

## QUARTERLY UPDATE TO THE 51st EDITION OF THE SASKATCHEWAN FORMULARY

### NEW LISTINGS

#### NEW EXCEPTION DRUG STATUS

##### AGENTS

Effective September 14, 2001 the following product is available under Exception Drug Status subject to the indicated criteria.

- **Etanercept, powder for injection, 25mg/vial (Enbrel-WYA)**  
**Exception Drug Status Criteria:**  
For patients with active rheumatoid arthritis who have failed on at least two DMARDs. Treatment should be combined with an immunosuppressant (e.g. methotrexate, azathioprine).  
*This product should be used in consultation with a specialist in this area.*

**ENBREL PATIENT REGISTRY**  
The manufacturer of Enbrel (Wyeth-Ayerst) requires physicians to enrol patients in their Enbrel Patient Registry prior to prescribing Enbrel. The registry will provide the physician with a "Distribution Control Number" to write on the prescription. Pharmacists will be unable to fill prescriptions for Enbrel without this number. Further information can be obtained by contacting Wyeth-Ayerst or by calling: 1-877-9ENBREL.

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

- **Amprenavir, capsule, 50mg, 150mg; oral solution, 15mg/mL (Agenerase-GSK)**  
**Exception Drug Status Criteria:**  
For the management of HIV disease in patients who have failed other protease inhibitor combinations. *This drug, as with other antivirals in the treatment of HIV, should be used under the direction of an infectious disease specialist.*
- **Estradiol & norethindrone acetate/estradiol, transdermal therapeutic system (8), 50ug & 140ug/50ug, 50ug & 250ug/50ug (Estalis-Sequi-NVR)**  
**Exception Drug Status Criteria:**  
For treatment in patients who are unable to tolerate oral hormone replacement therapy (either estrogen or progesterone).
- **Gatifloxacin, tablet, 400mg (Tequin-BMY)**  
**Exception Drug Status Criteria:**
  - (a) For treatment of infections in patients with underlying lung disease not responding to first-line antibiotics.
  - (b) For treatment of infections caused by organisms known to be resistant to alternative antibiotics.
  - (c) For treatment of infections in patients allergic to alternative antibiotics.
  - (d) For step-down care following hospital separation in patients treated with the intravenous form.

- **Peginterferon alfa-2b, powder for injection (vial), 50ug/0.5mL, 80ug/0.5mL, 120ug/0.5mL, 150ug/0.5mL (PEG-Intron-SCH)**  
**Exception Drug Status Criteria:**  
For treatment of chronic active Hepatitis C. Coverage will be provided for an initial 6 month period with potential renewal for 2 additional 6 month periods.
- **Sirolimus, oral solution, 1mg/mL (Rapamune-WYA)**  
**Exception Drug Status Criteria:**  
For prophylaxis of graft rejection in transplant patients.

#### NEW FULL FORMULARY LISTINGS

- Eprosartan mesylate, tablet, 600mg (Teveten-SLV)
- Hydroxybutyrate dehydrogenase, strip (Precision Xtra Blood Ketone Test-MDS)  
*The maximum quantity that can be claimed per beneficiary through the Drug Plan is 1 box (8 test strips) per year.*
- Warfarin, tablet, 1mg, 2mg, 2.5mg, 4mg, 5mg, 10mg (Apo-Warfarin-APX)  
*Interchangeable with currently listed brands.*

The Saskatchewan review committees have designated Apo-Warfarin as interchangeable with currently listed brands. Additional INR testing over and above that normally required for routine patient monitoring is not warranted if patients are switched between interchangeable warfarin brands.

