



**SASKATCHEWAN FORMULARY COMMITTEE
BULLETIN
UPDATE TO THE 54th EDITION**

NEW FULL FORMULARY LISTING

The following products will be listed effective October 1, 2004.

- Brimonidine tartrate/timolol maleate, ophthalmic solution, 0.2%/0.5% (Combigan-ALL)
- Metronidazole, topical lotion, 0.75%, (MetroLotion-GAC)
- Blood Glucose Test Strip, (Precision PC_X-ABB)
- Epinephrine HCL, injection solution, 1mg/mL (Epinephrine-ABB)

The following product will continue to be listed:

- **Hydroxybutyrate dehydrogenase, blood ketone test strip, (Precision Extra Ketone-MDS)**

Note: the quantity limit of 8 strips per year has been removed.

NEW EXCEPTION DRUG STATUS AGENTS

Effective October 1, 2004 the following products will be available under Exception Drug Status subject to the indicated criteria.

- **Almotriptan malate, tablet, 6.25mg, 12.5mg (Axert-JAN)**
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.

- **Atazanavir SO₄, capsule, 150mg, 200mg (Reyataz-BMY)**
For management of HIV disease. This drug, as with other antivirals in the treatment of HIV, should be used under the direction of an infectious disease specialist.
- **Ciprofloxacin, extended release tablet, 1000mg (Cipro XL-BAY)**
Same criteria as currently listed strengths and forms.
- **Mycophenolate Mofetil, powder for oral suspension, 200mg/mL (CellCept-HLR)**
For prevention of acute rejection in transplant patients.
- **Estradiol, transdermal therapeutic system (pkg), 25ug, 75ug (Climara 25-BEX), (Climara 75-BEX)**
(a) For treatment in patients who are unable to tolerate oral estrogen.
(b) For treatment of patients with a fasting plasma triglyceride level of 4.5 mmol/L or more.
- **Moxifloxacin HCl, ophthalmic solution, 0.5% (Vigamox-ALC)**
For ophthalmic infections not responding to alternative agents.
- **Imiquimod, topical cream (single-use packet), 5% (Aldara-MDA)**
For treatment of genital warts in patients not responding to podofilox and for treatment of patients with a large wart area.
- **Enfuvirtide, powder for solution, 108mg/vial (vial) (Fuzeon-HLR)**
Exception Drug Status coverage for the management of HIV disease on a case-by-case basis, following committee review of each case. (It was noted that enfuvirtide is not first-line therapy. The most appropriate use of this product is for “salvage therapy”). This drug, as with other antivirals in the treatment of HIV, should be used under the direction of an infectious disease specialist.
- **Telithromycin, tablet, 400mg (Ketek-AVT)**
(a) Pneumonia,
(b) Upper and lower respiratory tract bacterial infections known to be resistant to or not responding to alternative antibiotics,
(c) Infections in patients allergic to alternative antibiotics,
(d) Non-tuberculous Mycobacterium infections (and prophylaxis),
(e) For completion of treatment initiated in hospital with macrolides or quinolones, and
(f) For patients intolerant to erythromycin and/or other antibiotics.
(It was noted that telithromycin is as effective and safe as azithromycin and clarithromycin. Studies have not demonstrated a clinical advantage over other macrolides.)

Atrovent HFA inhaler aerosol

Based on clinical trials, Atrovent HFA will be listed as interchangeable with Atrovent (CFC). Patients may notice a difference in physical characteristics, such as taste between the 2 products. Atrovent (CFC) will be discontinued when supplies are exhausted.

**NEW FULL FORMULARY
INTERCHANGEABLE LISTINGS**

The following products will be listed as interchangeable effective October 1, 2004.

