



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

All of the following new listings are effective April 1, 2005:

NEW FULL FORMULARY LISTING:

- Eprosartan mesylate/hydrochlorothiazide, tablet, 600mg/12.5mg (Teveten Plus-SLV)
- Dutasteride, capsule, 0.5mg (Avodart-GSK)

MOVING TO FULL LISTING FROM EDS:

- Brimonidine tartrate, ophthalmic solution, 0.15% (Alphagan P-ALL)

NEW FULL FORMULARY INTERCHANGEABLE LISTINGS:

- Anagrelide HCl, capsule, 0.5mg (RhoXal-Anagrelide-RHO)
- Loperamide HCl, tablet, 2mg (RhoXal-Loperamide-RHO)
- Methylphenidate HCl, tablet, 10mg, 20mg, (Apo-Methylphenidate-APX)
- Dexamethasone, tablet, 0.5mg (Apo-Dexamethasone-APX)
- Metformin, tablet, 500mg, 850mg (CO Metformin-COB)
- Etidronate disodium, tablet, 200mg (CO Etidronate-COB)
- Amitriptyline, tablet, 10mg, 25mg, 50mg (pms-Amitriptyline-PMS)
- Metoprolol tartrate, tablet, 25mg (Novo-Metoprol CT-NOP)
- Salbutamol SO₄, inhalation solution preservative free, 1mg/mL (BCI Salbutamol-BAK)

- Fluvoxamine Maleate, tablet, 50mg, 100mg (BCI Fluvoxamine-BAK)
- Atenolol, tablet, 50mg, 100mg (BCI Atenolol-BAK)
- Clindamycin HCl, capsule, 150mg, 300mg (Gen-Clindamycin-GPM)
- Paroxetine HCl, tablet, 10mg, 20mg, 30mg (RhoXal-Paroxetine-RHO)
- Sotalol HCl, tablet, 80mg, 160mg (RhoXal-Sotalol-RHO)
- Acebutolol HCl, tablet, 100mg, 200mg, 400mg (RhoXal-Acebutolol-RHO)
- Terconazole, vaginal cream (pkg.), 0.4% (Taro-Terconazole-TAR)
- Mirtazapine, tablet 30mg (Novo-Mirtazapine-NOP)

NEW NON-INTERCHANGEABLE LISTINGS:

- Codeine phosphate, tablet, 15mg, 30mg (pms-Codeine-PMS)

NEW EXCEPTION DRUG STATUS INTERCHANGEABLE AGENTS:

The following drugs will be listed as interchangeable under Exception Drug Status according to the same criteria as currently listed brands:

- Fluconazole, tablet, 50mg, 100mg (Taro-Fluconazole-TAR)
- Estradiol, transdermal patch, 50ug/day, 75ug/day, 100ug/day (RhoXal-Estradiol Derm-RHO) (Interchangeable with Estradot only)

- Levofloxacin, tablet, 250mg, 500mg (Novo-Levofloxacin-NOP)
- Meloxicam, tablet, 7.5mg, 15mg (Novo-Meloxicam-NOP)
- Leflunomide, tablet, 10mg, 20mg (Apo-Leflunomide-APX)
- Leflunomide, tablet, 10mg, 20mg (Novo-Leflunomide-NOP)
- Tizanidine HCl, tablet, 4mg (Apo-Tizanidine-APX)

NEW EXCEPTION DRUG STATUS AGENTS:

- Levofloxacin, tablet, 750mg (Levaquin-JAN)

NOTE: the following criteria for the 750mg strength of Levaquin are different to EDS criteria for the currently listed strengths. This drug should only be used for a five day period.

For treatment of:

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

- Ciprofloxacin, extended-release tablet, 500mg (Cipro XL-BAY)
For treatment of patients with **uncomplicated** UTI, not responding to alternative first-line agents.
- Gatifloxacin, ophthalmic solution, 0.3% (Zymar-ALL)
For treatment of ophthalmic infections caused by gram-negative organisms or those not responding to alternative agents.
- Nelfinavir mesylate, tablet, 625mg (Viracept-PFI)
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.*
- Ethacrynic acid, tablet, 25mg (Edecrin-MSD)
For the treatment of patients who cannot tolerate furosemide.

