the RxDBL 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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Highlights of New Products Added

■ **ASACOL** (5-aminosalicylic acid) (PGA) **800 mg enteric-coated tablet** is a line extension to the currently listed 400 mg tablet. The Expert Committee noted that patients receiving ASACOL 400 mg for the treatment of ulcerative colitis may be required to take up to 12 tablets daily. With the introduction of the **800 mg** strength, patients would be able to take fewer tablets. In addition, it was noted that the **800 mg** strength is priced at parity with 2 x 400 mg. Accordingly, this product was recommended for addition as it provides an advantage of more convenient dosing for patients requiring higher doses of **ASACOL**.

■ **RISPERDAL M-TAB** (risperidone) (JOI) is an orally disintegrating or quick-dissolve tablet formulation of risperidone. The 0.5 mg, 1 mg & 2 mg strengths have been available on the *AHWDBL* since February 1, 2004. The manufacturer requested that the **3 mg & 4 mg** strengths also be considered for coverage, with the justification that these additional strengths would offer better dosing flexibility and ease of use. In addition, the Committee noted that they are available at lower cost than the corresponding strengths of the traditional tablet formulation. Accordingly, **RISPERDAL M-TAB 3 mg & 4 mg** have been added to the *AHWDBL*.

Highlights of Interchangeable Products Added

■ **APO-SUMATRIPTAN** (APX)**, CO SUMATRIPTAN** (COB)**, GEN-SUMATRIPTAN** (GEN) and **PMS-SUMATRIPTAN** (PMS) (sumatriptan succinate) **50 mg & 100 mg tablets** are all first-entry generic products that have been deemed interchangeable with IMITREX DF 50 mg & 100 mg tablets. These products qualified for fast-track addition to the *AHWDBL* by virtue of the savings offered to the government-sponsored programs. As a result, these products were added **effective November 1, 2005**.

■ **PMS-TOPIRAMATE** (topiramate) 25 mg, 100 mg & 200 mg tablets were deemed interchangeable with the innovator, TOPAMAX 25 mg, 100 mg & 200 mg, respectively. Due to the magnitude of savings offered by these products, they qualified for fast-track addition to the *AHWDBL*. Accordingly, **PMS-TOPIRAMATE** was added to the list effective **November 1, 2005**.

■ **PMS-OXYCODONE/ACETAMINOPHEN** (oxycodone HCl/acetaminophen) 5 mg/325 mg tablet was originally reviewed in 2003, at which time the Committee indicated that insufficient evidence had been provided to make a designation of interchangeability. In their resubmission, the manufacturer presented data from a recently conducted bioequivalence study that allowed **PMS-OXYCODONE/ACETAMINOPHEN** to be deemed interchangeable with the innovator, PERCOCET. As a result, this product was recommended for addition to the *AHWDBL*.

Optional Special Authorization (OSA)

New coverage criteria was introduced for the following quinolone antibiotics, **effective November 15, 2005**:

- **CIPROFLOXACIN** (all brands) 250 mg, 500 mg & 750 mg tablets
- **CIPRO** (ciprofloxacin HCl) (YNO) 2 mg/mL IV minibags for injection and 100 mg/mL oral suspension
- **LEVAQUIN** (levofloxacin) (JOI) 250 mg & 500 mg tablets
- **OFLOXACIN** (all brands) 200 mg, 300 mg & 400 mg tablets

In addition, also **effective November 15, 2005**, the following two new products were added to the *AHWDBL*, via OSA:

- **AVELOX** (moxifloxacin HCl) (YNO) 400 mg tablet
- **TEQUIN** (gatifloxacin) (BMS) 400 mg tablet

*Norfloxacin continues to be eligible for coverage as an unrestricted benefit.

Two options are available to prescribers to enable patient eligibility for coverage. Prescribers may choose to register as a 'designated prescriber', and will not be required to fill out special authorization (SA) documentation for coverage (i.e. as long as the prescription is written for a defined set of criteria); or they may choose not to register. Physicians not registering as 'designated prescribers' will be required to apply for SA coverage on a patient's behalf. In this case, a first forgiveness rule will apply allowing for payment of an initial claim; however, subsequent claims for the same active ingredient within a 90-day period will require SA coverage.

For further details and a full listing of criteria, please refer to section 3A in the current *AHWDBL*. Additional information is also available to prescribers via the OSA registration package (mailed to Alberta physicians in October 2005), and to pharmacy providers in *The Pharmacy Benefact* (Number 171, October 2005).

Highlights of Products Not Added

■ **ALDARA** (imiquimod) (MMH) 5% cream was resubmitted for consideration as a result of the new indication of clinically typical, nonhyperkeratotic, nonhypertrophic actinic keratosis on the face or balding scalp in adults. The Expert Committee gave due consideration to the information provided; however, the evidence failed to support that **ALDARA** offered a therapeutic and/or cost advantage over other topical and ablative therapies. Hence, the Committee concluded that this product should not be added to the *AHWDBL*.

■ **LIPIDIL EZ** (fenofibrate) (AOO) 48 mg & 145 mg tablets were submitted as line extensions to the currently listed LIPIDIL MICRO and SUPRA products. According to the manufacturer, **LIPIDIL EZ** has no food effect and may allow for a dose reduction. However, the Committee noted that submitted bioequivalence data did not demonstrate that **LIPIDIL EZ** offered an advantage over LIPIDIL SUPRA in terms of food effect. As a result, this product was recommended not to be listed.

Topical Products Used in the Treatment of Acne

A comprehensive review of the medical literature pertaining to topical products used in the treatment of acne was conducted as a component of the Review of Benefit Status (ROBS) process. The Expert Committee gave due consideration to the available information and recommended changes to the benefit status of a number of these products, **effective January 1, 2006**. A transition period will apply to products recommended for removal from the *AHWDBL*, and therefore claims for these products will be honored for processing until March 1, 2006. More detailed information on the ROBS process, including ROBS criteria, can be found in the currently published *AHWDBL*.

The following products will be delisted:

- **BENZOYL PEROXIDE** products (all brands) of 5% or less
- **DALACIN T** (clindamycin phosphate) (PFI) 1% topical solution
- **SANS-ACNE** (erythromycin/alcohol) (GAL) 2%/44% topical lotion

The following products will be moved to coverage via special authorization (Please refer to the current *AHWDBL* for a full listing of available formulations and special authorization criteria):

- **BENZOYL PEROXIDE** products (all brands) of 10% or greater
- **TRETINOIN** products (all brands)
- **CLINDOXYL** (clindamycin phosphate/benzoyl peroxide) (STI) 1%/5% topical gel
- **STIEVAMYCIN** (erythromycin/tretinoin) **MILD, MODERATE & FORTE**
- **NEO-MEDROL ACNE** (methylprednisolone acetate/neomycin sulfate/aluminum chlorhydroxide complex/sulfur) (PFI) 2.5 mg/mL/2.5 mg/mL/100 mg/mL/50 mg/mL topical lotion
- **MEDROL ACNE** (methylprednisolone acetate/aluminum chlorhydroxide complex/sulfur) (PFI) 2.5 mg/mL/100 mg/mL/50 mg/mL topical lotion
- **SULFACET-R** (sulfur/sulfacetamide sodium) (DER) 5%/10% topical lotion

Please note, the following product has also been added via special authorization **effective January 1, 2006** (Please refer to the current *AHWDBL* for full listing of special authorization criteria):

- **BENZACLIN** (clindamycin phosphate/benzoyl peroxide) (DER) 1%/5% topical gel