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SASKATCHEWAN FORMULARY COMMITTEE BULLETIN
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NEW LISTINGS

NEW EXCEPTION DRUG STATUS AGENTS

Effective July 1, 2001 the following products will be available under Exception Drug Status subject to the indicated criteria.

- **Lopinavir/ritonavir, capsule, 133.3mg/33.3mg; oral solution, 80mg/20mg (mL) (Kaletra-ABB)**
  Exception Drug Status Criteria:
  For management of HIV disease. This drug, as with other antivirals in treatment of HIV, should be used under the direction of an infectious disease specialist.

- **Raloxifene HCl, tablet, 60mg (Evista-LIL)**
  Exception Drug Status Criteria:
  - For treatment of osteoporosis in women unable to tolerate listed bisphosphonates.
  - For treatment of osteoporosis in women who do not respond to listed bisphosphonates after receiving treatment for one year.

NEW DOSAGE FORMS/STRENGTHS OF EXCEPTION DRUG STATUS AGENTS

Effective July 1, 2001 the following products will be covered under the same Exception Drug Status criteria as the currently listed forms.

- Epoetin alfa, pre-filled syringe, 6000IU/0.6mL, 8000IU/0.8mL (Eprex-JAN)
- Olanzapine, orally disintegrating tablet, 5mg, 10mg (Zyprexa Zydis-LIL)
- Quetiapine, tablet, 150mg (Seroquel-AST)
- Tacrolimus, capsule, 0.5mg (Prograf-FUJ)
- Zolmitriptan, orally dispersible tablet, 2.5mg (Zomig Rapimelt-AST)

FIRST ENTRY GENERIC

- Amoxicillin trihydrate/potassium clavulanate, tablet, 250mg/125mg, 500mg/125mg (Apo-Amoxi Clav-APX)
- Hydrocortisone valerate, topical cream, 0.2%; topical ointment, 0.2% (Hydroval-OPT)
- Hydromorphone HCl, tablet, 1mg, 8mg (pms-Hydromorphone-PMS)
- Trimethoprim, tablet, 100mg, 200mg (Apo-Trimethoprim-APX)
- Propafenone HCl, tablet, 150mg, 300mg (Apo-Propafenone-APX)
- Warfarin, tablet, 1mg, 2mg, 2.5mg, 3mg, 4mg, 5mg, 10mg (Taro-Warfarin-TAR)

NEW FULL FORMULARY LISTINGS

- Cerivastatin sodium, tablet, 0.8mg (Baycol-BAY)
- Glucose oxidase/peroxidase reagent, strip (Precision Xtra-MDS)
- Glucose oxidase/peroxidase reagent, strip (One Touch Ultra-LSN)
- Levonorgestrel, extended release intrauterine insert, 52mg (Mirena-BEX)

INTERCHANGEABILITY OF TARO-WARFARIN AND COUMADIN

Effective July 1, 2001 Taro-Warfarin will be listed as interchangeable with Coumadin. This listing follows an extensive and comprehensive review by the Drug Quality Assessment Committee of the bioequivalence and interchangeability of these two products.

Taro-Warfarin has met Health Canada's bioequivalence standards for narrow therapeutic range drugs and has been determined by both Health Canada and the US Food and Drug Administration (FDA) to be bioequivalent to Coumadin.

In addition to the bioequivalence studies required by Health Canada, Taro Pharmaceuticals conducted a four period replicate study. This study confirmed the switchability and interchangeability of Taro-Warfarin with Coumadin.

Based on all the clinical and scientific evidence submitted, the Drug Quality Assessment Committee and the Saskatchewan Formulary Committee have determined that these products can safely be substituted.

All warfarin therapy requires careful titration of the drug and regular testing to monitor the level of anticoagulation. Many factors, such as diet and other drugs, can affect the patient's response to warfarin and therefore the dosage must be individualized for each patient based on clinical and laboratory findings.