EXCEPTION DRUG STATUS WITH REVISED CRITERIA:

- Tacrolimus, capsule, 0.5mg, 1mg, 5mg; ampoule, 5mg/mL (Prograf-FUJ)
 - (a) for prophylaxis of graft rejection
 - (b) for prophylaxis of rejection in post bone marrow/stem cell transplant patients.
- Celecoxib, capsule, 100mg, 200mg (Celebrex-PFI)
Criteria (d) will be deleted in accordance with Health Canada's ruling. The revised criteria is as follows:
 - (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.

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

- Methylphenidate HCl, extended release tablet, 18mg, 36mg, 54mg (Concerta-JAN)(resubmitted)
- Cinacalcet HCl, tablet, 30mg, 60mg, 90mg (Sensipar-AMG)
- Verteporfin, powder for solution, 2mg/mL (15mg/vial) (7.5mL) (Visudyne-NVO)(resubmitted)
- Adalimumab, solution for injection, 40mg/0.8mL (Humira-ABB)
- Zolmitriptan, nasal spray, 5.0mg (pkg) (Zomig-AST)
- Drospirenone/Ethinyl Estradiol, 3.0mg/0.030mg (Yasmin 21-BEX, Yasmin 28-BEX)
- Memantine HCl, tablet, 10mg (Ebixa-LUD)
- Quinagolide HCl, tablet, 0.25mg, 0.5mg, 0.075mg, 0.150mg (Norprolac-FEI)
- Alefacept, powder for solution, 15mg/0.5mL (Amevive-BGN)
- Eletriptan hydrobromide, tablet, 20mg, 40mg (Relpax-PFI)
- Butoconazole nitrate, vaginal cream, 2% (Gynazole.1-FEI)
- Cyclosporine, liquid, 100mg/mL (Apo-Cyclosporine-APX)
- Cyclosporine, capsule, 100mg (RhoXal-Cyclosporine-RHO)
- Ciprofloxacin HCl/dexamethasone, otic suspension, 0.3%/0.1% (Ciprodex-ALC)
- Agalsidase alfa, injection, 1mg/mL (Replagal-PAL)
- Agalsidase Beta, injection, (Fabrazyme-GZY)
- Clozapine, tablet, 25mg, 100mg (Gen-Clozapine-GPM)

CURRENTLY UNDER REVIEW WITH THE COMMON DRUG REVIEW PROCESS

Lantus; Strattera; Telzir; Aldurazyme; VFend

PRODUCTS NOT RECOMMENDED FOR COVERAGE:

- Sodium hyaluronate, solution for injection (pre-filled syringe), 10mg/mL (Suplasyn-BIO); (Suplasyn m.d.-BIO) Not recommended as has been approved by Health Canada as a device rather than a drug.
- Sodium hyaluronate, solution for injection, 40mg/50mL (vial) (Cystistat-BIO) Not recommended as has been approved by Health Canada as a device rather than a drug.
- Miglustat, capsule, 100mg (Zavesca-ACT) not recommended as the clinical benefits of miglustat over best supportive therapy to improve quality of life and prevent serious complications must be better supported, by valid scientific evidence, to justify the incremental cost.
- Imiquimod, topical cream (single-use packet), 5% (Aldara-MDA) Not recommended for treatment of actinic keratoses, as the clinical benefit does not justify the incremental cost.
- Oxybutynin, transdermal system, 3.9mg/day (Oxytrol-PAL) Not recommended due to a lack of clinical evidence to support the manufacturer's proposed criteria.
- Teriparatide, injection solution (pre-filled pen), 250ug/mL (Forteo-LIL) Not recommended as there is insufficient evidence to demonstrate clinical efficacy and the product is significantly more costly than listed alternatives.