- Metoprolol tartrate, tablet, 25mg (pms-Metoprolol-L-PMS)
- Fenofibrate, capsule, 200mg (ratio-Fenofibrate MC-RPH)
- Medroxyprogesterone acetate, tablet, 2.5mg & 5mg (Nu-Medroxy-NXP)
- Amcinonide, topical lotion, 0.1% & topical ointment, 0.1% (ratio-Amcinonide-RPH)
- Citalopram hydrobromide, tablet, 20mg, 40mg (ratio-Citalopram-RPH)
- Simvastatin, tablet, 5mg, 10mg, 20mg, 40mg & 80mg (pms-Simvastatin-PMS)
- Ipratropium bromide, inhaler aerosol, 20mcg/actuation (Atrovent HFA-BOE)
- Furosemide, tablet, 20mg, 40mg (pms-Furosemide-PMS)
- Mirtazapine, tablet, 30mg (Dom-Mirtazapine-DOM)
- Metoprolol tartrate, tablet, 25mg, (Dom-Metoprolol-L-DOM)
- Hydrochlorothiazide, tablet, 25mg, 50mg (pms-Hydrochlorothiazide-PMS)
- Diazepam, tablet, 2mg, 5mg, 10mg (pms-Diazepam-PMS)
- Ranitidine, oral solution, 15mg/mL (Novo-Ranitidine-NOP)
- Quinine SO₄, capsule, 200mg, 300mg (Apo-Quinine-APX)
- Amiloride HCl, tablet, 5mg (Apo-Amiloride-APX)
- Chloral Hydrate, syrup, 100mg/mL (Apo-Chloral Hydrate Syrup-APX)
- Atenolol/Chlorthalidone, tablet, 50/25mg & 100/25mg (Apo-Atenidone-APX)
- Paroxetine HCl, tablet, 10mg, 20mg, 30mg (Prem-Paroxetine-PRM)

**NEW EXCEPTION DRUG
STATUS INTERCHANGEABLE
AGENTS:**

- Cyproterone acetate, tablet, 50mg (Apo-Cyproterone-APX)

- Carvedilol, tablet, 3.125mg, 6.25mg, 12.5mg, 25mg (ratio-Carvedilol-RPH)
- Ciprofloxacin, tablet, 250mg, 500mg, 750mg (Nu-Ciprofloxacin-NXP)
- Meloxicam, tablet, 7.5mg, 15mg (CO Meloxicam-COB)
- Alendronate sodium, tablet, 10mg (Apo-Alendronate-APX)
- Ofloxacin, ophthalmic solution, 0.3% (pms-Ofloxacin-PMS)

The following product has been RECOMMENDED under EXCEPTION DRUG STATUS according to the following revised criteria:

Tacrolimus, capsule, 0.5mg, 1mg, 5mg; ampoule, 5mg/mL (Prograf-FUJ)

- a) For prophylaxis of graft rejection
- b) In post bone marrow/stem cell transplant patients who:
 - i) experience graft-vs-host disease not responding to therapeutic doses of cyclosporine, or;
 - ii) with steroid refractory graft-vs-host disease, or;
 - iii) who do not tolerate the side effects of cyclosporine.

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

- Clozapine, tablet, 25mg, 100mg (Gen-Clozapine-GPM)
- Clozapine, tablet, 25mg, 100mg (Apo-Clozapine-APX)
- Peginterferon alfa-2b/ribavirin, powder for solution/capsule, 50ug/0.5mL, 80ug/0.5mL, 100ug/0.5mL, 120ug/0.5mL, 150ug/0.5mL (Pegetron Redipen-SCH)
- Peginterferon alfa-2a, injection (pre-filled syringe), 180ug/0.5mL, (vial) 180ug/1mL (Pegasys-HLR)
- Peginterferon alfa-2a/ribavirin, injection (pre-filled syringe)/tablet, 180ug/0.5mL /200mg; injection (vial)/tablet, 180ug/1mL/200mg (Pegasys RBV-HLR)

- Cyclosporine, liquid, 100mg/mL (Apo-Cyclosporine-APX)
- Cyclosporine, capsule, 100mg (RhoXal-Cyclosporine-RHO)
- Miglustat, capsule, 100mg (Zavesca-ACT)
- Ciprofloxacin HCl/dexamethasone, otic suspension, 0.3%/0.1% (Ciprodex-ALC)
- Clindamycin phosphate/benzoyl peroxide, topical gel, 1%/5% (BenzaClin-DER)
- Treprostinil sodium, injection solution, 1.0mg/mL, 2.5mg/mL, 5.0mg/mL, 10mg/mL (Remodulin-NTI)
- Olanzapine, powder for injection (vial), 10mg/vial (Zyprexa IM-LIL)

**PRODUCTS NOT
RECOMMENDED FOR
COVERAGE**

- Fluvastatin sodium, extended release tablet, 80mg (Lescol XL-NVR) as there is not a demonstrated need for this dose.
- Somatropin, injection (cartridge), 24mg (Humatrope-LIL) as there was no demonstrated need for this strength.
- Hydrocortisone acetate/pramoxine hydrochloride, rectal aerosol foam, 1% /1% (Proctofoam-HC-DUI) as clinical trials demonstrating a benefit of the combination over the individual agents were not submitted.
- Prenatal/Postpartum Vitamin, Mineral Supplement, (PregVit-DUI) Multivitamin products are not listed in the Formulary.
- Mirtazapine, orally disintegrating tablet, 15mg, 30mg, 45mg (Remeron RD-ORG) as there is no clinical advantage to this form of the drug.
- Norelgestromin/ethinyl estradiol, transdermal system, 6.0mg/.60mg (Evra-JAN) as the clinical benefit does not justify the incremental cost.