**MODIFICATIONS TO CURRENT EXCEPTION DRUG STATUS CRITERIA**

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

- **Dihydroergotamine mesylate, nasal spray, 4mg/mL (Migranal-NVR)**  
Exception Drug Status criteria has been revised to:  
For the treatment of migraines where standard therapy such as an analgesic has failed or cannot be tolerated.
- **Risedronate sodium, tablet, 5mg (Actonel-PGA)**  
Exception Drug Status criteria has been revised to:
  - (a) For treatment of osteoporosis in patients who do not respond to etidronate disodium/calcium (Didrocal) after receiving it for one year.
  - (b) For treatment of osteoporosis in patients unable to tolerate etidronate disodium/calcium (Didrocal).
  - (c) For treatment of osteoporosis in patients who have fresh fractures.

**MODIFICATIONS TO CURRENT EXCEPTION DRUG STATUS CRITERIA FOR "TRIPTANS"**

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

- **Sumatriptan, tablet, 25mg, 50mg, 100mg; injection solution, 6mg/0.5mL; nasal spray, 5mg, 20mg (Imitrex-GSK)**  
Exception Drug Status criteria has been revised to:  
For the treatment of migraine headaches where other standard therapy such as an analgesic has failed. *Eligibility will be restricted to beneficiaries over 18 and under 65 years of age.*

The maximum quantity that can be claimed through the Drug Plan is limited to 6 doses per 30 days within a 60 day period. Patients requiring more than 12 doses in a consecutive 60 day period should be considered for migraine prophylaxis therapy if they are not already receiving such therapy.

- **Naratriptan HCl, tablet, 1mg, 2.5mg (Amerge-GSK)**  
Same Exception Drug Status criteria as for sumatriptan (Imitrex-GSK) published in this bulletin.
- **Rizatriptan benzoate, tablet, 5mg, 10mg (Maxalt-MSD); wafer, 5mg, 10mg (Maxalt RPD-MSD)**  
Same Exception Drug Status criteria as for sumatriptan (Imitrex-GSK) published in this bulletin.
- **Zolmitriptan, tablet, 2.5mg (Zomig-AST); orally dispersible tablet, 2.5mg (Zomig Rapimelt-AST)**  
Same Exception Drug Status criteria as for sumatriptan (Imitrex-GSK) published in this bulletin.

**PRODUCTS REVIEWED AND NOT RECOMMENDED FOR LISTING**

- **Methadone HCl, oral concentrate, 10mg/mL (Metadol-PMS)**  
This product provides little advantage over the existing method of provision of methadone as a compound and is more expensive, especially at higher doses.

**SOME OF THE PRODUCTS CURRENTLY UNDER REVIEW BY THE FORMULARY COMMITTEE**

- Atorvastatin calcium, tablet, 80mg (Lipitor-PFI)
- Candesartan cilexetil/hydrochlorothiazide, tablet, 16mg/12.5mg (Atacand Plus-AST)
- Entacapone, tablet, 200mg (Comtan-NVR)
- Estradiol, transdermal therapeutic system (pkg), 37.5ug, 50ug, 75ug, 100ug (Estradot-NVR)
- Galantamine hydrobromide, tablet, 4mg, 8mg, 12mg (Reminyl-JAN)
- Glucose oxidase/peroxidase reagent, strip (Accu-Chek Compact-BOM)
- Hydromorphone HCl, controlled-release capsule, 18mg (Hydromorph Contin-PFR)
- Infliximab, lyophilized concentrate for iv injection, 100mg/20mL vial (Remicade-SCH)
- Meloxicam, tablet, 7.5mg, 15mg (Mobicox-BOE)
- Mirtazapine, tablet, 30mg (Remeron-ORG)
- Sevelamer HCl, capsule, 403mg (Renagel-GZY)

***Cerivastatin (Baycol)***

*Bayer Inc. has discontinued marketing and distributing Baycol 0.2mg, 0.3mg, 0.4mg, and 0.8mg tablets. Post-marketing reports of rhabdomyolysis revealed an increased rate of rhabdomyolysis with Baycol relative to other statins, especially when gemfibrozil is prescribed as a co-medication. Bayer Inc. has therefore decided to withdraw Baycol from the market. Patients who are currently taking Baycol should have their Baycol discontinued and be switched to alternative therapy.*

## **HOSPITAL BENEFIT DRUG LIST UPDATE September, 2001**

See Appendix B of the Formulary for the Hospital Benefit Drug List. The following are revisions to the published criteria and additions to the list.

