QUARTERLY UPDATE TO THE 51st EDITION OF THE SASKATCHEWAN FORMULARY

NEW LISTINGS

NEW EXCEPTION DRUG STATUS AGENTS

The following product is now available under Exception Drug Status subject to the indicated criteria.

- **Infliximab, injection (mg), 100mg/vial (Remicade-SCH)**
  Exception Drug Status Criteria:
  Moderate to severe Crohn's Disease
  (a) For treatment of patients who demonstrate continuing symptoms despite the use of optimal conventional therapies such as 5-ASA agents, glucocorticoids and immunosuppressive therapy.
  (b) For treatment of patients who are unable to tolerate conventional therapy including 5-ASAagents, glucocorticoids and immunosuppressive therapy.
  Note: This product should be used in consultation with a specialist in this area.

  Fistulizing Crohn's Disease
  For treatment of patients with symptomatic enterocutaneous or perineal fistulae, enterovaginal fistulae or enterovesical fistulae.
  Note: This product should be used in consultation with a specialist in this area.

Exception Drug Status Criteria:
Rheumatoid Arthritis
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).
Note: This product should be used in consultation with a specialist in this area.

Patients who are approved for Remicade under the EDS program are encouraged to apply for Special Support. The Special Support program is designed to assist patients whose drug costs are high in relation to their income. Application forms are available at pharmacies or by calling the Drug Plan in Regina at 787-3317 or 1-800-667-7581(toll free).

NEW EXCEPTION DRUG STATUS AGENTS

Effective January 1, 2002 the following products are available under Exception Drug Status subject to the indicated criteria.

- **Estradiol, transdermal therapeutic system (pkg), 37.5ug, 50ug, 75ug, 100ug (Estradot-NVR)**
  Exception Drug Status Criteria:
  For treatment in patients who are unable to tolerate oral estrogen.

- **Linezolid, tablet, 600mg (Zyvoxam-PHU)**
  Exception Drug Status Criteria:
  For the treatment of methicillin resistant Staphylococcus aureus infections (MRSA) following consultation with an infectious disease specialist.

- **Meloxicam, tablet, 7.5mg, 15mg (Mobicox-BOE)**
  Exception Drug Status Criteria:
  (a) For treatment in patients age 65 and over (approved automatically through the on-line computer system).
  (b) For treatment of rheumatoid arthritis and osteoarthritis in patients who have one of the following factors:
  - past history of ulcers;
  - concurrent prednisone therapy;
  - concurrent warfarin therapy.
  (c) For treatment of patients with an intolerance to other NSAIDs listed in the Formulary.

- **Sevelamer HCl, tablet, 400mg, 800mg (Renagel-GZY)**
  Exception Drug Status Criteria:
  (a) For treatment of patients in endstage renal disease with intolerance to aluminum or calcium containing phosphate binding agents.
  (b) For treatment of patients in endstage renal disease where aluminum or calcium containing phosphate binding agents are inappropriate.

NEW EDS AGENTS (continued)

- **Galantamine hydrobromide, tablet, 4mg, 8mg, 12mg (Reminyl-JAN)**
  Exception Drug Status Criteria:
  (a) A diagnosis of probable Alzheimer's Disease as per DSM-IV criteria.
  (b) A mild to moderate stage of the disease with a MMSE score of 10-26 established within 60 days prior to application for coverage by a clinician.
  (c) A Functional Activities Questionnaire (FAQ) must be completed.
  (d) Patients must discontinue all drugs with anticholinergic activity at least 14 days before the MMSE and FAQ are administered. Drugs with anticholinergic activity are not to be used concurrently with galantamine therapy. List all current medications patient was taking at the time of assessment.
  (e) Patients **intolerant** to one drug may be switched to another drug in this class. Intolerance should be observed within the first month of treatment.

✧ **Eligible patients currently taking galantamine** would require assessment at 6 month intervals. To continue receiving galantamine, patients must not have both a greater than 2 point reduction in MMSE and a 1 point increase in FAQ in a 6 month evaluation period. Scores are compared to the most recent test results.

✧ **Eligible new patients** will enter a 3 month treatment period with galantamine. During the 3 month trial, patients must exhibit an improvement from the initial MMSE or FAQ to continue treatment with galantamine. The improvement must be at least 2 MMSE points or -1 FAQ. Patients who meet these requirements will be re-evaluated at 6 month intervals. To continue receiving galantamine, patients must not have both a greater than 2 point reduction in MMSE and a 1 point increase in FAQ in a 6 month evaluation period. Scores are compared to the most recent test results.