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

This Bulletin is not to be reproduced or republished except with the approval of the Saskatchewan Formulary Committee. Inquiries should be directed to the address shown at left.

FORMULARY AND EDS UPDATES EFFECTIVE OCTOBER 1, 2004

<u>GENERIC & TRADE NAME</u>	<u>STRENGTH & FORM</u>	<u>DIN</u>	<u>UNIT PRICE</u>	<u>LEGEND</u>
Alendronate Sodium				
Apo-Alendronate (EDS)	10mg tablet	02248728	1.1997	I/C EDS
Almotriptan Malate				
Axert (EDS)	6.25mg tablet	02248128	14.0508	EDS
Axert (EDS)	12.5mg tablet	02248129	14.0508	EDS
Amcinonide				
ratio-Amcinonide	0.1% topical lotion	02247097	0.2466	I/C
ratio-Amcinonide	0.1% topical ointment	02247096	0.2970	I/C
Amiloride HCl				
Apo-Amiloride	5mg tablet	02249510	0.2173	I/C
Atazanavir SO₄				
Reyataz (EDS)	150mg capsule	02248610	10.4000	EDS
Reyataz (EDS)	200mg capsule	02248611	10.4000	EDS
Atenolol/Chlorthalidone				
Apo-Atenidone	50/25mg tablet	02248763	0.4713	I/C
Apo-Atenidone	100/25mg tablet	02248764	0.7723	I/C
Blood Glucose Test Strip				
Precision PC _x	strip	00950935	0.7476	
Brimonidine Tartrate/Timolol Maleate				
Combigan	0.2%/0.5% ophthalmic solution	02248347	4.2749	
Carvedilol				
ratio-Carvedilol (EDS)	3.125mg tablet	02252309	0.9646	I/C EDS
ratio-Carvedilol (EDS)	6.25mg tablet	02252317	0.9646	I/C EDS
ratio-Carvedilol (EDS)	12.5mg tablet	02252325	0.9646	I/C EDS
ratio-Carvedilol (EDS)	25mg tablet	02252333	0.9646	I/C EDS
Chloral Hydrate				
Apo-Chloral Hydrate Syrup	100mg/mL syrup	02250195	0.0470	I/C
Ciprofloxacin				
Nu-Ciprofloxacin (EDS)	250mg tablet	02249634	1.6869	I/C EDS
Nu-Ciprofloxacin (EDS)	500mg tablet	02249642	1.9032	I/C EDS
Nu-Ciprofloxacin (EDS)	750mg tablet	02249650	3.5895	I/C EDS
Ciprofloxacin				
Cipro XL (EDS)	1000mg extended release tablet	02251787	2.9729	EDS
Citalopram Hydrobromide				
Prem-Citalopram	20mg tablet	02249227	0.9494	I/C
ratio-Citalopram	20mg tablet	02252112	0.9494	I/C
Prem-Citalopram	40mg tablet	02249235	0.9494	I/C
ratio-Citalopram	40mg tablet	02252120	0.9494	I/C
Cyproterone Acetate				
Apo-Cyproterone (EDS)	50mg tablet	02245898	1.5284	I/C EDS
Diazepam				
pms-Diazepam	2mg tablet	02247490	0.0662	I/C
pms-Diazepam	5mg tablet	02247491	0.0952	I/C
pms-Diazepam	10mg tablet	02247492	0.1129	I/C
Enfuvirtide				
Fuzeon (EDS)	108mg/vial powder for solution	02247725	40.2600	EDS
Estradiol				
Climara 25 (EDS)	25ug transdermal therapeutic system	02247499	19.8000	EDS
Climara 75 (EDS)	75ug transdermal therapeutic system	02247500	22.5200	EDS
Epinephine HCl				
Epinephrine (ABB)	1mg/mL injection solution	00721891	1.8879	

FORMULARY AND EDS UPDATES EFFECTIVE OCTOBER 1, 2004 CON'T.