### **EPTIFIBITIDE INJECTION (Integrilin™)**

Restricted Coverage: When used on the recommendation of a cardiologist for the treatment of High Risk Unstable Angina and Non-ST Segment Elevation Myocardial Infarction according to the guidelines of The American College of Cardiology & American Heart Association, Inc. (Circulation, 2000; 102: 1193-1209)

### **TIROFIBAN INJECTION (Aggrastat™)**

Restricted Coverage: When used on the recommendation of a cardiologist for the treatment of High Risk Unstable Angina and Non-ST Segment Elevation Myocardial Infarction according to the guidelines of The American College of Cardiology & American Heart Association, Inc. (Circulation, 2000; 102: 1193-1209)

### **PANTOPRAZOLE IV INJECTION (Panto IV™)**

Restricted Coverage:

- when ordered in a high dose (80mg IV bolus followed by 8mg/hour x 72 hours) by a gastroenterologist or general surgeon following endoscopic hemostasis for non-variceal upper gastrointestinal bleeding; or
- when ordered as 40mg IV q24h for patients who are strict NPO (i.e. not taking any oral medications or oral diet) and have:
  - non-variceal upper GI bleeding not requiring endoscopic hemostasis; or
  - severe erosive esophagitis; or
  - Exception Drug Status (EDS) for a Proton Pump Inhibitor taken prior to admission.

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**EDS UPDATE EFFECTIVE SEPTEMBER 14, 2001**

<b><u>GENERIC &amp; TRADE NAME</u></b>	<b><u>STRENGTH &amp; FORM</u></b>	<b><u>DIN</u></b>	<b><u>UNIT PRICE</u></b>	<b><u>LEGEND</u></b>
Etanercept <i>Enbrel</i>	25mg/vial powdr for inj (vial)	02242903	172.5000	<i>EDS</i>

**FORMULARY AND EDS UPDATES EFFECTIVE OCTOBER 1, 2001**

<b><u>GENERIC &amp; TRADE NAME</u></b>	<b><u>STRENGTH &amp; FORM</u></b>	<b><u>DIN</u></b>	<b><u>UNIT PRICE</u></b>	<b><u>LEGEND</u></b>
Alfacalcidol <i>One-Alpha</i>	2ug/mL (mL) oral drops	02240329	5.0746	<i>EDS</i>
Amoxicillin trihydrate/ potassium clavulanate <i>Alti-Amoxi Clav</i>	250mg/125mg tablet	02243770	0.6758	<i>I/C EDS</i>
<i>Alti-Amoxi Clav</i>	500mg/125mg tablet	02243771	1.0136	<i>I/C EDS</i>
Amprenavir <i>Agenerase</i>	50mg capsule	02243541	0.6944	<i>EDS</i>
<i>Agenerase</i>	150mg capsule	02243542	2.0450	<i>EDS</i>
<i>Agenerase</i>	15mg/mL oral sol	02243543	0.2084	<i>EDS</i>
Doxazosin mesylate <i>Alti-Doxazosin Mesylate</i>	1mg tablet	02243215	0.3760	<i>I/C</i>
<i>Alti-Doxazosin Mesylate</i>	2mg tablet	02243216	0.4512	<i>I/C</i>
<i>Alti-Doxazosin Mesylate</i>	4mg tablet	02243217	0.5865	<i>I/C</i>
Eprosartan mesylate <i>Teveten</i>	600mg tablet	02243942	1.1067	
Estradiol & norethindrone acetate/estradiol <i>Estalis-Sequi</i>	50ug & 140ug/50ug (pkg)	02243529	22.4100	<i>EDS</i>
<i>Estalis-Sequi</i>	50ug & 250ug/50ug (pkg)	02243530	22.4100	<i>not I/C EDS</i>
Fenofibrate <i>Novo-Fenofibrate Micronized</i>	200mg capsule	02243552	1.1816	<i>I/C EDS</i>
Gatifloxacin <i>Tequin</i>	400mg tablet	02243182	5.4359	<i>EDS</i>
Gentamicin SO4 <i>Gentamicin (Sabex)</i>	40mg/mL inj sol	02242652	4.3000	<i>I/C</i>
Hydroxybutyrate dehydrogenase <i>Precision Xtra Blood Ketone Test</i>	strip	00950896	1.6344	
Labetalol HCl <i>Apo-Labetalol</i>	100mg tablet	02243538	0.1787	<i>I/C</i>
<i>Apo-Labetalol</i>	200mg tablet	02243539	0.3161	<i>I/C</i>
Peginterferon alfa-2b <i>PEG-Intron</i>	50ug/0.5mL vial	02242966	425.8500	<i>EDS</i>
<i>PEG-Intron</i>	80ug/0.5mL vial	02242967	425.8500	<i>EDS</i>
<i>PEG-Intron</i>	120ug/0.5mL vial	02242968	425.8500	<i>EDS</i>
<i>PEG-Intron</i>	150ug/0.5mL vial	02242969	425.8500	<i>EDS</i>