- Treprostinil sodium, injection solution, 1.0mg/mL, 2.5mg/mL, 5.0mg/mL, 10mg/mL (Remodulin-NTI)
Not recommended as the clinical benefit does not justify the incremental cost.
- Zopiclone, tablet, 5mg, 7.5mg (RhoXal-Zopiclone-RHO) Not recommended for coverage as the innovator brand was not recommended for listing.

PLEASE NOTE: Verteporfin

(Visudyne) is provided as a 100% benefit by health regions for patients meeting the following criteria:

- for treatment of predominately classic subfoveal choroidal neovascularization and for pathologic myopia.
- Eligibility will be determined by the ophthalmologist. For eligible patients the cost of the drug and procedure are fully covered by the Department of Health via the health region.

EXEMPTIONS to the MAC POLICY regarding PPI's:

Exemptions will be provided on a case by case basis for patients intolerant or refractory to at least two PPIs within the MAC price. Requests for exemptions with detailed information should be made to the Drug Plan via the EDS process by prescribers or pharmacists.

*Note: currently there are only two PPI's (Pariet and Apo Omeprazole) which are below the MAC price.

RECOMMENDED FOR DELISTING EFFECTIVE October 1, 2005:

Liothyronine Sodium (Cytomel-THM) as this product offers no therapeutic advantage over l-thyroxine.

FROM THE ADVISORY COMMITTEE ON INSTITUTIONAL PHARMACY PRACTICE:

Additions to the Hospital Benefit Drug List:

The following brands were approved as interchangeable:

- flumazenil, injection, 0.1mg/mL (Anexate-HLR); (Flumazenil-SAB)
- Octreotide acetate, injection, 50ug/mL, 100ug/mL, 200ug/mL, 500ug/mL (Omega-OMG)
- Fluconazole, injection, 2mg/mL (Fluconazole injection-SAB)
- Vasopressin, injection, 20units/mL (Vasopressin-SAB)

Separate listings of these products will not appear in the Hospital Benefit Drug list as these drugs are currently listed.

REVISED RECOMMENDATION ON OLANZAPINE INJECTION (ZYPREXA IM-LILLY)

This product was previously not recommended for listing. The reason has been revised to the following : Not recommended due to concerns about inappropriate use and safety issues when used in combination with benzodiazepines. The Zyprexa Zydis formulation is effective in most patients while Clopixol offers the advantage of a longer duration of action.

NOTE REGARDING BILLING OF NEW REQUESTS FOR FLOLAN INJECTION:

New requests for Flolan should be submitted to the Drug Plan in the same manner as Exception Drug Status requests. A manual billing process is required for prescriptions filled for Flolan. Pharmacies should send billings to the Drug Plan, attention Gail Bradley. These prescriptions cannot be billed through the Drug Plan on-line process. As in the past the drug will be provided at no charge to patients who have prior approval.