<u>GENERIC & TRADE NAME</u>	<u>STRENGTH & FORM</u>	<u>DIN</u>	<u>UNIT PRICE</u>	<u>LEGEND</u>
Fenofibrate				
ratio-Fenofibrate MC	200mg capsule	02250039	1.1816	I/C
Furosemide				
pms-Furosemide	20mg tablet	02247493	0.0483	I/C
pms-Furosemide	40mg tablet	02247494	0.0727	I/C
Hydrochlorothiazide				
pms-Hydrochlorothiazide	25mg tablet	02247386	0.0517	I/C
pms-Hydrochlorothiazide	50mg tablet	02247387	0.0707	I/C
Hydroxychloroquine SO₄				
Gen-Hydroxychloroquine	200mg tablet	02252600	0.3582	I/C
Imiquimod				
Aldara (EDS)	5% topical cream (single use packet)	02239505	12.3900	EDS
Ipratropium Bromide				
Atrovent HFA	20ug inhaler aerosol	02247686	19.1800	I/C
Medroxyprogesterone Acetate				
Nu-Medroxy	2.5mg tablet	02252740	0.0862	I/C
Nu-Medroxy	5mg tablet	02252759	0.1703	I/C
Meloxicam				
CO Meloxicam (EDS)	7.5mg tablet	02250012	0.5332	I/C EDS
CO Meloxicam (EDS)	15mg tablet	02250020	0.6152	I/C EDS
Metoprolol Tartrate				
Dom-Metoprolol-L	25mg tablet	02252252	0.0733	I/C
pms-Metoprolol-L	25mg tablet	02248855	0.0698	I/C
Metronidazole				
MetroLotion	0.75% topical lotion	02248206	0.5354	
Mirtazapine				
Dom-Mirtazapine	30mg tablet	02252287	1.1302	I/C
Moxifloxacin HCl				
Vigamox (EDS)	0.5% ophthalmic solution	02252260	4.3400	EDS
Mycophenolate Mofetil				
CellCept (EDS)	200mg/mL powder for oral susp.	02242145	1.7899	EDS
Ofloxacin				
pms-Ofloxacin (EDS)	0.3% ophthalmic solution	02252570	1.0764	I/C EDS
Paroxetine HCl				
Prem-Paroxetine	10mg tablet	02251345	1.2125	I/C
Prem-Paroxetine	20mg tablet	02251353	1.2939	I/C
Prem-Paroxetine	30mg tablet	02251361	1.3753	I/C
Quinine SO₄				
Apo-Quinine	200mg capsule	02254514	0.2594	I/C
Apo-Quinine	300mg capsule	02254522	0.4069	I/C
Ranitidine				
Novo-Ranitidine	15mg/mL oral solution	02242940	0.1416	I/C
Simvastatin				
pms-Simvastatin	5mg tablet	02252619	0.6152	I/C
pms-Simvastatin	10mg tablet	02252635	1.2168	I/C
pms-Simvastatin	20mg tablet	02252643	1.5039	I/C
pms-Simvastatin	40mg tablet	02252651	1.5039	I/C
pms-Simvastatin	80mg tablet	02252678	1.5039	I/C
Telithromycin				
Ketek (EDS)	400mg tablet	02247520	3.3690	EDS

LEGEND: EDS = Exception Drug Status

I/C = interchangeable

not I/C = not interchangeable

EDS UPDATE EFFECTIVE OCTOBER 1, 2004

CRITERIA FOR NEW EXCEPTION DRUG STATUS (EDS) ADDITIONS

Effective October 1, 2004 the following products will be available for coverage under Exception Drug Status subject to the indicated criteria.

alendronate sodium, tablet, 10mg (Apo-Alendronate-APX)

New interchangeable - same criteria as other brands listed in Appendix A, page 225.

almotriptan malate, tablet, 6.25mg, 12.5mg (Axert-JAN)

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.

atazanavir SO₄, capsule, 150mg, 200mg (Reyataz-BMY)

For management of HIV disease. This drug, as with other antivirals in the treatment of HIV should be used under the direction of an infectious disease specialist.

carvedilol, tablet, 3.125mg, 6.25mg, 12.5mg, 25mg (ratio-Carvedilol-RPH)

New interchangeable - same criteria as other brands listed in Appendix A, page 229.

ciprofloxacin, tablet, 250mg, 500mg, 750mg (Nu-Ciprofloxacin-NXP)

New interchangeable - same criteria as other brands listed in Appendix A, page 230.

ciprofloxacin, extended release tablet, 1000mg (Cipro XL-BAY)

New strength and formulation - same criteria as other brands listed in Appendix A, page 230.

cyproterone acetate, tablet, 50mg (Apo-Cyproterone-APX)

New interchangeable - same criteria as other brands listed in Appendix A, page 232.

enfuvirtide, powder for solution, 108mg/vial (vial) (Fuzeon-HLR)