✧ The MMSE score must remain at 10 or greater at all times to be eligible for coverage.

✧ Patients who do not meet criteria to continue galantamine can be re-evaluated within 3 months to confirm deterioration before coverage is discontinued.

✧ Galantamine does not need to be discontinued prior to MMSE or FAQ testing.

✧ A patient intolerant of one drug in this class and switching to a second will be considered a "new" patient and will be assessed as such.

✧ Coverage will not be considered for patients who have **failed** on other drugs in this class.

Application for EDS and EDS renewals for Reminyl, Aricept, and Exelon will only be accepted from physicians on the Aricept/Exelon/ Reminyl EDS application form. A new form has been included with this mailing. Please discard old forms.

CHANGE IN STATUS FROM EDS TO FULL FORMULARY

Effective January 1, 2002:

- Fenofibrate (micronized), capsule, 200mg (Lipidil Micro, Apo-Feno-Micro, Gen-Fenofibrate Micro, pms-Fenofibrate Micro, Dom-Fenofibrate Micro, Novo-Fenofibrate Micronized)
- Dihydroergotamine mesylate, nasal spray, 4mg/mL (Migranal-NVR)

NEW FULL FORMULARY LISTINGS

- Atorvastatin calcium, tablet, 80mg (Lipitor-PFI)
- Betahistine HCl, tablet, 16mg (Serc-SLV)
- Candesartan cilexetil/ hydrochlorothiazide, tablet, 16mg/12.5mg (Atacand Plus-AST)
- Enalapril maleate/ hydrochlorothiazide, tablet, 5mg/12.5mg (Vaseretic-MSD)
- Entacapone, tablet, 200mg (Comtan-NVR) - this new product is a COMT inhibitor used to treat Parkinson's Disease.
- Glucose oxidase/peroxidase reagent, strip (Accu-Chek Compact-BOM)
- Hydromorphone HCl, controlled-release capsule, 18mg (Hydromorph Contin-PFR)
- Mirtazapine, tablet, 30mg (Remeron-ORG) - this new product is a noradrenergic and specific serotonergic antidepressant.
- Telmisartan/hydrochlorothiazide, tablet, 80mg/12.5mg (Micardis Plus-BOE)

FIRST ENTRY GENERIC

- Cefuroxime axetil, tablet, 250mg, 500mg (Alti-Cefuroxime-ALT)
- Cefuroxime axetil, tablet, 250mg, 500mg (Apo-Cefuroxime-APX)
- Misoprostol, tablet, 100ug, 200ug (Apo-Misoprostol-APX)
- Nitroglycerin, sublingual spray (pkg), 0.4mg/dose (Gen-Nitro SL Spray-GPM

Fenofibrate, capsule, 100mg (Apo-Fenofibrate-APX, Nu-Fenofibrate-NXP) *The 100mg strength of fenofibrate will be delisted effective July 1, 2002 due to minimal demand of this strength. It was suggested that this strength discourages appropriate dosing. Patients who currently have EDS for this strength will continue to be covered.*

MODIFICATIONS TO CURRENT EXCEPTION DRUG STATUS CRITERIA

Effective January 1, 2002 the Exception Drug status criteria for the following products will be as indicated.

- **Alendronate sodium, tablet, 40mg (Fosamax-MSD)**
  Exception Drug Status criteria has been revised to include:
  - For treatment of osteoporosis (on a weekly basis) in patients who do not respond to etidronate disodium/calcium (Didrocal) after receiving it for one year.
  - For treatment of osteoporosis (on a weekly basis) in patients unable to tolerate etidronate disodium/calcium (Didrocal).

- **Bezafibrate, tablet, 200mg (pms-Bezafibrate-PMS); sustained release tablet, 400mg (Bezalip SR-HLR)**
  Exception Drug Status criteria has been revised to:
  - For treatment of patients with hyperlipidemia who have failed to respond to gemfibrozil or fenofibrate.
  - For treatment of patients with hyperlipidemia who have experienced side effects with gemfibrozil or fenofibrate.

