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SASKATCHEWAN FORMULARY COMMITTEE BULLETIN UPDATE TO THE 54th EDITION

NEW FULL FORMULARY LISTING:

The following products will be listed effective January 1, 2005.

- Diltiazem HCl, extended release tablet, 120mg, 180mg, 240mg, 300mg, 360mg (Tiazac XC-BVL)
- Mirtazapine, orally disintegrating tablet, 15mg, 30mg, 45mg (Remeron RD- ORG)

NEW FULL FORMULARY INTERCHANGEABLE LISTINGS:

The following products will be listed as interchangeable effective January 1, 2005:

- Trifluridine, ophthalmic solution, 1% (Sab-Trifluridine-SAB)
- Simvastatin, tablet, 5mg, 10mg, 20mg, 40mg, 80mg (Dom-Simvastatin-DOM)
- Lovastatin, tablets, 20mg, 40mg (CO-Lovastatin-COB)
- Diltiazem HCl, controlled-delivery capsule, 120mg, 180mg, 240mg, 300mg (Gen-Diltiazem CD-GPM)
- Mirtazapine, tablet, 15mg, 30mg, 45mg (Gen-Mirtazapine-GPM)

NEW EXCEPTION DRUG STATUS INTERCHANGEABLE AGENTS:

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

- Clonidine HCl, tablet, 0.025mg (Apo-Clonidine-APX)
- Bisoprolol fumarate, tablet, 5mg, 10mg (Apo-Bisoprolol-APX)
- Meloxicam, tablet, 7.5mg, 15mg (Gen-Meloxicam-GPM)

NEW EXCEPTION DRUG STATUS AGENTS:

Effective January 1, 2005 the following products will be available under Exception Drug Status:

- Somatropin, injection cartridge, 10mg (Nutropin AQ Pen-HLR)
  For treatment of children who have growth failure due to inadequate secretion of normal endogenous growth hormone, and who have growth failure associated with chronic renal insufficiency.
  Exception Drug Status coverage is not required for S.A.I.L. patients. Coverage is provided under Saskatchewan Aids to Independent Living (S.A.I.L.) Program.
  The following 3 products for treatment of chronic active hepatitis C will be covered for a duration of up to 48 weeks. Genotypes 2 and 3 may respond to 24 weeks of therapy:
- Peginterferon alfa-2b/ribavirin, powder for solution/capsule, 50ug/0.5mL/200mg, 80ug/0.5mL/200mg, 100ug/0.5mL/200mg, 120ug/0.5mL/200mg, 150ug/0.5mL/200mg (Pegetron Redipen-SCH) **AND**
- Peginterferon alfa-2a/ribavirin, injection (pre-filled syringe)/tablet, 180ug/0.5mL /200mg; injection (vial)/tablet, 180ug/1mL/200mg (Pegasys RBV-HLR) **AND**
- Peginterferon alfa-2a, injection (pre-filled syringe), 180ug/0.5mL, (vial) 180ug/1mL (Pegasys-HLR)

EXCEPTION DRUG STATUS WITH REVISED CRITERIA:

- Valganciclovir HCL, tablet, 450mg (Valcyte-HLR)
  Coverage for prophylaxis and treatment of CMV infection in solid organ transplant patients is increased to 6 months.

PLEASE NOTE the following revised criteria for all of the listed interferons for the treatment of Hepatitis C:

For treatment of chronic active hepatitis C for a duration of up to 48 weeks therapy. Genotypes 2 and 3 may respond to 24 weeks of therapy.

The products affected are:

- Interferon alfa-2b, powder for injection, 10 million IU; injection solution albumin (human) free, 6 million IU/mL (0.5mL), 10million IU/mL (0.5mL, 1mL); multi-dose pen (kit) albumin (human) free, 18 million IU/pen, 30 million IU/pen, 60 million IU/pen (Intron-A-SCH)
- Interferon alfa-2a, injection solution albumin (human) free, 3 million IU/1mL, 9million IU/1mL,18 million IU/3mL (Roferon A-HLR)
- Peginterferon alfa-2b, powder for injection (vial), 50ug/0.5mL, 80ug/0.5mL, 120ug/0.5mL, 150ug/0.5mL (Unitron Peg-SCH)
- Interferon alfa-2b/Ribavirin, multi-dose pen albumin (human) free/capsule (package), 15 million IU/mL/200mg (Rebetron-SCH)
- Peginterferon alfa-2b/ribavirin, powder for solution/capsule, 50ug/200mg, 80ug/200mg, 100ug/200mg, 120ug/200mg, 150ug/200mg (Pegetron-SCH)

Revised criteria for Ciprofloxacin extended-release, tablet, 1000mg (Cipro XL-BAY) effective January 1, 2005:
For the treatment of complicated urinary tract infections not responding to first-line agents.

