Saskatchewan Health

Drug Plan and Extended Benefits Branch

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SASKATCHEWAN FORMULARY COMMITTEE UPDATE BULLETIN 52nd Edition

NEW EXCEPTION DRUG STATUS AGENTS

Effective April 1, 2003 the following products are available under Exception Drug Status subject to the indicated criteria:

- **Peginterferon alfa-2b/ribavirin, powder for solution/capsule, 50ug/200mg, 80ug/200mg, 100ug/200mg, 120ug/200mg, 150ug/200mg (Pegetron-SCH)**
  Exception Drug Status Criteria:
  For the treatment of hepatitis C. Coverage will be provided for an initial 6 month period with potential renewal for 2 additional 6 month periods.

- **Valganciclovir HCl, tablet, 450mg (Valcyte-HLR)**
  Exception Drug Status Criteria:
  For treatment of retinitis arising from CMV infection in patients with HIV infection.

NEW DOSAGE FORMS/ STRENGTHS OF EXCEPTION DRUG STATUS AGENTS

Effective April 1, 2003 the following products will be covered under the same Exception Drug Status criteria as the currently listed forms/strengths.

- Efavirenz, tablet, 600mg (Sustiva-BMY)
- Estradiol, transdermal therapeutic system (pkg), 25ug (Estradot-NVR)

NEW FULL FORMULARY LISTINGS:

- Glucose oxidase/peroxidase reagent, strip (BD Latitude-BDC)
- Quinine SO4, tablet, 300mg (Quinine-Odan-ODN)
- Atenolol, tablet, 25mg (pms-Atenolol-PMS)

CHANGE IN STATUS FROM EXCEPTION DRUG STATUS TO FULL FORMULARY

- Quetiapine, tablet, 25mg, 100mg, 150mg, 200mg, 300mg (Seroquel-AST)

NEW FULL FORMULARY INTERCHANGEABLE LISTINGS

- Polymyxin B SO_4/Bacitracin (Zinc)/Neomycin SO_4/Hydrocortisone, ophthalmic ointment, 10000u/400u/5mg/10mg per gram (3.5g) (Sab-Cortimyxin-SAB)
- Indapamide hemihydrate, tablet, 1.25mg (Apo-Indapamide-APX)
- Gabapentin, capsules 100mg, 300mg, 400mg (Nu-Gabapentin – NXP)

Effective ***April 1, 2003,*** the following products will change from interchangeable to ***NOT interchangeable*** with the currently listed brands:

Acetaminophen/Caffeine/ Codeine, tablet, with 15mg codeine; with 30mg codeine (Atasol-15-HOR, Atasol-30-HOR)

MODIFICATIONS TO CURRENT EXCEPTION DRUG STATUS CRITERIA

Effective April 1, 2003 the Exception Drug status criteria for the following products were modified as indicated:

- **Raloxifene HCl, tablet, 60mg (Evista-LIL)**

(a) For treatment of osteoporosis in patients who do not respond to etidronate disodium/ calcium (Didrocal) after receiving it for 1 year.

(b) For treatment of osteoporosis in patients unable to tolerate etidronate disodium/calcium (Didrocal).

- **Infliximab, injection, 100mg/vial (Remicade-SCH)**
  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.)
  Treatment should be combined with an immunosuppressant. This product should be used in consultation with a specialist in this area.
  Note: Remicade EDS criteria for Crohn's Disease is unchanged.

- **Etanercept powder for injection, 25mg/vial (Enbrel-WYA)**
  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.