- **Epoetin alfa, pre-filled syringe, 1,000 IU/0.5mL, 2,000IU/0.5mL, 3,000IU/0.3mL, 4,000IU/0.4mL, 6,000IU/0.6mL, 8,000IU/0.8mL, 10,000IU/mL; sterile solution for injection, 20,000IU (Eprex-JAN)**
  Exception Drug Status criteria has been revised to include:
  For treatment of anemia in transplant patients.

- **Ketoconazole, tablet, 200mg (Nizoral-MCL) (Apo-Ketoconazole-APX) (Nu-Ketocon-NXP) (Novo-Ketoconazole-NOP)**
  Exception Drug Status criteria has been revised to:
  (a) For treatment of severe or life-threatening fungal infections.
  (b) For treatment of severe dermatophytoses.
  (c) For treatment of dermatophytoses not responding to other forms of therapy.

- **Lansoprazole, delayed release capsule, 15mg, 30mg (Prevacid-ABB)**
  Exception Drug Status criteria has been revised to include:
  For first line prevention of gastroduodenal haemorrhage in high risk patients with prior history of gastroduodenal bleeds for whom anticoagulant, glucocorticosteroid, or NSAID therapy cannot be avoided.
  EDS coverage is renewable on a yearly basis for patients if discontinuation of offending agents or replacement with less damaging alternatives is not feasible.

- **Omeprazole, delayed release tablet, 10mg, 20mg (Losec-AST)**
  Same Exception Drug Status criteria revision as for lansoprazole (Prevacid-ABB) published in this bulletin.

- **Pantoprazole, enteric coated tablet, 40mg (Pantoloc-SLV)**
  Same Exception Drug Status criteria revision as for lansoprazole (Prevacid-ABB) published in this bulletin.

- **Pioglitazone HCl, tablet, 15mg, 30mg, 45mg (Actos-LIL)**
  Exception Drug Status criteria has been revised to:
  For treatment of diabetes in patients who are not adequately controlled on or are intolerant to metformin or sulfonylureas.

- **Rosiglitazone maleate, tablet, 2mg, 4mg, 8mg (Avandia-GSK)**
  Exception Drug Status criteria has been revised to:
  For treatment of diabetes in patients who are not adequately controlled on or are intolerant to metformin or sulfonylureas.

- **Salmeterol xinafoate/fluticasone propionate, powder for inhalation, 50ug/100ug, 50ug/250ug, 50ug/500ug (Advair Diskus-GSK)**
  Exception Drug Status criteria has been revised to:
  (a) For treatment of asthma in patients not adequately controlled on steroid therapy. *It is important that these patients also have access to a short-acting beta-2 agonist for symptomatic relief.*
  (b) For treatment of chronic obstructive pulmonary disease (COPD) in patients not adequately controlled on long-acting beta-2 agonists alone.

- **Somatropin, injection, 3.33mg, 5mg (Saizen-SRO)**
  Exception Drug Status criteria has been revised to:
  For treatment of children who have growth failure due to inadequate secretion of normal endogenous growth hormone, or who have growth failure associated with chronic renal insufficiency. *Note: Exception Drug Status coverage is not required for S.A.I.L. patients.*

MODIFICATIONS TO EXCEPTION DRUG STATUS CRITERIA FOR "TRIPTANS"

Effective January 1, 2002 the Exception Drug status criteria for the following products will be as indicated.

- **Naratriptan HCl, tablet, 1mg, 2.5mg (Amerge-GSK)**
  Exception Drug Status criteria has been revised to:
  For treatment of migraine headaches. *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.

- **Rizatriptan benzoate, tablet, 5mg, 10mg (Maxalt-MSD); wafer, 5mg, 10mg (Maxalt RPD-MSD)**
  Same Exception Drug Status criteria as for naratriptan (Amerge-GSK) published in this bulletin.

- **Sumatriptan, tablet, 25mg, 50mg, 100mg; injection solution, 6mg/0.5mL; nasal spray, 5mg, 20mg (Imitrex-GSK)**
  Same Exception Drug Status criteria as for naratriptan (Amerge-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 naratriptan (Amerge-GSK) published in this bulletin.