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FORMULARY AND EDS UPDATES EFFECTIVE APRIL 1, 2005

<u>GENERIC & TRADE</u>			<u>UNIT</u>	
<u>NAME</u>	<u>STRENGTH & FORM</u>	<u>DIN</u>	<u>PRICE</u>	<u>LEGEND</u>
Acebutolol HCl				
Rhoxal-Acebutolol	100mg tablet	02257599	0.1769	I/C
Rhoxal-Acebutolol	200mg tablet	02257602	0.2648	I/C
Rhoxal-Acebutolol	400mg tablet	02257610	0.5260	I/C
Amitriptyline				
pms-Amitriptyline	10mg tablet	02247302	0.0565	I/C
pms-Amitriptyline	25mg tablet	02247303	0.1080	I/C
pms-Amitriptyline	50mg tablet	02247304	0.2008	I/C
Anagrelide HCl				
Rhoxal-Anagrelide	0.5mg capsule	02260107	3.6338	I/C
Atenolol				
BCI Atenolol	50mg tablet	02257629	0.3814	I/C
BCI Atenolol	100mg tablet	02257637	0.6268	I/C
Brimonidine tartrate				
Alphagan P	0.15% ophthalmic solution	02248151	2.5100	
Ciprofloxacin				
Cipro XL (EDS)	500mg extended release tablet	02247916	2.9729	EDS
Clindamycin HCl				
Gen-Clindamycin	150mg capsule	02258331	0.5306	I/C
Gen-Clindamycin	300mg capsule	02258358	1.0612	I/C
Codeine phosphate				
pms-Codeine	15mg tablet	02243978	0.0754	Not I/C
pms-Codeine	30mg tablet	02243979	0.0839	Not I/C
Dexamethasone				
Apo-Dexamethasone	0.5mg tablet	02261081	0.2138	I/C
Dutasteride				
Avodart	0.5mg capsule	02247813	1.7686	
Eprosartan mesylate/hydrochlorothiazide				
Teveten Plus	600mg/12.5mg tablet	02253631	1.1067	
Estradiol				
Rhoxal-Estradiol Derm (EI 50UG Transdermal patch (pkg)		02246967	14.8000	I/C with Estradot
Rhoxal-Estradiol Derm (EI 75UG Transdermal patch (pkg)		02246968	15.8900	I/C with Estradot
Rhoxal-Estradiol Derm (EI 100UG Transdermal patch (pkg)		02246969	16.7100	I/C with Estradot
Ethacrynic acid				
Edecrin (EDS)	25mg tablet	02258528	0.3292	EDS
Etidronate disodium				
CO Etidronate	200mg tablet	02248686	0.9955	I/C

<u>GENERIC & TRADE</u> <u>NAME</u>	<u>STRENGTH & FORM</u>	<u>DIN</u>	<u>UNIT</u> <u>PRICE</u>	<u>LEGEND</u>
Fluconazole				
Taro-Fluconazole (EDS)	50mg tablet	02249294	3.3924	I/C EDS
Taro-Fluconazole (EDS)	100mg tablet	02249308	6.0181	I/C EDS
Fluvoxamine maleate				
BCI Fluvoxamine	50mg tablet	02257661	0.5373	I/C
BCI Fluvoxamine	100mg tablet	02257688	0.9659	I/C
Gatifloxacin				
Zymar	0.3% ophthalmic solution	02257270	2.7342	EDS
Leflunomide				
Apo-Leflunomide (EDS)	10mg tablet	02256495	6.5553	I/C EDS
Apo-Leflunomide (EDS)	20mg tablet	02256509	6.5553	I/C EDS
Novo-Leflunomide (EDS)	10mg tablet	02261251	6.5553	I/C EDS
Novo-Leflunomide (EDS)	20mg tablet	02261278	6.5553	I/C EDS
Levofloxacin				
Levaquin (EDS)	750mg tablet	02246804	10.2533	EDS
Levofloxacin				
Novo-Levofloxacin	250mg tablet	02248262	3.3722	I/C EDS
Novo-Levofloxacin	500mg tablet	02248263	3.8051	I/C EDS
Loperamide HCl				
Rhoxal-Loperamide	2mg tablet	02257564	0.2676	I/C
Meloxicam				
Novo-Meloxicam (EDS)	7.5mg tablet	02258315	0.5332	I/C EDS
Novo-Meloxicam (EDS)	15mg tablet	02258323	0.6152	I/C EDS
Metformin				
CO Metformin	500mg tablet	02257726	0.1320	I/C
CO Metformin	850mg tablet	02257734	0.2268	I/C
Methylphenidate HCl				
Apo-Methylphenidate	10mg tablet	02249324	0.1726	I/C
Apo-Methylphenidate	20mg tablet	02249332	0.3837	I/C
Metoprolol tartrate				
Novo-Metoprol CT	25mg tablet	02261898	0.0698	I/C
Mirtazapine				
Novo-Mirtazapine	30mg tablet	02259354	0.8476	I/C
Nelfinavir mesylate				
Viracept (EDS)	625mg tablet	02248761	4.8000	EDS
Paroxetine HCl				
Rhoxal-Paroxetine	10mg tablet	02254743	1.1317	I/C
Rhoxal-Paroxetine	20mg tablet	02254751	1.0869	I/C
Rhoxal-Paroxetine	30mg tablet	02254778	1.1552	I/C