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

- Clozapine, tablet, 25mg, 100mg (Apo-Clozapine-APX)
- Clozapine, tablet, 25mg, 100mg (Gen-Clozapine-GPM)
- Cyclosporine, liquid, 100mg/mL (Apo-Cyclosporine-APX)
- Cyclosporine, capsule, 100mg (Rhoxal-Cyclosporine-RHO)
- Miglustat, capsule, 100mg (Zavesca-ACT)
- Ciprofloxacin, extended-release tablet, 500mg (Cipro XL-BAY)
- Mixed salts amphetamine, extended release capsule, 5mg, 10mg, 15mg, 20mg, 25mg, 30mg (Adderall XR-RBP)

PRODUCTS NOT RECOMMENDED FOR COVERAGE:

- Olanzapine, powder for injection (vial), 10mg/vial (Zyprexa IM-LIL)
- Levothyroxine (Sodium), tablet, 0.137mg (Synthroid-ABB)
- Tenofovir disoproxil fumarate, tablet, 300mg (Viread-GSI)
- Oseltamivir phosphate, capsule, 75mg; powder for solution, 12mg/mL (Tamiflu-HLR)

SOME OF THE PRODUCTS CURRENTLY UNDER REVIEW BY THE NEW COMMON DRUG REVIEW PROCESS:

Replagal
Humira
Sensipar
Fabrazyme
Relpax
Teveten Plus
Forteo
Remodulin
Gynazole.1
Ciprodex

TOLTERODINE L-TARTRATE, extended release capsule, 2mg, 4mg
Pfizer has notified the Drug Plan of a name change for the above product, from Unidet to Detrol LA.
This is a name change only, there is no change to DIN, price or formulation. The product remains an EDS drug with the same criteria previously listed on page 256 of the Formulary.

WITHDRAWAL OF VIOXX FROM THE WORLD MARKET
Effective September 30, 2004, Merck Frosst has voluntarily withdrawn the drug, Vioxx (rofecoxib), from the world market because the findings of a recent study indicate the drug may increase the risk of a heart attack or stroke.

Health Canada and Merck Frosst have issued an advisory recommending that patients taking Vioxx consult their physicians about discontinuing use of the product and about treatment alternatives.

Merck Frosst will be advising pharmacies about their Reimbursement Policy and Procedure.
In an effort to ease transition to alternatives, the Drug Plan & Extended Benefits Branch has granted Exception Drug Status (EDS) coverage for Celebrex and Bextra effective October 2, 2004 to all patients who currently have EDS coverage for Vioxx. This means that if a patient is switched to Celebrex or Bextra, EDS coverage will already be in place. Patients would still need, however, to contact their physician to discuss which alternative therapy is most appropriate for them.

If you have any questions regarding this coverage please contact the Drug Plan at 306-787-8744 or 1-800-667-7578.

FROM THE ADVISORY COMMITTEE ON INSTITUTIONAL PHARMACY PRACTICE:
Additions to the Hospital Benefit Drug List:
The following drugs have been approved as benefits under the Saskatchewan Hospital Drug Benefits list effective October 1, 2004:
Octreotide acetate, injection, 50ug/mL, 100ug/mL, 200ug/mL, 500ug/mL-Omega
Fluconazole, injection, 2mg/mL-SAB
Vasopressin, injection, 2mg/mL-SAB
Flumazenil, injection, 0.1mg/mL-SAB
NOTE: Olanzapine, powder for injection (vial), 10mg/vial (Zyprexa IM-LIL was not recommended for listing due to a lack of information on safety and appropriate use. The Zyprexa Zydis formulation is effective in most patients and 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 JANUARY 1, 2005