**FORMULARY AND EDS UPDATES EFFECTIVE OCTOBER 1, 2001**

<u>GENERIC &amp; TRADE NAME</u>	<u>STRENGTH &amp; FORM</u>	<u>DIN</u>	<u>UNIT PRICE</u>	<u>LEGEND</u>
Pravastatin				
<i>Apo-Pravastatin</i>	10mg tablet	02243506	1.1491	<i>I/C</i>
<i>Apo-Pravastatin</i>	20mg tablet	02243507	1.3560	<i>I/C</i>
<i>Apo-Pravastatin</i>	40mg tablet	02243508	1.6330	<i>I/C</i>
Propafenone HCl				
<i>pms-Propafenone</i>	150mg tablet	02243727	0.7395	<i>I/C</i>
<i>pms-Propafenone</i>	300mg tablet	02243728	1.3037	<i>I/C</i>
Ranitidine				
<i>Dom-Ranitidine</i>	150mg tablet	02243038	0.4605	<i>I/C</i>
<i>Dom-Ranitidine</i>	300mg tablet	02243039	0.8871	<i>I/C</i>
Sirolimus				
<i>Rapamune</i>	1mg/mL oral sol	02243237	7.3889	<i>EDS</i>
Temazepam				
<i>Alti-Temazepam</i>	15mg capsule	02243023	0.1196	<i>I/C</i>
<i>Alti-Temazepam</i>	30mg capsule	02243024	0.1439	<i>I/C</i>
Warfarin				
<i>Apo-Warfarin</i>	1mg tablet	02242924	0.2149	<i>I/C</i>
<i>Apo-Warfarin</i>	2mg tablet	02242925	0.2272	<i>I/C</i>
<i>Apo-Warfarin</i>	2.5mg tablet	02242926	0.1821	<i>I/C</i>
<i>Apo-Warfarin</i>	4mg tablet	02242927	0.2817	<i>I/C</i>
<i>Apo-Warfarin</i>	5mg tablet	02242928	0.1823	<i>I/C</i>
<i>Apo-Warfarin</i>	10mg tablet	02242929	0.3271	<i>I/C</i>

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**LEGEND:** EDS = Exception Drug Status

I/C = interchangeable

not I/C = not interchangeable

## CRITERIA FOR NEW EXCEPTION DRUG STATUS (EDS) ADDITIONS

Effective **September 14, 2001**, the following product is available for coverage subject to the indicated criteria.

### **etanercept, powder for injection (vial), 25mg/vial (Enbrel-WYA)**

For treatment of patients with active rheumatoid arthritis who have failed on at least two DMARDs. Treatment should be combined with an immunosuppressant (e.g. methotrexate, azathioprine). *This product should be used in consultation with a specialist in this area.*

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Effective **October 1, 2001**, the following products will be available for coverage subject to the indicated criteria.