<u>GENERIC & TRADE</u> <u>NAME</u>	<u>STRENGTH & FORM</u>	<u>DIN</u>	<u>UNIT</u> <u>PRICE</u>	<u>LEGEND</u>
Salbutamol SO4				
BCI Salbutamol	1mg/mL inhalation solution	02259583	0.6610	I/C
Sotalol HCl				
Rhoxal-Sotalol	80mg tablet	02257831	0.6437	I/C
Rhoxal-Sotalol	160mg tablet	02257858	0.7044	I/C
Terconazole				
Taro-Terconazole	0.4% vaginal cream	02247651	13.3200	I/C
Tizanidine HCl				
Apo-Tizanidine (EDS)	4mg tablet	02259893	0.5540	I/C EDS

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

CRITERIA FOR NEW EXCEPTION DRUG STATUS (EDS) ADDITIONS

NEW EXCEPTION DRUG STATUS AGENTS

Effective April 1, 2005 the following products will be available for coverage under Exception Drug Status subject to the indicated criteria:

ciprofloxacin, extended-release tablet, 500mg (Cipro XL-BAY)

For patients with **uncomplicated** UTI, not responding to alternative first-line agents.

ethacrynic acid, tablet, 25mg (Edecrin-MSD)

For treatment of patients who cannot tolerate furosemide.

fluconazole, tablet, 50mg, 100mg (Taro-Fluconazole-TAR)

New interchangeable - same criteria as other brands listed in Appendix A on page 237.

gatifloxacin, ophthalmic solution, 0.3% (Zymar-ALL)

For treatment of ophthalmic infections caused by gram-negative organisms or those not responding to alternative agents.

leflunomide, tablet, 10mg, 20mg (Apo-Leflunomide-APX) (Novo-Leflunomide-NOP)

New interchangeable - same criteria as other brands listed in Appendix A on page 243.

levofloxacin, tablet, 250mg, 500mg (Novo-Levofloxacin-NOP)

New interchangeable - same criteria as other brands listed in Appendix A on page 243.

levofloxacin, tablet, 750mg (Levaquin-JAN)

EDS coverage will only be approved for five days.

For treatment of:

- (a) Pneumonia in patients with underlying lung disease (excluding asthma) and pneumonia in nursing home patients.
- (b) Pneumonia in patients allergic to two or more alternative antibiotics
- (c) Pneumonia known to be resistant to alternative antibiotics. Resistance must be determined by C & S. Where 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 of pneumonia initiated in hospital when alternatives are not appropriate.

meloxicam, tablet, 7.5mg, 15mg (Novo-Meloxicam-NOP)

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

nelfinavir mesylate, tablet, 625mg (Viracept-PFI)

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.*

tizanidine HCl, tablet, 4mg (Apo-Tizanidine-APX)

New interchangeable - same criteria as other brands listed in Appendix A on page 255.

MODIFICATIONS TO CURRENT EXCEPTION DRUG STATUS (EDS) CRITERIA

Effective *April 1, 2005* criteria for the following products are modified as indicated:

celecoxib, capsule, 100mg, 200mg (Celebrex-PFI)

- (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.

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

- (b) in post-bone marrow/stem cell transplant patients.

CHANGE IN STATUS FOR THE FOLLOWING PRODUCTS

Effective *April 1, 2005* the following product changed in status from EDS to full formulary:

brimonidine tartrate, ophthalmic solution, 0.15% (Alphagan P-ALL)

Effective *April 1, 2005* the following product changed in status from not interchangeable to interchangeable with Estradot:

estradiol, transdermal patch, 50ug/day, 75ug/day, 100ug/day (Rhoxal-Estradiol Derm-RHO)

Effective *April 1, 2005* the following products are Not-Interchangeable with currently listed products:

codeine phosphate, tablet, 15mg, 30mg (pms-Codeine-PMS)