For management of HIV disease on a case-by-case basis, following committee review of each case. (It was noted that enfuvirtide is not first-line therapy. The most appropriate use of this product is for "salvage therapy"). This drug, as with other antivirals in the treatment of HIV, should be used under the direction of an infectious disease specialist.

estradiol, transdermal therapeutic system (pkg), 25ug, 75ug (Climara-BEX)

New strengths - same criteria as other brand listed in Appendix A, page 236.

imiquimod, topical cream (single-use packet), 5% (Aldara-MDA)

For treatment of genital warts in patients not responding to podofilox and for treatment of patients with a large wart area.

meloxicam, tablet, 7.5mg, 15mg (CO Meloxicam-COB)

New interchangeable - same criteria as other brands listed in Appendix A, page 244.

moxifloxacin HCl, ophthalmic solution, 0.5% (Vigamox-ALC)

For treatment of ophthalmic infections not responding to alternative agents.

mycophenolate mofetil, powder for oral suspension, 200mg/mL (CellCept-HLR)

New strength and formulation - same criteria as other brand listed in Appendix A, page 245.

ofloxacin, ophthalmic solution, 0.3% (pms-Ofloxacin-PMS)

New interchangeable - same criteria as other brands listed in Appendix A, page 247.

telithromycin, tablet, 400mg (Ketek-AVT)

For treatment of:

- (a) Pneumonia,
- (b) Upper and lower respiratory tract bacterial infections known to be resistant to or not responding to alternative antibiotics,
- (c) Infections in patients allergic to alternative antibiotics,
- (d) Non-tuberculous Mycobacterium infections (and prophylaxis),
- (e) For completion of treatment initiated in hospital with macrolides or quinolones, and
- (f) For patients intolerant to erythromycin and/or other antibiotics.

MODIFICATIONS TO CURRENT EXCEPTION DRUG STATUS (EDS) CRITERIA

*Effective **October 1, 2004** the EDS criteria for the following products were modified as indicated regarding the application process:*

donepezil HCl, tablet, 5mg, 10mg (Aricept-PFI)

Initial EDS applications for patients for donepezil (Aricept) will only be accepted from physicians on the Aricept/Exelon/Reminyl EDS application form. This form is available on-line at <http://formulary.drugplan.health.gov.sk.ca> or by calling the Drug Plan. **EDS renewals can be submitted either by telephone, mail or fax.**

galantamine hydrobromide, tablet, 4mg, 8mg, 12mg (Reminyl-JAN)

Initial EDS applications for patients for galantamine hydrobromide (Reminyl-JAN) will only be accepted from physicians on the Aricept/Exelon/Reminyl EDS application form. This form is available on-line at <http://formulary.drugplan.health.gov.sk.ca> or by calling the Drug Plan. **EDS renewals can be submitted either by telephone, mail or fax.**

rivastigmine, capsule, 1.5mg, 3mg, 4.5mg, 6mg; oral solution, 2mg/mL (Exelon-NVR)

Initial EDS applications for patients for rivastigmine (Exelon-NVR) will only be accepted from physicians on the Aricept/Exelon/Reminyl EDS application form. This form is available on-line at <http://formulary.drugplan.health.gov.sk.ca> or by calling the Drug Plan. **EDS renewals can be submitted either by telephone, mail or fax.**

tacrolimus, capsule, 0.5mg, 1mg, 5mg; ampoule, 5mg/mL (Prograf-FUJ)

- (a) For prophylaxis of graft rejection.
- (b) In post bone marrow/stem cell transplant patients who:
 - i) experience graft-vs-host disease not responding to therapeutic doses of cyclosporine, or;
 - ii) with steroid refractory graft-vs-host disease, or;
 - iii) who do not tolerate the side effects of cyclosporine.

REAFFIRMATION OF CURRENT EXCEPTION DRUG STATUS (EDS) CRITERIA FOR EACH OF THE FOLLOWING EFFECTIVE FEBRUARY 1, 2004:

gatifloxacin, tablet, 400mg (Tequin-BMY)

levofloxacin, tablet, 250mg, 500mg (Levaquin-JAN)

moxifloxacin HCl, tablet, 400mg (Avelox-BAY)

For treatment of:

- (a) Pneumonia in patients with underlying lung disease (excluding asthma) and pneumonia in nursing home patients.
- (b) Infections in patients allergic to two or more alternative antibiotics.
- (c) Infections known to be resistant to alternative antibiotics. Resistance must be determined by C & S. Where a C & S cannot be obtained coverage will be approved when a patient has failed at least 2 other classes of antibiotics.
- (d) For completion of antibiotic treatment initiated in hospital when alternatives are not appropriate.