### **alfacalcidol, oral drops, 2ug/mL (mL) (One-Alpha-LEO)**

New form only - same criteria as capsules listed in Appendix A, page 207.

### **amoxicillin trihydrate/potassium clavulanate, tablet, 250mg/125mg, 500mg/125mg (Alti-Amoxi Clav-ALT)**

New interchangeable - same criteria as other brands listed in Appendix A, page 207.

### **amprenavir, capsule, 50mg, 150mg; oral solution, 15mg/mL (Agenerase-GSK)**

For management of HIV disease in patients who have failed other protease inhibitor combinations. *This drug, as with other antivirals in treatment of HIV, should be used under the direction of an infectious disease specialist.*

### **estradiol & norethindrone acetate/estradiol, transdermal therapeutic system (8), 50ug & 140ug/50ug, 50ug & 250ug/50ug (Estalis-Sequi-NVR)**

For treatment in patients who are unable to tolerate oral hormone replacement therapy (either estrogen or progesterone).

### **fenofibrate (micronized), capsule, 200mg (Novo-Fenofibrate Micronized-NOP)**

New interchangeable - same criteria as other brands listed in Appendix A, page 217.

### **gatifloxacin, tablet, 400mg (Tequin-BMY)**

- (a) For treatment of infections in patients with underlying lung disease not responding to first-line antibiotics.
- (b) For treatment of infections caused by organisms known to be resistant to alternative antibiotics.
- (c) For treatment of infections in patients allergic to alternative antibiotics.
- (d) For step-down care following hospital separation in patients treated with the intravenous form.

### **peginterferon alfa-2b, powder for injection (vial), 50ug/0.5mL, 80ug/0.5mL, 120ug/0.5mL, 150ug/0.5mL (PEG-Intron-SCH)**

For treatment of chronic active hepatitis C. Coverage will be provided for an initial 6 month period with potential renewal for 2 additional 6 month periods.

**sirolimus, oral solution, 1mg/mL (Rapamune-WYA)**

For prophylaxis of graft rejection in transplant patients.

**MODIFICATIONS TO CURRENT EXCEPTION DRUG STATUS (EDS) CRITERIA**

*Effective October 1, 2001, the EDS criteria for the following products will be as indicated.*

**dihydroergotamine mesylate, nasal spray, 4mg/mL (Migranal-NVR)**

For treatment of migraines where standard therapy such as an analgesic has failed or cannot be tolerated.

**naratriptan HCl, tablet, 1mg, 2.5mg (Amerge-GSK)**

For treatment of migraine headaches where other standard therapy such as an analgesic has failed. *Eligibility will be restricted to beneficiaries over 18 and under 65 years of age.*

*The maximum quantity that can be claimed through the Drug Plan is limited to 6 doses per 30 days within a 60 day period. Patients requiring more than 12 doses in a consecutive 60 day period should be considered for migraine prophylaxis therapy if they are not already receiving such therapy.*

**risedronate sodium, tablet, 5mg (Actonel-PGA)**

- (a) For treatment of osteoporosis in patients who do not respond to etidronate disodium/calcium (Didrocal) after receiving it for one year.
- (b) For treatment of osteoporosis in patients unable to tolerate etidronate disodium/calcium (Didrocal).
- (c) For treatment of osteoporosis in patients who have fresh fractures.

**rizatriptan benzoate, tablet, 5mg, 10mg (Maxalt-MSD); wafer, 5mg, 10mg (Maxalt RPD-MSD)**

Criteria same as for naratriptan HCl (Amerge) above.

**sumatriptan, tablet, 25mg, 50mg, 100mg; injection solution, 6mg/0.5mL; nasal spray, 5mg, 20mg (Imitrex-GSK)**

Criteria same as for naratriptan HCl (Amerge) above.

**zolmitriptan, tablet, 2.5mg (Zomig-AST); orally dispersible tablet, 2.5mg (Zomig Rapimelt-AST)**

Criteria same as for naratriptan HCl (Amerge) above.