpropamide) (APX) **100 mg & 250 mg tablets** and **APO-TOLBUTAMIDE** (tolbutamide) (APX) **500 mg tablet** were recommended to be de-listed from the *AHWDBL* as they were found to no longer possess demonstrated therapeutic advantage compared to other presently accepted therapies or treatments, as well as to enable broader coverage of higher priority products.

■ **HUMALOG MIX25** (insulin lispro/insulin lispro protamine) (LIL) **25%/75% (100 U/mL)** was also recommended to be de-listed from the *AHWDBL* as it was found to no longer possess demonstrated therapeutic advantage compared to other presently accepted therapies or treatments, as well as to enable broader coverage of higher priority products. In 2007, **HUMALOG MIX50** (insulin lispro/ insulin lispro protamine) (LIL) **50%/50% (100 U/mL)** was not added to the *AHWDBL* as it was noted that the clinical data did not demonstrate a clear therapeutic advantage for this product over other currently listed alternatives.

■ **PIOGLITAZONE HYDROCHLORIDE 15 mg, 30 mg & 45 mg tablets** (APX, COB, MYP, NOP, PMS, RPH, SDZ, TAK) and **AVANDIA** (rosiglitazone maleate) (GSK) **2 mg, 4 mg & 8 mg tablets** were recommended to move from regular benefits to step therapy/special authorization. Coverage will be available where patients do not respond to an adequate trial of, or are intolerant or have a contraindication to metformin. **AVANDAMET** (rosiglitazone maleate/metformin hydrochloride) (GSK) **1 mg/500 mg, 2 mg/500 mg, 2 mg/1000 mg, 4 mg/500 mg & 4 mg/1000 mg tablets** were also recommended to move to a step therapy/ special authorization listing for patients not responding to an adequate trial of metformin alone.

**Patients currently receiving coverage for the affected products will continue to receive coverage.**

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## *Fucithalmic De-Listed*

■ **FUCITHALMIC (UNPRESERVED)** (fusidic acid) (LEO) **1% ophthalmic gel** has received no claims since being added to the *AHWDBL* in April 2006. Following a comprehensive review by the Expert Committee, and due consideration of a response from the manufacturer, this product was recommended to be de-listed from the *AHWDBL*.

## *Highlights of Interchangeable Products Added*

■ The following are first-entry generic products deemed interchangeable with the respective innovator products, and recommended for addition to the *AHWDBL* in interchangeable groupings:

- **APO-GLICLAZIDE MR** (gliclazide) (APX) **30 mg tablet**, for DIAMICRON MR
- **CO OLANZAPINE ODT** (olanzapine) (COB), **PMS-OLANZAPINE** (olanzapine) (PMS) and **SANDOZ OLANZAPINE** (olanzapine) (SDZ) **5 mg & 10 mg orally disintegrating tablets**, for ZYPREXA ZYDIS
- **SANDOZ RIVASTIGMINE** (rivastigmine hydrogen tartrate) (SDZ) **1.5 mg, 3 mg, 4.5 mg & 6 mg capsules**, for EXELON, added to the *AHWDBL* via special authorization in an interchangeable grouping, effective November 15, 2009.

## *Highlights of Products Not Added*

■ **DURAGESIC MAT** (fentanyl) (JOI) **25 mcg/hr, 50 mcg/hr, 75 mcg/hr & 100 mcg/hr transdermal patches** are a newer matrix formulation intended to eventually replace the original reservoir patches. This product is priced at parity with the currently listed DURAGESIC reservoir formulation; however, a number of generic products are listed in an interchangeable grouping with DURAGESIC. It was felt information provided in the product submission failed to support a therapeutic advantage of **DURAGESIC MAT** over currently listed alternatives, and with LCA pricing applied to the grouping, it does not provide a cost advantage. Accordingly, this product was not added to the *AHWDBL*.

■ **LUMIGAN** (bimatoprost) (ALL) **0.01% ophthalmic solution** was reviewed as a line extension to the currently listed LUMIGAN 0.03%. The Committee indicated that this product failed to demonstrate a therapeutic or cost advantage. Accordingly, it was not recommended for addition to the *AHWDBL*. Further, concern was expressed over the concentration of benzalkonium chloride in **LUMIGAN 0.01%**.

■ **NORLEVO** (levonorgestrel) (BAI) **0.75 mg tablet** – The Expert Committee reviewed the manufacturer's submission and concluded that this product failed to provide a therapeutic or cost advantage over existing therapy. Accordingly, this product was not recommended for addition to the *AHWDBL*.