PRODUCTS REVIEWED AND NOT RECOMMENDED FOR LISTING

- **Fenofibrate, tablet, 100mg, 160mg (Lipidil Supra-FFR)**
  This formulation offers no significant clinical or cost advantage over the other formulation of fenofibrate.
- **Oseltamivir phosphate, capsule, 75mg (Tamiflu-HLR)**
  The clinical benefit of treatment of influenza does not justify the incremental cost. It was noted there is lack of evidence supporting the use of this agent in the prophylaxis of influenza.
- **Oxybutynin chloride, extended release tablet, 5mg, 10mg (Ditropan XL-JAN)**
  There is lack of evidence to support an improved side effect profile in patients intolerant to the regular tablet.
- **Riluzole, tablet, 50mg (Rilutek-AVT)**
  The clinical benefit does not justify the incremental cost.
- **Testosterone therapeutic system, 12.2mg (2.5mg/day) (Androderm-PAL)**
  The clinical benefit does not justify the incremental cost.

SOME OF THE PRODUCTS CURRENTLY UNDER REVIEW BY THE FORMULARY COMMITTEE

- Doxercalciferol, capsule, 2.5mg (Hectoro
- Esomeprazole magnesium trihydrate, delayed release tablet, 20mg, 40mg (Nexium-AST)
- Fusidic acid, ophthalmic drops 1% (Fucithalmic-LEO)
- Gliclazide, modified release tablet, 30mg (Diamicron MR-SEV)
- Glucose oxidase/peroxidase reagent, strip (Sof-Tact-MDS)
- Quetiapine, tablet, 300mg (Seroquel-AST)
- Tacrolimus, topical ointment, 0.03%, 0.1% (Protopic-FUJ)
- Tazarotene, topical cream, 0.05%, 0.1% (Tazorac-ALL)l-DPY)

CHANGE IN STATUS FROM NOT-INTERCHANGEABLE TO INTERCHANGEABLE

- Polymyxin B SO_4/Neomycin SO_4/Gramicidin, eye/ear solution, 10,000U/2.5mg/0.025mg per mL (Optimyxin Plus-SAB)

HOSPITAL BENEFIT DRUG LIST UPDATE - January 2002

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.

GATIFLOXACIN INJECTION (Tequin™)

Restricted Coverage: When used according to the Exceptional Drug Status Criteria shown in the October, 2001 sticker updates to **The Saskatchewan Formulary.**

MEROPENEM INJECTION (Merrem™)

Restricted Coverage: For the treatment of severe infections on the recommendation of an infectious disease specialist; internist or medical microbiologist.

Saskatchewan Formulary Committee
2nd Floor, 3475 Albert Street
Regina, Saskatchewan S4S 6X6

FORMULARY AND EDS UPDATES EFFECTIVE JANUARY 1, 2002

GENERIC & TRADE NAME	***STRENGTH & FORM***	***DIN***	***UNIT PRICE***	***LEGEND***
Atorvastatin calcium				
Lipitor	80mg tablet	02243097	2.3328	
Betahistine HCl				
Serc	16mg tablet	02243878	0.4557	
Candesartan cilexetil/hydrochlorothiazide				
Atacand Plus	16mg/12.5mg tablet	02244021	1.1718	
Cefuroxime axetil				
Alti-Cefuroxime	250mg tablet	02242656	1.0994	*I/C EDS*
Alti-Cefuroxime	500mg tablet	02242657	2.1779	*I/C EDS*
Apo-Cefuroxime	250mg tablet	02244393	1.0994	*I/C EDS*
Apo-Cefuroxime	500mg tablet	02244394	2.1779	*I/C EDS*
Deferoxamine mesylate				
pms-Deferoxamine	2g/vial pwr for sol	02243450	45.5700	*I/C EDS*
Divalproex sodium				
pms-Divalproex	125mg enteric tablet	02244138	0.1661	*I/C*
pms-Divalproex	250mg enteric tablet	02244139	0.2984	*I/C*
pms-Divalproex	500mg enteric tablet	02244140	0.5971	*I/C*
Enalapril maleate/hydrochlorothiazide				
Vaseretic	5mg/12.5mg tablet	02242826	0.8666	
Entacapone				
Comtan	200mg tablet	02243763	1.5190	
Estradiol				
Estradot	37.5ug (pkg)	02243999	19.8000	*EDS*
Estradot	50ug (pkg)	02244000	21.1600	*EDS*
Estradot	75ug (pkg)	02244001	22.7100	*EDS*
Estradot	100ug (pkg)	02244002	23.8700	*EDS*
Fluphenazine decanoate				
Apo-Fluphenazine	25mg/mL inj sol (5mL)	02244166	25.1300	*I/C*
Gabapentin				
Apo-Gabapentin	100mg capsule	02244304	0.3038	*I/C*
Apo-Gabapentin	300mg capsule	02244305	0.7390	*I/C*
Apo-Gabapentin	400mg capsule	02244306	0.8807	*I/C*
Galantamine hydrobromide				
Reminyl	4mg tablet	02244298	2.4901	*EDS*
Reminyl	8mg tablet	02244299	2.4901	*EDS*
Reminyl	12mg tablet	02244300	2.4901	*EDS*
Glucose oxidase/peroxidase reagent				
Accu-Chek Compact	strip	00950900	0.8680	
Haloperidol decanoate				
Haloperidol Long Acting	50mg/mL inj sol	02236866	30.4200	*I/C*
Haloperidol Long Acting	100mg/mL inj sol	02242631	60.1100	*I/C*