Effective April 1, 2003 the Exception Drug Status criteria for the following products will be as indicated:

- **Estradiol, transdermal gel (metered dose pump), 0.06% (Estrogel-SCH); transdermal therapeutic system, 25ug, 50ug, 100ug (Estraderm-NVR), 37.5ug, 50ug, 75ug, 100ug (Vivelle-NVR), 50ug, 100ug (Climara-BEX), 25ug, 50ug (Oesclim-PAL), 37.5ug, 50ug, 75ug, 100ug (Estradot-NVR) Estradiol/norethindrone acetate, transdermal therapeutic system, 50ug/140ug, 50ug/250ug (Estalis-NVR) Estradiol & norethindrone acetate/estradiol, transdermal therapeutic system, 50ug & 140ug/50ug (Estalis-Sequi-NVR) 50ug & 250ug/50ug (Estracomb-NVR) (Estalis-Sequi-NVR)**
  In addition to the current criteria: For treatment of patients with a fasting plasma triglyceride level of 4.5 mmol/L or more.

Please note as published in Pharmacy Bulletin #334(b) that effective February 1, 2003, simvastatin, tablet, 5mg, 10mg, 20mg, 40mg, 80mg (Apo-Simvastatin) (Gen-Simvastatin) and amiodarone, tablet, 200mg (Novo-Amiodarone-NOP) (Gen-Amiodarone-GPM) (pms-Amiodarone-PMS) (Rhoxal-Amiodarone-RHO) were recommended for full Formulary listing interchangeable with currently listed brands.

SOME OF THE PRODUCTS CURRENTLY UNDER REVIEW BY THE FORMULARY COMMITTEE

- Cyclosporine, liquid, 100mg/mL (Apo-Cyclosporine-APX)
- Cyclosporine, capsule, 100mg (Rhoxal-Cyclosporine-RHO)
- Valdecoxib, tablet, 10mg, 20mg (Bextra-PHU)
- Latanoprost/timolol maleate, ophthalmic solution (2.5mL), 50ug/mL/5mg/mL (Xalacom-PHU)
- Hydroxychloroquine SO_4, tablet, 200mg (Apo-Hydroxyquine-APX)
- Rosuvastatin, 10mg, 20mg, 40mg (Crestor-AST)
- Clozapine, tablet, 25mg, 100mg (Gen-Clozapine-GPM)

PRODUCTS REVIEWED AND NOT RECOMMENDED FOR LISTING

- **Metronidazole, extended-release tablet, 750mg (Florazole ER-FEI*)*** The clinical benefit of once a day dosing does not justify the incremental cost.

- **Testosterone, transdermal delivery system, 24.3mg (5mg/day) (Androderm-PAL*)***
  The clinical benefit does not justify the significantly higher cost over the listed alternatives.

- **Thyrotropin alfa, powder for injection, 0.9mg/mL (Thyrogen-GZY)**
  This drug was referred to the Saskatchewan Cancer Agency as this drug is considered adjunctive therapy to cancer treatment and may be considered for coverage by the Cancer Agency.

- **Tegaserod hydrogen maleate, tablet, 6mg (Zelnorm-NVR)**
  There is a lack of comparative studies, and information regarding long-term risks as well as only modest therapeutic benefit provided by this drug.

- **Fondaparinux sodium, injection solution (pre-filled syringe), 2.5mg/0.5mL (Arixtra-OSS)**
  This product offers no clinical advantage relative to the incremental cost. There is a potential for increased risk of bleeding.

DELISTED PRODUCTS

As noted in previous bulletins:

- *All strengths of cefaclor have been delisted effective April 1, 2003.*
- *Tolterodine L-tartrate, tablet, 1mg, 2mg (Detrol-PHU) have been delisted effective April 1, 2003. Patients who have EDS for Detrol will continue to be covered.*

The following products will be delisted from the Formulary effective **October 1, 2003*:***

- *Metronidazole, capsule, 500mg (Flagyl-RHO) (Trikacide-PMS)*

Update & Update Index Stickers

Enclosed with this mailing are update and update index stickers for the 52nd Edition of the Formulary. New this year, the "update index" stickers are to be placed in the Formulary starting on page 380. These index stickers will assist in locating products on the update stickers.