GENERIC & TRADE NAME	*STRENGTH & FORM*	*DIN*	*UNIT PRICE*	*LEGEND*
Bisoprolol fumarate				
Apo-Bisoprolol	5mg tablet	02256134	0.2393	I/C EDS
Apo-Bisoprolol	10mg tablet	02256177	0.3965	I/C EDS
Clonidine HCl				
Apo-Clonidine	0.025mg tablet	02248732	0.1972	I/C EDS
Clindamycin phosphate/benzoyl peroxide				
BenzaClin	1%/5% topical gel	02248472	0.9266	I/C
Diltiazem HCl				
Gen-Diltiazem CD	120mg controlled delivery capsule	02254808	0.8703	I/C
Gen-Diltiazem CD	180mg controlled delivery capsule	02254816	1.1551	I/C
Gen-Diltiazem CD	240mg controlled delivery capsule	02254824	1.5322	I/C
Gen-Diltiazem CD	300mg controlled delivery capsule	02254832	1.9153	I/C
Diltiazem HCl				
Tiazac XC	120mg extended release tablet	02256738	0.8334	
Tiazac XC	180mg extended release tablet	02256746	1.1062	
Tiazac XC	240mg extended release tablet	02256754	1.4673	
Tiazac XC	300mg extended release tablet	02256762	1.4673	
Tiazac XC	360mg extended release tablet	02256770	1.4673	
Lovastatin				
CO Lovastatin	20mg tablet	02248572	1.1834	I/C
CO Lovastatin	40mg tablet	02248573	2.1827	I/C
Meloxicam				
Gen-Meloxicam	7.5mg tablet	02255987	0.5332	I/C EDS
Gen-Meloxicam	15mg tablet	02255995	0.6152	I/C EDS
Mirtazapine				
Gen-Mirtazapine	15mg tablet	02256096	0.4069	I/C
Gen-Mirtazapine	30mg tablet	02256118	0.9418	I/C
Gen-Mirtazapine	45mg tablet	02256126	1.2207	
Mirtazapine				
Remeron RD	15mg orally disintegrating tablet	02248542	0.4232	
Remeron RD	30mg orally disintegrating tablet	02248543	0.8463	
Remeron RD	45mg orally disintegrating tablet	02248544	1.2695	
Peginterferon Alfa-2a				
Pegasys	180ug/0.5mL (pre-filled syringe)	02248077	425.8400	EDS
Pegasys	180ug/1mL injection (vial)	02248078	425.8400	EDS

GENERIC & TRADE NAME	***STRENGTH & FORM***	***DIN***	***UNIT PRICE***	***LEGEND***
Peginterferon Alfa-2a				
Pegasys RBV	180ug/0.5mL (p.f. syringe)/200mg tablet	02253429	425.8400	EDS
Pegasys RBV	180ug/1mL inj (vial)/200mg tablet	02253410	425.8400	EDS
Peginterferon Alfa-2b/Ribavarin				
Pegetron Redipen	50ug/0.5mL pwd for sol/200mg cap	02254573	782.2000	EDS
Pegetron Redipen	80ug/0.5mL pwd for sol/200mg cap	02254581	782.2000	EDS
Pegetron Redipen	100ug/0.5mL pwd for sol//200mg cap	02254603	782.2000	EDS
Pegetron Redipen	120ug/0.5mL pwd for sol/200mg cap	02254638	861.1800	EDS
Pegetron Redipen	150ug/0.5mL pwd for sol/200mg cap	02254646	861.1800	EDS
Simvastatin				
Dom-Simvastatin	5mg tablet	02253747	0.6460	I/C
Dom-Simvastatin	10mg tablet	02253755	1.2776	I/C
Dom-Simvastatin	20mg tablet	02253763	1.5790	I/C
Dom-Simvastatin	40mg tablet	02253771	1.5790	I/C
Dom-Simvastatin	80mg tablet	02253798	1.5790	I/C
Somatropin				
Nutropin AQ Pen	10mg injection (cartridge)	02249002	411.8000	EDS
Trifluridine				
Sab-Trifluridine	1% ophthalmic solution (7.5mL)	02248529	26.5900	I/C

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

bisoprolol fumarate, tablet, 5mg, 10mg (Apo-Bisoprolol-APX)
New interchangeable - same criteria as other brands listed in Appendix A, page 227.

