Saskatchewan Health | **Drug Plan and Extended Benefits Branch** | **July 2005 Bulletin #103**
ISSN 0708-3246

SASKATCHEWAN FORMULARY COMMITTEE BULLETIN 55th EDITION

All listings are effective July 1, 2005

NEW FULL FORMULARY INTERCHANGEABLE LISTINGS:

- Fosinopril, tablet, 10mg, 20mg (pms-Fosinopril-PMS)
- Atenolol, tablet, 50mg, 100mg (CO Atenolol-COB)
- Fluvoxamine maleate, tablet, 50mg, 100mg (CO Fluvoxamine-COB)
- Fosinopril, tablet, 10mg, 20mg (Gen-Fosinopril-GPM)
- Terbinafine HCl, tablet 250mg (CO Terbinafine-COB)
- Gabapentin, tablet, 100mg, 300mg, 400mg (CO Gabapentin-COB)
- Warfarin, tablet, 1mg, 2mg, 2.5mg, 3mg, 4mg, 5mg (Novo-Warfarin-NOP)
- Divalproex sodium, enteric-coated tablet, 125mg, 250mg and 500mg (Gen-Divalproex-GPM)
- Metformin, tablet, 500mg 850mg (BCI Metformin-BAK)
- Pravastatin, tablet, 10mg, 20mg, 40mg (BCI Pravastatin-BAK)
- Simvastatin, tablet, 5mg, 10mg, 20mg, 40mg, 80mg (BCI Simvastatin-BAK)
- Ranitidine, tablet, 150mg, 300mg (BCI Ranitidine-BAK)

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:

- Bupropion HCl, tablet, 150mg (Novo-Bupropion SR-NOP)
- Ciprofloxacin, ophthalmic solution 0.3% (pms-Ciprofloxacin-PMS)
- Enoxaparin, syringe, 30mg/0.3mL, 40mg/0.4mL, 60mg/0.6mL, 80mg/0.8mL, 100mg/1.0mL (Enoxaparin Injection-NOP)
- Clozapine, tablet, 25mg, 100mg (Gen-Clozapine-GPM) **PLEASE SEE ATTACHED INFORMATION**

NEW EXCEPTION DRUG STATUS AGENTS:

- Adalimumab, solution for injection, 40mg/0.8mL (Humira-ABB)
  For treatment of patients with active rheumatoid arthritis who have failed or are intolerant to methotrexate and leflunomide. *Treatment should be combined with an immunosuppressant. This product should be used in consultation with a specialist in this area: NOTE: Exceptions can be considered in cases where methotrexate or leflunomide are contraindicated.*
- Zolmitriptan, nasal spray, 5mg (Zomig Nasal Spray-AST)
  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.
- Rosiglitazone maleate/metformin hydrochloride, tablet, 1mg/500mg, 2mg/500mg, 4mg/500mg, 2mg/1000mg, 4mg/1000mg (Avandamet-GSK)
  For treatment of diabetes in patients who have met the Exception Drug Status criteria for coverage of rosiglitazone (i.e. treatment of diabetes in patients who have failed or are intolerant to metformin or sulfonylureas) but are inadequately controlled on rosiglitazone.

EXCEPTION DRUG STATUS REVISED CRITERIA:

- Ciprofloxacin, extended-release tablet, 500mg (Cipro XL-BAY)
  For treatment of patients with **uncomplicated** UTI, not responding or allergic to first-line agents.
- Ciprofloxacin, extended-release tablet, 1000mg (Cipro XL-BAY)
  For treatment of patients with **complicated** UTI, not responding or allergic to first-line agents.
- Etanercept, powder for injection (vial) 25mg/vial (Enbrel-AMG)
  Same as current criteria with the addition of: treatment should be combined with an immunosuppressant.
- Anakinra, subcutaneous injection (pre-filled syringe), 100mg/0.67mL (Kineret-AMG)
  Same as current criteria with the addition of: treatment should be combined with an immunosuppressant.

- Botulinum Toxin Type A, sterile lyophilised powder (IU), 100IU (Botox-ALL)
  Same as current criteria with the addition of: treatment of hyperhidrosis of the axilla.
- Desmopressin, tablet, 0.1mg, 0.2mg (DDAVP-FEI) intranasal solution, 10ug/dose (DDAVP-FEI) (Apo-Desmopressin-APX), Same as current criteria with the addition of: treatment of nocturia in patients with a recognized neurologic disorder which causes detrusor over-activity confirmed by cystogram in the absence of obstruction, who have not responded or are intolerant to at least two anticholinergic drugs.