FORMULARY AND EDS UPDATES EFFECTIVE JANUARY 1, 2002

GENERIC & TRADE NAME	***STRENGTH & FORM***	***DIN***	***UNIT PRICE***	***LEGEND***
Hydromorphone HCl				
Hydromorph Contin	18mg controlled-release capsule	02243562	2.4413	
Ipratropium bromide				
Apo-Ipravent	0.0125% inh sol (2mL)	02243827	0.8200	*I/C*
Lactulose				
Apo-Lactulose	667mg/mL syrup	02242814	0.0158	*not I/C EDS*
Linezolid				
Zyvoxam	600mg tablet	02243684	72.1390	*EDS*
Lorazepam				
pms-Lorazepam	0.5mg tablet	00728187	0.0507	*I/C*
pms-Lorazepam	1mg tablet	00728195	0.0517	*I/C*
pms-Lorazepam	2mg tablet	00728209	0.0840	*I/C*
Meloxicam				
Mobicox	7.5mg tablet	02242785	0.8463	*EDS*
Mobicox	15mg tablet	02242786	0.9765	*EDS*
Mirtazapine				
Remeron	30mg tablet	02243910	1.3454	
Misoprostol				
Apo-Misoprostol	100ug tablet	02244022	0.2066	*I/C*
Apo-Misoprostol	200ug tablet	02244023	0.3440	*I/C*
Nitroglycerin				
Gen-Nitro SL Spray	0.4mg/dose spray	02243588	10.5000	*I/C*
Pravastatin				
Nu-Pravastatin	10mg tablet	02244350	1.0345	*I/C*
Nu-Pravastatin	20mg tablet	02244351	1.2202	*I/C*
Nu-Pravastatin	40mg tablet	02244352	1.4697	*I/C*
Ranitidine				
Rhoxal-Ranitidine	150mg tablet	02243229	0.4386	*I/C*
Rhoxal-Ranitidine	300mg tablet	02243230	0.8449	*I/C*
Sevelamer HCl				
Renagel	400mg tablet	02244309	0.7704	*EDS*
Renagel	800mg tablet	02244310	1.5407	*EDS*
Telmisartan/hydrochlorothiazide				
Micardis Plus	80mg/12.5mg tablet	02244344	1.1610	
Ticlopidine HCl				
Dom-Ticlopidine	250mg tablet	02243808	0.7844	*I/C EDS*
Rhoxal-Ticlopidine	250mg tablet	02243587	0.7471	*I/C EDS*

LEGEND: EDS = Exception Drug Status
I/C = interchangeable
not I/C = not interchangeable

EDS UPDATE EFFECTIVE NOVEMBER 15, 2001

GENERIC, TRADE NAME, STRENGTH & FORM	***DIN***	***UNIT PRICE***	***LEGEND***
Infliximab, injection (mg), 100mg/vial			
Remicade (Crohn's Disease)	00950899	11.8000*	*EDS*
Remicade (Rheumatoid Arthritis)	02244016	11.8000*	*EDS*

*When billing prescriptions for Remicade, please ensure you use the correct DIN (depending on the patient's diagnosis) and the **quantity submitted is in terms of milligrams** and not per vial or per mL.

CRITERIA FOR EXCEPTION DRUG STATUS (EDS) COVERAGE

infliximab, injection (mg), 100mg/vial (Remicade-SCH)

Crohn's Disease:

(a) Moderate to severe Crohn's Disease:

- For treatment of patients who demonstrate continuing symptoms despite the use of optimal conventional therapies such as 5-ASA agents, glucocorticoids and immunosuppressive therapy.
- For treatment of patients who are unable to tolerate conventional therapy including 5-ASA agents, glucocorticoids and immunosuppressive therapy.