■ **PMS-OLANZAPINE ODT** (olanzapine) (PMS) **15 mg orally disintegrating tablet** was reviewed as a line-extension to the other strengths of **PMS-OLANZAPINE ODT**, as the 15 mg strength of the innovator ZYPREXA ZYDIS has not been listed on the *AHWDBL*. **PMS-OLANZAPINE ODT 15 mg** was not recommended for addition as it was not found to provide a therapeutic or cost advantage.

■ **RENAGEL** (sevelamer hydrochloride) (GZM) **800 mg tablet** was reviewed subsequent to a resubmission by the manufacturer. As part of their review, the Committee requested information via the Health Technology Inquiry Service (HTIS) provided by the Canadian Agency for Drugs and Technologies in Health (CADTH). Due consideration was given to all available information; however, the Committee concluded that no new information had been provided that would warrant a change in the original recommendation, not to add this product to the *AHWDBL*.

■ **APO-CLARITHROMYCIN** (clarithromycin) (APX) **250 mg & 500 mg tablets** – A resubmission for this product was reviewed; however, it was concluded that the information provided to date was insufficient to deem **APO-CLARITHROMYCIN 250 mg & 500 mg tablets** interchangeable with the innovator under the submission requirements published at the time of review.

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■ **MINT-TOPIRAMATE** (topiramate) (MPI) **25 mg, 100 mg & 200 mg tablets** – Upon reviewing a resubmission for this product, the Committee concluded that the bioequivalence data provided utilizing a non-Canadian reference product was insufficient to allow the designation of **MINT-TOPIRAMATE** as interchangeable with other currently listed topiramate products.

■ **APO-RIVASTIGMINE** (rivastigmine) (APX), **MYLAN-RIVASTIGMINE** (rivastigmine) (MYP), **NOVO-RIVASTIGMINE** (rivastigmine) (NOP), **PMS-RIVASTIGMINE** (rivastigmine) (PMS) and **RATIO-RIVASTIGMINE** (rivastigmine) (RPH) **1.5 mg, 3 mg & 4.5 mg capsules** were unable to be deemed interchangeable with the innovator, EXELON 1.5 mg, 3 mg & 4.5 mg capsules, as the bioavailability data provided in the manufacturer's product submissions failed to meet submission requirements in effect at the time of review. Please note, the **6 mg** strengths of these generic products were added to the *AHWDBL* in an interchangeable grouping, as information was available to allow a determination of interchangeability with the innovator, EXELON 6 mg capsule.

■ The following products, reviewed via the CDR process, received recommendations not to list from the Canadian Expert Drug Advisory Committee (CEDAC):

- **DUODOPA** (levodopa/carbidopa) (SLO) **20 mg/mL/5 mg/mL intraintestinal gel**
- **FORTEO** (teriparatide) (LIL) **250 mcg/mL injection**
- **INSPRA** (eplerenone) (PFI) **25 mg & 50 mg tablets**
- **LEVEMIR PENFILL** (insulin detemir) (NNA) **100 U/mL cartridge injection**
- **LYRICA** (pregabalin) (PFI) **25 mg, 50 mg, 75 mg, 150 mg & 300 mg capsules**
- **PRISTIQ** (desvenlafaxine succinate) (WAY) **50 mg & 100 mg extended release tablets**

■ In addition, **COPAXONE** (glatiramir acetate) (TMP) **20 mg/ mg injection syringe** was reviewed for the indication of Clinically Isolated Syndrome via the CDR process and received a recommendation not to list for this indication.

For further information on the CDR review and CEDAC recommendations for these products please visit http://www.cadth.ca/index.php/en/cdr.

## *Updated Price Policy*

As a component of Phase 2 of the Alberta Pharmaceutical Strategy (APS), an announcement was made in October 2009 that the price for **new** generic drugs would be reduced to 45% of the brand price. In addition, starting in April 2010, the price for generic drugs in established interchangeable groupings will be reduced to 56% of the brand price. Accordingly, an updated pricing policy for products listed on, or considered for addition to, the *AHWDBL* was published on February 12, 2010. To view the Price Policy, please visit https://www.ab.bluecross.ca/dbl/pdfs/ahwdbl_sec1_prpol.pdf.

## *Expedited Review for Interchangeable Products & Revised Submission Requirements*

Further, related to the key component concerning timely drug approval in Phase 1 of the APS, an Expedited Review Process has been introduced for select interchangeable products. As a result, the product Submission Requirements have also been reviewed and updated. Further details on the submission and review process for all products, including interchangeable products, may be found at https://www.ab.bluecross.ca/dbl/pdfs/ahwdbl_sec1_drug.pdf.

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