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

- Methylphenidate HCl, extended release tablet, 18mg, 36mg, 54mg (Concerta-JAN) (resubmitted)
- Cyclosporine, liquid, 100mg/mL (Apo-Cyclosporine-APX)
- Cyclosporine, capsule, 100mg (Rhoxal-Cyclosporine-RHO)
- Clozapine, tablet, 25mg, 100mg (Apo-Clozapine-APX)
- Risperidone, powder for suspension sustained-release, 25mg/vial, 37.5mg/vial, 50mg/vial (Risperdal Consta-JAN)
- Agalsidase beta, powder for solution, 5mg/mL (Fabrazyme-GZY)
- Agalsidase alfa, 1mg/mL, injection (Replagal-PAL)

CURRENTLY UNDER REVIEW WITH THE COMMON DRUG REVIEW PROCESS

- Lantus; Strattera; Telzir; Aldurazyme; Norprolac; Xolair; Myfortic; Yasmin; Amevive; Ebixa

PRODUCTS NOT RECOMMENDED FOR COVERAGE:

- Cinacalcet HCl, tablet, 30mg, 60mg, 90mg (Sensipar-AMG) Not recommended as there is insufficient evidence to demonstrate clinical efficacy.
- Eletriptan hydrobromide, tablet, 20mg, 40mg (Relpax-PFI) Not recommended as the product offers no clinical or economic advantage over currently listed products and has a greater potential for drug interactions.
- Butoconazole nitrate, vaginal cream, 2% (Gynazole.1-FEI) Not recommended as it offers no therapeutic or cost advantage over listed alternatives.
- Ciprofloxacin HCl/dexamethasone, otic suspension, 0.3%/0.1% (Ciprodex-ALC) Not recommended as it offers no clinical advantage over currently listed products and it is slightly more expensive than listed alternatives
- Imiquimod, topical cream, 5% (Aldara-MDA)-not recommended for primary superficial basal cell carcinoma.
- Diclofenac sodium, topical solution, 1.5% (Pennsaid-SLV). The clinical benefit does not justify the incremental cost.

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; for pathologic myopia and for treatment of ocular histoplasmosis. Eligibility, based on the above criteria, 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.

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 drugs were approved as restricted benefits to the Hospital Benefit List :

- Argatroban-for the treatment of heparin-induced thrombocytopenia (H.I.T.) in consultation with a haematologist.
- Lepirudin-for the treatment of heparin-induced thrombocytopenia (H.I.T.) in consultation with a haematologist.
- Danaparoid-criteria revised to: treatment of heparin-induced thrombocytopenia (H.I.T.) in consultation with a haematologist
- Pamidronate injection-for the treatment of non-malignant hypercalcemia (Note coverage for treatment of hypercalcemia of malignancy would be covered by the Saskatchewan Cancer Agency.
- Calcitonin salmon, injection-approved for the treatment of non-malignant hypercalcemia (Note: coverage for the treatment of hypercalcemia of malignancy would be covered by the Saskatchewan Cancer Agency).
- Fomepizole-will be restricted to use only in consultation with the Poison and Drug Information Service (PADIS).
- Ranitidine injection (Sabex)-approved as interchangeable.

Note: Change re: Submission of Triplicate Information

The supplementary information section regarding the Triplicate Prescription Program (starting on page 48 at the back of the Formulary) has been updated, to reflect changes to the process for submission of information.

In the fall 2004, the Drug Plan began collecting more complete prescription information from pharmacies, including non-benefit drugs and prescriptions for people who are not eligible under the Drug Plan. The purpose of this expanded information collection is to build a history of prescriptions dispensed to persons in Saskatchewan, as a building block for future phases that will provide more information to health care providers when making decisions about their patients' drug therapy.
An immediate benefit of the expanded information collection is that **more information is being sent electronically to the College of Physicians & Surgeons for the purposes of the Triplicate Prescription Program**. The Drug Plan system now collects prescription information for benefit and non-benefit Triplicate drugs, for Drug Plan beneficiaries and non-beneficiaries, and sends this information electronically to the College of Physicians & Surgeons. This **streamlines the collection process** and makes it more timely, by reducing the manual entry required for prescriptions for non-benefit Triplicate drugs and for non-beneficiaries of the Drug Plan.