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

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FORMULARY AND EDS UPDATES EFFECTIVE APRIL 1, 2003

GENERIC & TRADE NAME	*STRENGTH & FORM*	*DIN*	*UNIT PRICE*	*LEGEND*
Amiodarone				
Gen-Amiodarone	200mg tablet	02240604	1.4074	*I/C*
Novo-Amiodarone	200mg tablet	02239835	1.4074	*I/C*
pms-Amiodarone	200mg tablet	02242472	1.4074	*I/C*
Rhoxal-Amiodarone	200mg tablet	02243836	1.4074	*I/C*
Simvastatin				
Apo-Simvastatin	5mg tablet	02247011	0.6836	*I/C*
Gen-Simvastatin	5mg tablet	02246582	0.6836	*I/C*
Apo-Simvastatin	10mg tablet	02247012	1.3520	*I/C*
Gen-Simvastatin	10mg tablet	02246583	1.3520	*I/C*
Apo-Simvastatin	20mg tablet	02247013	1.6709	*I/C*
Gen-Simvastatin	20mg tablet	02246737	1.6709	*I/C*
Apo-Simvastatin	40mg tablet	02247014	1.6709	*I/C*
Gen-Simvastatin	40mg tablet	02246584	1.6709	*I/C*
Apo-Simvastatin	80mg tablet	02247015	1.6709	*I/C*
Gen-Simvastatin	80mg tablet	02246585	1.6709	*I/C*
Atenolol				
pms-Atenolol	25mg tablet	02246581	0.1908	
Efavirenz				
Sustiva	600mg tablet	02246045	14.2900	*EDS*
Estradiol				
Estradot	25ug transdermal therapeutic system (pkg)	02245676	19.8000	*EDS*
Gabapentin				
Nu-Gabapentin	100mg tablet	02246742	0.2735	*I/C*
Nu-Gabapentin	300mg tablet	02246743	0.6651	*I/C*
Nu-Gabapentin	400mg tablet	02246744	0.7926	*I/C*
Glucose oxidase/peroxidase reagent				
BD Latitude	strip	00950911	0.8626	
Indapamide hemihydrate				
Apo-Indapamide	1.25mg tablet	02245246	0.2037	*I/C*
Quinine SO4				
Quinine-Odan	300mg tablet	00695432	0.3418	

Peginterferon alfa-2b/ribavirin

FORMULARY AND EDS UPDATES EFFECTIVE APRIL 1, 2003

GENERIC & TRADE NAME	***STRENGTH & FORM***	***DIN***	***UNIT PRICE***	*LEGEND*
Pegetron	50ug/0.5mL pwd for sol/200mg cap (pkg)	02246026	782.2000	*EDS*
Pegetron	80ug/0.5mL pwd for sol/200mg cap (pkg)	02246027	782.2000	*EDS*
Pegetron	100ug/0.5mL pwd for sol/200mg cap (pkg)	02246028	782.2000	*EDS*
Pegetron	120ug/0.5mL pwd for sol/200mg cap (pkg)	02246029	861.1800	*EDS*
Pegetron	150ug/0.5mL pwd for sol/200mg cap (pkg)	02246030	861.1800	*EDS*
Polymyxin B SO4/Bacitracin (zinc)/Neomycin SO4/Hydrocortisone				
Sab-Cortimyxin	10,000u/400u/5mg/10mg per g oph oint (3.5g)	02242485	9.7300	*I/C*
Valganciclovir HCl				
Valcyte	450mg tablet	02245777	22.9100	*EDS*

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

EDS UPDATE EFFECTIVE APRIL 1, 2003

*Effective **April 1, 2003** the following products will be available for coverage under Exception Drug Status subject to the indicated criteria.*

estradiol, transdermal therapeutic system (pkg), 25ug (Estradot-NVR)

(a) For treatment in patients who are unable to tolerate oral estrogen.
(b) For treatment of patients with a fasting plasma triglyceride level of 4.5mmol/L or more.

peginterferon alfa-2b/ribavirin, pwd for sol/capsule (pkg), 50ug/0.5mL pwd for sol/200 mg capsule, 80ug/0.5mL pwd for sol/200mg capsule, 100ug/0.5mg pwd for sol/200mg capsule, 120ug/0.5mL pwd for sol/200mg capsule, 150ug/0.5mL pwd for sol/200mg capsule

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

valganciclovir HCl, tablet, 450mg (Valcyte-HLR)

For treatment of retinitis arising from CMV infection in patients with HIV infection.

