the DBL report

Issue #34, January 2005

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

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ABC 81171 (01/2005)

Highlights from the Review of Antimicrobials

As detailed in the *Alberta Health and Wellness Drug Benefit List (AHWDBL),* the Review of Benefit Status (ROBS) is a process by which the benefit status of products, classes or categories of drugs listed on the *AHWDBL* may be reviewed. At the request of the Minister of Health and Wellness, the Expert Committee on Drug Evaluation and Therapeutics recently completed a review of antimicrobials listed on the *AHWDBL*. This comprehensive review was performed in consultation with various health care professionals representing several areas of clinical practice, including individuals with expertise in infectious diseases. The goal was to evaluate antimicrobials that are currently listed and those under consideration for addition to the *AHWDBL*, and to provide advice and recommendations to encourage optimal utilization and aid in the control and prevention of antimicrobial resistance.

The following is a summary of the changes in benefit status of affected antimicrobials. For further information on the coverage of specific products or the ROBS process, please refer to the current *AHWDBL*.

Special Authorization

As a result of the antimicrobial review, the benefit status of the following products will be revised from unrestricted listing to special authorization (SA), ***effective March 1, 2005***:

- **AMPICILLIN** (ampicillin) (all brands)
  250 mg & 500 mg capsules and 25 mg/mL & 50 mg/mL oral suspensions
- **CEFADROXIL** (cefadroxil) (all brands)
  500 mg capsule
- **PRIMAXIN** (imipenem monohydrate) (MFC)
  250 mg/250 mg & 500 mg/500 mg injections
- **TAZOCIN** (piperacillin sodium/tazobactam sodium) (WAY)
  2 G/250 mg, 3 G/375 mg & 4 G/500 mg injections
- **VANCOCIN** (vancomycin HCl) (LIL)
  125 mg & 250 mg capsules

In addition, the following products had revisions to their SA criteria:

- **LINEZOLID** (zyvoxam) (PHD) 600 mg tablet
- **MERREM** (meropenem) (AZC) 500 mg & 1 G injections

Lastly, ***effective January 1, 2005***, the following new product has been added via SA:

- **KETEK** (telithromycin) (AVE) 400 mg tablet has been added to the *AHWDBL* for the treatment of community acquired pneumonia or acute exacerbation of chronic bronchitis, after failure of first line therapy.

For additional details and a full listing of SA criteria for these products, please refer to the current *AHWDBL*.

Highlights of Products Added

- **METHOTREXATE** (methotrexate) (MNP) 10 mg tablet is a line extension to the currently listed Mayne Pharma 10 mg/mL and 25 mg/mL injections. This product will facilitate dosing in patients who require higher doses of oral methotrexate and are currently required to take multiple tablets (e.g. 4 x 2.5 mg).

- **APO-ATENIDONE** (atenolol/chlorthalidone) (APX) 50/25 mg and 100/25 mg are first-entry generic products that were deemed interchangeable with the innovator, Tenoretic. These products are priced 32% < the innovator, and therefore, their addition to the *AHWDBL* could offer potential savings of over $90,000 in the first year of listing.

- **GEN-MIRTAZAPINE** (mirtazapine) (GPM) 30 mg tablet is a subsequent-entry generic product that was recommended for listing in an interchangeable grouping with the other currently listed mirtazapine 30 mg products. This product is priced 35% < the innovator, Remeron, and 12.5% < the current LCA. Therefore, the listing of this product on the *AHWDBL* will offer additional savings, as it will become the new LCA.

Discontinued Listings

The antimicrobial review also resulted in the following products being removed from the *AHWDBL*, effective January 1, 2005:

- **CEFACLOR** (cefaclor) (all brands) 250 mg & 500 mg capsules and 25 mg/mL, 50 mg/mL & 75 mg/mL oral suspensions
- **BACITRACIN** (bacitracin) (PHD) 50,000 U/vial injection
- **CEFIZOX** (ceftizoxime sodium) (GSK) 1 G/vial & 2 G/vial injections
- **CEFOTAN** (cefotetan disodium) (WAY) 1 G/vial & 2 G/vial injections
- **CEFOXITIN SODIUM** (NOP) 1 G/vial & 2 G/vial injections
- **HIP-REX** (methenamine hippurate) (MMH) 1 G tablet
- **MANDELAMINE** (methenamine mandelate) (PFI) 500 mg tablet
- **MONUROL** (fosfomycin tromethamine) (PUR) 3 G sachet
- **NEGGRAM** (nalidixic acid) (WIN) 500 mg caplet
- **PEDIAZOLE** (erythromycin ethylsuccinate/sulfisoxazole acetyl) (ABB) 40 mg/mL/120 mg/ml oral suspension
- **PONDOCILLIN** (pivampicillin) (LEO) 500 mg tablet & 35 mg/mL oral suspension
- **TIMENTIN** (ticarcillin disodium/potassium clavulanate) (GSK) 3 G/100 mg injection vial
- **ZINACEF** (cefuroxime sodium) (GSK) 750 mg/vial & 1.5 G/vial injections

Recently discontinued products also recommended for delisting include **SELEXID** (pivmecillinam HCl) (LEO) 200 mg tablet, **PENGLOBE** (bacampicillin HCl) (AZC) 400 mg tablet, **ROVAMYCINE-500** (spiramycin) (AVE) 1,500,000 U capsule and **NETROMYCIN** (netilmicin sulfate) (SCH) 50 mg/mL injection. ***Please note: A transition period will apply for the removal of all the aforementioned products and therefore, claims for these products will be honored for processing until April 1, 2005.***

In making their recommendation to remove these products from the *AHWDBL*, the Expert Committee indicated that these products no longer possess demonstrated therapeutic advantage compared to other presently accepted therapies or treatments for which they are indicated.

Additional Highlights

- **COMBIGAN** (brimonidine tartrate/timolol maleate) (ALL) 0.2%/0.5% ophthalmic solution has been added to the *AHWDBL* via special authorization, with the following criteria for coverage: “For patients who have had an inadequate response in lowering of intraocular pressure with a beta-blocking agent alone and are currently receiving the individual components (i.e. brimonidine and timolol) in combination. Special authorization may be granted for 12 months.”

- **VALCYTE** (valganciclovir) (HLR) 450 mg tablet – An additional special authorization criterion was added in order to allow coverage “For the prevention of CMV disease in solid organ transplant patients at high risk (i.e. risk is defined as donor +ve/recipient -ve for CMV or recipient +ve post-active treatment of CMV disease with IV ganciclovir). Special authorization may be granted for 3 months.”