(b) Fistulizing Crohn's Disease:

- For treatment of patients with symptomatic enterocutaneous or perineal fistulae, enterovaginal fistulae or enterovesical fistulae.

Note: This product should be used in consultation with a specialist in this area.

Pharmacies note: claims on behalf of Crohn's Disease patients must use the following identifying number (not the DIN):

00950899

Rheumatoid Arthritis:

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). *Note: This product should be used in consultation with a specialist in this area.*

CHANGE IN STATUS FOR THE FOLLOWING PRODUCTS

Effective ***January 1, 2002***, the following product will be ***interchangeable*** with the currently listed brand:

- **Optimyxin Plus 10,000U/2.5mg/0.025mg per mL eye/ear solution**

Effective ***January 1, 2002,*** the following products will ***not require*** Exception Drug Status (EDS) coverage and are to be considered full formulary benefits:

- **Fenofibrate (micronized), capsule 200mg (Lipidil-Micro, Apo-Feno-Micro, Gen-Fenofibrate Micro, pms-Fenofibrate Micro, Dom-Fenofibrate Micro, Novo-Fenofibrate Micro)**

- **Migranal 4mg/mL nasal spray**

Effective ***July 1, 2002,*** the following products will be **delisted** from the Saskatchewan Formulary due to minimal utilization of the 100mg strength. Patients who currently have EDS coverage for this strength will continue to be covered.

- **Fenofibrate, capsule, 100mg (Apo-Fenofibrate, Nu-Fenofibrate)**

CRITERIA FOR NEW EXCEPTION DRUG STATUS (EDS) ADDITIONS

*Effective **January 1, 2002**, the following products will be available for coverage subject to the indicated criteria.*

cefuroxime axetil, tablet, 250mg, 500mg (Alti-Cefuroxime-ALT) (Apo-Cefuroxime-APX)
New interchangeables – same criteria as brand listed in Appendix A, page 211.

deferoxamine mesylate, powder for solution, 2g/vial (pms-Deferoxamine-PMS)
New interchangeable – same criteria as brand listed in Appendix A, page 214.

estradiol, transdermal therapeutic system, 37.5ug, 50ug, 75ug, 100ug (Estradot-NVR)
New non-interchangeable – same criteria as other products listed in Appendix A, page 217.

galantamine hydrobromide, tablet, 4mg, 8mg, 12mg (Reminyl-JAN)
New product – same criteria as Aricept (donepezil HCl) listed in Appendix A, page 215.

lactulose, syrup, 667mg/mL (Apo-Lactulose-APX)
New non-interchangeable – same criteria as other brands listed in Appendix A, page 221.

linezolid, tablet, 600mg (Zyvoxam-PHU)
For treatment of methicillin-resistant staphylococcus aureus infections (MRSA) following consultation with an infectious disease specialist.

meloxicam, tablet, 7.5mg, 15mg (Mobicox-BOE)
New product – same criteria as Celebrex (celecoxib) listed in Appendix A, page 211.

sevelamer HCl, tablet, 400mg, 800mg (Renagel-GZY)

(a) For treatment of patients in endstage renal disease with intolerance to aluminum or calcium containing phosphate binding agents.
(b) For treatment of patients in endstage renal disease where aluminum or calcium containing phosphate binding agents are inappropriate.

ticlopidine HCl, tablet, 250mg (Dom-Ticlopidine-DOM) (Rhoxal-Ticlopidine-RHO)

New interchangeables – same criteria as other brands listed in Appendix A, page 232.

MODIFICATIONS TO CURRENT EXCEPTION DRUG STATUS (EDS) CRITERIA

*Effective **January 1, 2002**, the EDS criteria for the following products will be as indicated.*

alendronate sodium, tablet, 40mg (Fosamax-MSD)

(a) For treatment of symptomatic Paget's Disease of the bone.
(b) For treatment of osteoporosis (on a weekly basis) in patients who do not respond to etidronate disodium/calcium (Didrocal) after receiving it for one year.
(c) For treatment of osteoporosis (on a weekly basis) in patients unable to tolerate etidronate disodium/calcium (Didrocal).

bezafibrate, tablet, 200mg (pms-Bezafibrate-PMS); sustained release tablet, 400mg (Bezalip SR-HLR)