Pharmacists please note: You must **continue to mail** the College copy for any Triplicate **prescriptions that are not successfully "adjudicated" or "captured" by the Drug Plan system**. Please call the Drug Plan if you have any questions.

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

FORMULARY AND EDS UPDATES EFFECTIVE JULY 1, 2005

GENERIC & TRADE NAME	*STRENGTH & FORM*	*DIN*	*UNIT PRICE*	*LEGEND*
Adalimumab				
Humira	40mg/0.8mL inj. sol. (p.f. syringe)	02258595	675.0000	EDS
Atenolol				
CO Atenolol	50mg tablet	02255545	0.3814	I/C
CO Atenolol	100mg tablet	02255553	0.6268	I/C
Bupropion HCl				
Novo-Bupropion SR	150mg tablet	02260239	0.6076	I/C EDS
Ciprofloxacin				
pms-Ciprofloxacin 0.3%	0.3% ophthalmic solution	02253933	1.2239	I/C EDS
Divalproex sodium				
Gen-Divalproex	125mg enteric coated tablet	02265133	0.1494	I/C
Gen-Divalproex	250mg enteric coated tablet	02265141	0.2686	I/C
Gen-Divalproex	500mg enteric coated tablet	02265168	0.5373	I/C
Enoxaparin				
Enoxaparin Injection	30mg/0.3mL syringe	02265206	4.5900	I/C EDS
Enoxaparin Injection	40mg/0.4mL syringe	02265214	6.0800	I/C EDS
Enoxaparin Injection	60mg/0.6mL syringe	02265222	9.1200	I/C EDS
Enoxaparin Injection	80mg/0.8mL syringe	02265230	12.1600	I/C EDS
Enoxaparin Injection	100mg/1.0mL syringe	02265249	15.1900	I/C EDS
Fluvoxamine maleate				
CO Fluvoxamine	50mg tablet	02255529	0.5373	I/C
CO Fluvoxamine	100mg tablet	02255537	0.9659	I/C
Fosinopril				
Gen-Fosinopril	10mg tablet	02262401	0.5400	I/C
pms-Fosinopril	10mg tablet	02255944	0.5400	I/C
Gen-Fosinopril	20mg tablet	02262428	0.6494	I/C
pms-Fosinopril	20mg tablet	02255952	0.6494	I/C
Gabapentin				
CO Gabapentin	100mg tablet	02256142	0.2735	I/C
CO Gabapentin	300mg tablet	02256150	0.6651	I/C
CO Gabapentin	400mg tablet	02256169	0.7926	I/C
Metformin				
BCI Metformin	**500mg tablet**	**02265575**	**0.0646**	**I/C**
BCI Metformin	**850mg tablet**	**02265583**	**0.1588**	**I/C**
Pravastatin				
BCI Pravastatin	10mg tablet	02265613	1.0340	I/C
BCI Pravastatin	20mg tablet	02265621	1.2199	I/C
BCI Pravastatin	40mg tablet	02265648	1.4695	I/C

GENERIC & TRADE NAME	***STRENGTH & FORM***	***DIN***	***UNIT PRICE***	***LEGEND***
Ranitidine				
BCI Ranitidine	150mg tablet	02265591	0.4386	I/C
BCI Ranitidine	300mg tablet	02265605	0.8449	I/C
Rosiglitazone maleate/metformin HCl				
Avandamet	1mg/500mg tablet	02247085	0.6510	EDS
Avandamet	2mg/500mg tablet	02247086	1.1773	EDS
Avandamet	4mg/500mg tablet	02247087	1.6167	EDS
Avandamet	2mg/1000mg tablet	02248440	1.2858	EDS
Avandamet	4mg/1000mg tablet	02248441	1.7577	EDS
Simvastatin				
BCI Simvastatin	5mg tablet	02265656	0.6152	I/C
BCI Simvastatin	10mg tablet	02265664	1.2168	I/C
BCI Simvastatin	20mg tablet	02265672	1.5039	I/C
BCI Simvastatin	40mg tablet	02265680	1.5039	I/C
BCI Simvastatin	80mg tablet	02265699	1.5039	I/C
Terbinafine HCl				
CO Terbinafine	150mg tablet	02254727	2.7391	I/C
Warfarin				
Novo-Warfarin	1mg tablet	02265273	0.1934	I/C
Novo-Warfarin	2mg tablet	02265281	0.2046	I/C
Novo-Warfarin	2.5mg tablet	02265303	0.1638	I/C
Novo-Warfarin	3mg tablet	02265311	0.2536	I/C
Novo-Warfarin	4mg tablet	02265338	0.2536	I/C
Novo-Warfarin	5mg tablet	02265346	0.1641	I/C
Zolmitriptan				
Zomig	5.0mg nasal spray	02248993	28.9500	EDS