*Effective **April 1, 2003** the following product will be covered under the same Exception Drug Status criteria as the currently listed forms/strengths.*

efavirenz, tablet, 600mg (Sustiva-BMY)

New strength - same criteria as tablets listed in Appendix A, page 233.
For management of HIV disease. *This drug, as with other retrovirals in treatment of HIV, should be used under the direction of an infectious disease specialist.*

MODIFICATIONS TO CURRENT EXCEPTION DRUG STATUS (EDS) CRITERIA

*Effective **April 1, 2003** the EDS criteria for the following products will be as indicated:*

raloxifene HCl, tablet, 60mg (Evista-LIL)

Exception Drug Status criteria was revised to read as follows:

(a) For treatment of osteoporosis in patients who do not respond to etidronate disodium/calcium (Didrocal) after receiving it for 1 year.
(b) For treatment of osteoporosis in patients unable to tolerate edironate disodium/calcium (Didrocal).

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

Exception Drug Status criteria for Rheumatoid Arthritis was revised to read as follows:

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

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

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

Exception Drug Status criteria was revised to read as follows:

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.

estradiol, transdermal gel (metered dose pump), 0.06% (Estrogel-SCH); transdermal therapeutic system, 25ug, 50ug, 100ug (Estraderm-NVR), 37.5ug, 50ug, 75ug, 100ug (Vivelle-NVR), 50ug, 100ug (Climara-BEX), 25ug, 50ug (Oesclim-PAL), 37.5ug, 50ug, 75ug, 100ug (Estradot-NVR)
estradiol & norethindrone acetate/estradiol, transdermal therapeutic system (8), 50ug & 140ug/50ug (Estralis-Sequi-NVR); 50ug & 250ug/50ug (Estracomb-NVR) (Estralis-Sequi-NVR)
Exception Drug Status criteria has been revised to include:

(b) For treatment of patients with a fasting plasma triglyceride level of 4.5 mmol/L or more.

CHANGE IN STATUS FOR THE FOLLOWING PRODUCTS

Effective ***April 1, 2003*** the following products will change from interchangeable to ***NOT interchangeable*** with the currently listed brands:

- **acetaminophen/caffeine/codeine, tablet, with 15mg codeine; with 30mg codeine (Atasol-15-HOR, Atasol-30-HOR)**

Effective ***April 1, 2003*** the following product will ***not require*** Exception Drug Status (EDS) coverage and is to be considered a full formulary benefit:

- **quetiapine, tablet, 25mg, 100mg, 150mg, 200mg, 300mg (Seroquel-AST)**

Effective ***April 1, 2003*** the following products will be **delisted** from the Saskatchewan Formulary:

- **tolterodine l-tartrate, tablet, 1mg, 2mg (Detrol-PHU)**
  Patients who currently have EDS coverage for this drug will continue to be covered.

- **cefaclor, suspension, 25mg/mL, 50mg/mL (Apo-Cefaclor-APX) (Dom-Cefaclor-DOM) (pms-Cefaclor-PMS) (Ceclor-LIL); capsule, 250mg, 500mg (pms-Cefaclor-PMS) (Apo-Cefaclor-APX) (Dom-Cefaclor-DOM) (Nu-Cefaclor-NXP)**
  (N ovo-Cefaclor-NOP); 75mg/mL (pms-Cefaclor-PMS) (Apo-Cefaclor-APX) (Dom-Cefaclor-DOM) (Ceclor BID-PMS)