(a) For treatment of patients with hyperlipidemia who have failed to respond to gemfibrozil or fenofibrate.
(b) For treatment of patients with hyperlipidemia who have experienced side effects with gemfibrozil or fenofibrate.

epoetin alfa, pre-filled syringe, 1,000 IU/0.5mL, 2,000IU/0.5mL, 3,000IU/0.3mL, 4,000IU/0.4mL, 6,000IU/0.6mL, 8,000IU/0.8mL, 10,000IU/mL; sterile solution for injection, 20,000IU (Eprex-JAN)

Note: criteria (a) and (b) unchanged. Addition of (c) as follows:

(c) For treatment of anemia in transplant patients.

ketoconazole, tablet, 200mg (Nizoral-MCL) (Apo-Ketoconazole-APX) (Nu-Ketocon-NXP) (Novo-Ketoconazole-NOP)

(a) For treatment of severe or life-threatening fungal infections.
(b) For treatment of severe dermatophytoses.
(c) For treatment of dermatophytoses not responding to other forms of therapy.

lansoprazole, delayed release capsule, 15mg, 30mg (Prevacid-ABB)

Note: criteria (a) to (d) unchanged. Addition of (e) as follows:

(e) For first-line prevention of gastroduodenal hemorrhage in high risk patients with prior history of gastroduodenal bleeds for whom anticoagulant, glucocorticosteroid or NSAID therapy cannot be avoided. *Coverage is renewable on a yearly basis for patients if discontinuation of offending agents or replacement with less damaging alternatives is not feasible.*

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

For treatment of migraine headaches. *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.*

omeprazole, delayed release tablet, 10mg (Losec-AST)

Note: criteria (a) & (b) unchanged. Addition of (c) as follows:

(c) For first-line prevention of gastroduodenal hemorrhage in high risk patients with prior history of gastroduodenal bleeds for whom anticoagulant, glucocorticosteroid or NSAID therapy cannot be avoided. *Coverage is renewable on a yearly basis for patients if discontinuation of offending agents or replacement with less damaging alternatives is not feasible.*

omeprazole, enteric coated tablet, 20mg (Losec-AST)

Note: criteria (a) to (d) unchanged. Addition of (e) as follows:

(e) For first-line prevention of gastroduodenal hemorrhage in high risk patients with prior history of gastroduodenal bleeds for whom anticoagulant, glucocorticosteroid or NSAID therapy cannot be avoided. *Coverage is renewable on a yearly basis for patients if discontinuation of offending agents or replacement with less damaging alternatives is not feasible.*

pantoprazole, enteric coated tablet, 40mg (Pantoloc-SLV)

Note: criteria (a) to (d) unchanged. Addition of (e) as follows:

(e) For first-line prevention of gastroduodenal hemorrhage in high risk patients with prior history of gastroduodenal bleeds for whom anticoagulant, glucocorticosteroid or NSAID therapy cannot be avoided. *Coverage is renewable on a yearly basis for patients if discontinuation of offending agents or replacement with less damaging alternatives is not feasible.*

pioglitazone HCl, tablet, 15mg, 30mg, 45mg (Actos-LIL)

For treatment of diabetes in patients who are not adequately controlled on or are intolerant to metformin or sulfonylureas.

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

Criteria same as for naratriptan HCl (Amerge) above.

rosiglitazone maleate, tablet, 2mg, 4mg, 8mg (Avandia-GSK)

For treatment of diabetes in patients who are not adequately controlled on or are intolerant to metformin or sulfonylureas.

salmeterol xinafoate/fluticasone propionate, powder for inhalation (package), 50ug/100ug, 50ug/250ug, 50ug/500ug (Advair Diskus-GSK)

(a) For treatment of asthma in patients not adequately controlled on steroid therapy. *It is important that these patients also have access to a short-acting beta-2 agonist for symptomatic relief*

(b) For treatment of chronic obstructive pulmonary disease (COPD) in patients who are not adequately controlled on long-acting beta-2 agonists alone.

somatropin, injection, 3.33mg, 5mg (Saizen-SRO)

For treatment of children who have growth failure due to inadequate secretion of normal endogenous growth hormone, or who have growth failure associated with chronic renal insufficiency. *Note: Exception Drug Status coverage is not required for S.A.I.L. patients, coverage is provided under the Saskatchewan Aids to Independent Living (S.A.I.L.) Program.*

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.