LEGEND:
EDS = Exception Drug Status
I/C = Interchangeable
Not I/C = Not Interchangeable
***Bold Type** = SOC Contract

CRITERIA FOR NEW EXCEPTION DRUG STATUS (EDS) ADDITIONS

NEW EXCEPTION DRUG STATUS AGENTS

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

adalimumab, solution for injection, 40mg/0.8mL (Humira-ABB)

For treatment of patients with active rheumatoid arthritis who have failed or are intolerant to methotrexate and leflunomide.

Note: Treatment should be combined with an immunosuppressant. This product should be used in consultation with a specialist in this are. Exceptions can be considered in cases where methotrexate or leflunomide are contraindicated.

bupropion HCl, tablet, 150mg (Novo-Bupropion SR-NOP)

New interchangeable - same criteria as other brand listed in Appendix A, on page 224.

ciprofloxacin HCl, ophthalmic solution, 0.3% (pms-Ciprofloxacin-PMS)

New interchangeable - same criteria as other brands listed in Appendix A, on page 226.

enoxaparin, syringe, 30mg/0.3mL, 40mg/0.4mL, 60mg/0.6mL, 80mg/0.8mL, 100mg/1.0mL (Enoxaparin Injection-NOP)

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

rosiglitazone maleate/metformin HCl, tablet, 1mg/500mg, 2mg/500mg, 4mg/500mg, 2mg/1000mg, 4mg/100mg (Avandamet-GSK)

For treatment of diabetes in patients who have met the Exception Drug Status criteria for coverage of rosiglitazone (i.e. treatment of diabetes who have failed or are intolerant to metformin or sulfonylureas) but are inadequately controlled on rosiglitazone.

zolmitriptan, nasal spray, 5mg (Zomig Nasal Spray-AST)

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.

MODIFICATIONS TO CURRENT EXCEPTION DRUG STATUS (EDS) CRITERIA

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

anakinra, subcutaneous injection (pre-filled syringe), 100mg/0.67mL (Kineret-AMG)

For treatment of patients with active rheumatoid arthritis who have failed or are intolerant to methotrexate and leflunomide. (Note - exceptions can be considered in cases where methotrexate or leflunomide are contraindicated). *This product should be used in consultation with a specialist in this area.*

Note: Coverage will not be provided when used in combination with TNF blocking agents (i.e. infliximab and etanercept) due to the significantly higher risk of adverse events.

Treatment should be combined with an immunosuppressant.

botulinum toxin type A, sterile lyophilized powder, 100IU (Botox-ALL)

(a) For treatment of eye dystonias, that is, blepharospasm and strabismus.
(b) For treatment of cervical dystonia, that is, torticollis.
(c) For treatment of other forms of severe spasticity.
(d) For the treatment of hyperhidrosis of the axilla.

desmopressin, tablet, 0.1mg, 0.2mg (DDAVP-FEI)
***intranasal solution, 10ug/dose (DDAVP-FEI) (Apo-Desmopressin-APX)**

(a) For treatment of diabetes insipidus.
(b) For treatment of enuresis in children over 5 years of age refractory to bed-wetting alarms or alternative agents listed in the Formulary.
(c) For the treatment of nocturia in patients with a recognized neurologic disorder which causes detrusor over-activity confirmed by cystogram in the absence of obstruction, who have not responded or are intolerant to at least two anticholinergic drugs.

etanercept, powder for injection (vial), 25mg/vial (Enbrel-AMG)

(a) For treatment of patients with active rheumatoid arthritis who have failed or are intolerant to methotrexate and leflunomide.
(b) For treatment of paediatric patients with active juvenile rheumatoid arthritis who have failed one DMARD.

This product should be used in consultation with a specialist in this area.
Note: Exceptions can be considered in cases where methotrexate or leflunomide are contraindicated. Treatment should be combined with an immunosuppressant.