MODIFICATIONS TO CURRENT EXCEPTION DRUG STATUS CRITERIA

Effective July 1, 2001 the Exception Drug status criteria for the following products will be as indicated.

- **Calcitonin salmon, nasal spray, 200IU/dose (Miacalcin-NVR)**
  Additional EDS criteria:
  - For treatment of osteoporosis in patients unable to tolerate listed bisphosphonates.
  - For treatment of osteoporosis in patients not responding to listed bisphosphonates after treatment for one year.

- **Modafinil, tablet, 100mg (Alertec-DPY)**
  EDS criteria has been revised to:
  For treatment of narcolepsy and idiopathic CNS hypersomnia in patients whose symptoms of daytime sleepiness are not controlled on methylphenidate or dextroamphetamine.

- **Quetiapine, tablet, 25mg, 100mg, 150mg, 200mg (Seroquel-AST)**
  Additional EDS criteria:
  For treatment of psychosis caused by drugs used in the treatment of Parkinson's Disease.

ON-LINE FORMULARY

The Saskatchewan Health Drug Plan Formulary is available on-line. It can be accessed via the Internet @ ***http://formulary.drugplan.health.gov.sk.ca***
Recent additions to the Application Forms section include the new Exception Drug Status Fax form and the Aricept/Exelon Exception Drug Status Application form. Also available on this site is information regarding the Drug Plan & Extended Benefits Branch programs and Formulary Committee bulletins.

SOME OF THE PRODUCTS CURRENTLY UNDER REVIEW BY THE FORMULARY COMMITTEE

- Etanercept, powder for injection, 25mg/vial (Enbrel-WYA)
- Hydroxybutyrate dehydrogenase, strip (Precision Xtra Blood Ketone Test-MDS)
- Infliximab, lyophilized concentrate for iv injection, 100mg/20mL vial (Remicade-SCH)
- Methadone HCl, oral concentrate, 10mg/mL (Metadol-PMS)
- Sevelamer HCl, capsule, 403mg (Renagel-GZY)
- Warfarin, tablet, 1mg, 2mg, 2.5mg, 4mg, 5mg, 10mg (Apo-Warfarin-APX)

PRODUCTS REVIEWED AND NOT RECOMMENDED FOR LISTING

- **Ethinyl estradiol/norethindrone acetate, tablet, 5ug/1mg (FemHRT-PFI)**
  The clinical benefit does not justify the significantly higher cost of this product over listed alternatives.
- **Riluzole, tablet, 50mg (Rilutek-AVT)**
  The clinical benefit does not justify the cost. It was noted that clinical studies did not demonstrate an improvement in the quality of life.
- **Testosterone therapeutic system, 12.2mg (2.5mg/day) (Androderm-PAL)**
  The clinical benefit does not justify the significantly higher cost over the listed injectable form.

REVIEW OF THE EXCEPTION DRUG STATUS LISTING OF SALMETEROL, FORMOTEROL, MONTELUKAST, AND ZAFIRLUKAST

The Saskatchewan Formulary Committee recently reviewed the Exception Drug Status (EDS) listing of these drugs when used in asthma and has reaffirmed the current EDS listing. The EDS criteria is consistent with the Canadian Asthma Consensus Report. Concerns were expressed by the Committee that these products would be used first line if they were listed as full formulary.

Verteporfin, injection, 2mg/ml (15mg/vial) (Visudyne-CBV)

Visudyne is now available through the Regina and Saskatoon Health Districts. The cost of the treatment will be covered for patients with age related macular degeneration with predominately classic subfoveal choroidal neovascularization (CNV). This is currently the only indication for which Health Canada has approved this drug. Visudyne therapy is a two-stage process requiring administration of intravenous verteporfin followed by activation of the drug by a non-thermal laser. Patients should see their physician or ophthalmologist for a referral to one of the retinal specialists in the Saskatoon or Regina Health Districts who will be providing the Visudyne/laser therapy.

Hospital Benefit Drug List
The updated Hospital Benefit Drug List is located in Appendix B in the Formulary.

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