clonidine HCl, tablet, 0.025mg (Apo-Clonidine-APX)
New interchangeable - same criteria as other brand listed in Appendix A, page 231.

meloxicam, tablet, 7.5mg, 15mg (Gen-Meloxicam-GPM)
New interchangeable - same criteria as other brands listed in Appendix A, page 244.

peginterferon alfa-2a, injection (pre-filled syringe) 180ug/0.5mL; injection (vial), 180ug/1mL (Pegasys-HLR)
For the treatment of hepatitis C. Coverage will be provided for a duration of up to 48 weeks. Genotypes 2 and 3 may respond to 24 weeks of therapy.

peginterferon alfa-2a/ribavirin, injection (pre-filled syringe)/tablet, 180ug/0.5mL /200mg; injection (vial)/tablet, 180ug/1mL/200mg (Pegasys RBV-HLR)
For the treatment of hepatitis C. Coverage will be provided for a duration of up to 48 weeks. Genotypes 2 and 3 may respond to 24 weeks of therapy.

peginterferon alfa-2b/ribavirin, powder for solution/capsule, 50ug/0.5mL/200mg, 80ug/0.5mL/200mg, 100ug/0.5mL/200mg, 120ug/0.5mL/200mg, 150ug/0.5mL/200mg (Pegetron Redipen-SCH)
For the treatment of hepatitis C. Coverage will be provided for a duration of up to 48 weeks. Genotypes 2 and 3 may respond to 24 weeks of therapy.

somatropin, injection cartridge, 5mg (Nutropin AQ Pen-HLR)
For treatment of children who have growth failure due to inadequate secretion of normal endogenous growth hormone, and who have growth failure associated with chronic renal insufficiency.
Exception Drug Status coverage is not required for S.A.I.L. patients. Coverage is provided under Saskatchewan Aids to Independent Living (S.A.I.L.) Program.

MODIFICATIONS TO CURRENT EXCEPTION DRUG STATUS (EDS) CRITERIA

*Effective **January 1, 2005** criteria for the following products were modified as indicated:*

ciprofloxacin, extended release tablet, 1000mg (Cipro XL-BAY)
For treatment of complicated urinary tract infections not responding to first-line agents.

interferon alfa-2a, injection solution albumin (human) free, 3 million IU/1mL, 9 million IU/1mL, 18 million IU/3mL (Roferon-A-LIL)
b) For treatment of chronic active hepatitis C for a duration of up to 48 weeks therapy. Genotypes 2 and 3 may respond to 24 weeks of therapy.

interferon alfa-2b, powder for injection, 10 million IU; injection solution albumin (human) free, 6 million IU/mL (0.5mL), 10 million IU/mL (0.5mL, 1mL); multi-dose pen (kit) albumin (human) free, 18 million IU/pen, 30 million IU/pen, 60 million IU/pen (Intron-A-SCH)

b) For treatment of chronic active hepatitis C for a duration of up to 48 weeks therapy. Genotypes 2 and 3 may respond to 24 weeks of therapy.

interferon alfa-2b/ribavirin, multi-dose pen albumin (human) free/capsule (package), 15 million IU/mL/200mg (Rebetron-SCH)

b) For treatment of chronic active hepatitis C for a duration of up to 48 weeks therapy. Genotypes 2 and 3 may respond to 24 weeks of therapy.

peginterferon alfa-2b, powder for injection (vial), 50ug/0.5mL, 80ug/0.5mL, 120ug/0.5mL, 150ug/0.5mL (Unitron PEG-SCH)

b) For treatment of chronic active hepatitis C for a duration of up to 48 weeks therapy. Genotypes 2 and 3 may respond to 24 weeks of therapy.

peginterferon alfa-2b/ribavirin, powder for solution/capsule, 50ug/200mg, 80ug/200mg, 100ug/200mg, 120ug/200mg, 150ug/200mg (Pegetron-SCH)

b) For treatment of chronic active hepatitis C for a duration of up to 48 weeks therapy. Genotypes 2 and 3 may respond to 24 weeks of therapy.

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

b) For prophylaxis and treatment of CMV infection in solid organ transplant patients. Coverage will be approved for a six month period.