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SASKATCHEWAN FORMULARY COMMITTEE UPDATE BULLETIN TO THE 55th EDITION OF THE SASKATCHEWAN FORMULARY

All listings are effective **April 1, 2006** unless otherwise indicated.

NEW STRENGTHS/FORMS FULL FORMULARY LISTINGS:

- Risperidone, orally disintegrating tablet, 3mg, 4mg (Risperdal M-Tab-JAN)
- Tamsulosin HCl, controlled release tablet, 0.4mg (Flomax CR-BOE)
- Epinephrine, injection solution (package), 0.15mg& 0.3mg/dose (Twinject-PAL)
- Valsartan, tablet, 40mg (Diovan-NVR)
- Hydrochlorothiazide, tablet, 12.5mg (pms-Hydrochlorothiazide-PMS)

NEW FULL FORMULARY INTERCHANGEABLE LISTINGS:

- Diltiazem HCl, capsule, 120mg, 180mg, 240mg, 300mg, 360mg (Novo-Diltiazem HCl ER-NOP)
- Diltiazem HCl, capsule, 120mg, 180mg, 240mg, 300mg, 360mg (Sandoz Diltiazem T-SDZ)
- Anagrelide HCI, capsule, 0.5mg (PMS-Anagrelide-PMS)
- Isotretinoin, capsule, 10mg, 40mg (Clarus-PRM)

NOTE: listed effective February 1, 2006:

- Topiramate, tablet, 25mg, 100mg, 200mg (Rhoxal-Topiramate-RHO)
- Topiramate, tablet, 25mg, 100mg, 200mg (Dom-Topiramate-DOM)
- Sertraline HCl, capsule, 25mg,
- 50mg, 100mg (Novo-Sertraline-NOP)
- Buspirone, tablet, 10mg (CO Buspirone-COB)
- Mirtazapine, tablet, 15mg (pms-Mirtazapine-PMS)
- Mirtazapine, tablet, 30mg (ratio-Mirtazapine-RPH)
- Levetiracetam, tablet, 250mg,500mg,750mg (CO Levetiracetam-COB)

NEW EXCEPTION DRUG STATUS (EDS) LISTINGS:

- Abacavir SO4/lamivudine, tablet, 600mg/300mg (Kivexa-GSK) for the 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. This is consistent with the Canadian Expert Drug Advisory Committee (CEDAC) recommendation.
- Zoledronic acid, solution, 5mg/100mL (Aclasta-NVR) for symptomatic treatment of Paget's disease of the bone. Note: Only one treatment per year is required.

NEW STRENGTHS/FORMS OF CURRENTLY LISTED EDS PRODUCTS:

- Etanercept, pre-filled syringe, 50mg/mL (Enbrel-AMG)
- Dalteparin sodium, injection solution, single dose syringe, 25,000 IU/mL (0.3mL) (Fragmin-PFI)
- Somatropin, injection, 8.8mg (5.83mg) (vial) (Saizen-SRO)

NEW INTERCHANGEABLE EXCEPTION DRUG STATUS LISTINGS:

Note: Listed effective February 1, 2006:

- Desferoxamine mesylate, powder for solution, 500mg/vial, 2G/vial (Desferrioxamine mesilate - DBU)
- Alendronate sodium, tablet, 70mg (pms-Alendronate-PMS)
- Azithromcyin, tablet, 250mg, 600mg (pms-Azithromycin-PMS)
- Azithromycin, tablet, 250mg (Sandoz Azithromycin-SDZ)
- Azithromycin, tablet, 250mg, 600mg (CO Azithromycin-COB)
- Sumatriptan, tablet, 50mg, 100mg (ratio-Sumatriptan-RPH)
- Sumatriptan, tablet, 25mg, 50mg, 100mg (Dom-Sumatriptan-DOM)

EXCEPTION DRUG STATUS REVISED CRITERIA:

- Rosiglitazone maleate/metformin HCl, tablet, 2mg/1000mg, 4mg/1000mg (Avandamet-GSK) for the convenience of patients who have been stabilized on metformin and rosiglitazone.
- Low molecular weight heparins - dalteparin sodium, syringe, 2,500IU (0.2mL), 5,000IU (0.2mL); injection solution, 10,000IU/mL (1mL), 25,000IU/mL (3.8mL) (Fragmin-PFI); enoxaparin, syringe, 30mg/mL, 40mg/mL, 60mg/mL, 80mg/mL, 100mg/mL (Lovenox-AVT) (Enoxaparin Inj.-NOP); injection solution, 100mg/mL (3mL); 150mg/mL (Lovenox HP-AVT); nadroparin calcium,

syringe, 9,500IU/mL (0.3mL, 0.4mL, 0.6mL, 0.8mL, 1.0mL) (Fraxiparine-AVT); syringe, 19,000IU/mL (0.6mL, 0.8mL, 1mL) (Fraxiparine Forte-AVT); tinzaparin sodium, syringe, 10,000IU/mL (0.35mL, 0.45mL), 20,000IU/mL (0.5mL, 0.7mL, 0.9mL); injection solution, 10,000IU/mL (2mL), 20,000IU/mL (2mL) (Innohep-LEO) in addition to the current EDS criteria the following revision: For prophylaxis in patients undergoing total hip replacement or following hip fracture surgery for up to 35 days following the procedure.

- Mycophenolate mofetil, capsule, 250mg; tablet, 500mg; powder for oral suspension, 200mg/mL (CellCept-HLR) in addition to the current EDS criteria: For the treatment of proliferative lupus nephritis in patients refractory or intolerant to standard therapy such as cyclophosphamide and cyclosporine.
- Peginterferon alfa-2a, pre-filled syringe, 180ug/0.5mL; injection), 180ug/1mL (Pegasys-HLR) for the additional criteria: For the management of hepatitis B for up to 48 weeks.

CURRENTLY UNDER REVIEW WITH THE COMMON DRUG REVIEW PROCESS (as of publication date of this Bulletin):

Advicor, Aptivus, Caduet, Levemir, Macugen, Novomix-30, Raptiva, Somavert, Trelstar, Viread

SOME OF THE OTHER PRODUCTS UNDER REVIEW BY THE REVIEW COMMITTEES:

- Cyclosporine, liquid, 100mg/mL (Apo-Cyclosporine-APX)
- Cyclosporine, capsule, 25mg, 50mg, 100mg (Rhoxal-Cyclosporine-RHO)
- Omalizumab, powder for solution, 150mg/vial (Xolair-NVR)

PRODUCTS NOT RECOMMENDED FOR COVERAGE :

- Memantine HCl, tablet, 10mg (Ebixa-LUD)
- Pregabalin, capsule, 25mg, 50mg, 75mg, 150mg, 300mg (Lyrica-PFI
- Atomoxetine HCl, capsule, 10mg, 18mg, 25mg, 40mg, 60mg (Strattera-LIL)

The Canadian Expert Drug Advisory Committee (CEDAC) recommended that the above products not be listed. Details of these recommendations can be found on the CCOHTA website at **www,ccohta.ca/CDR/CEDACRecommendations.**

The Saskatchewan review committees support the recommendations of CEDAC.

Other products not recommended for coverage by the Saskatchewan review committees are:

- Somatropin, lyophilised powder for injection 5mg & 10mg (vial), injection solution, 10mg/2mL injection cartridge, 10mg/2mL (Nutropin & Nutropin AQ-HLR) and
- Somatropin, injection, 3.3mg, 5mg & 8.8mg (Saizen-SRO)

The above two products were not recommended for the treatment of growth hormone deficiency in adults as there was insufficient clinical evidence to justify the incremental cost. Coverage continues under EDS according to the current criteria listed in Appendix A of the Formulary.

- Glimepiride, tablet, 1mg, 2mg, 4mg (Novo-Glimepiride-NOP) and
- Glimepiride, tablet, 1mg, 2mg, 4mg (Sandoz-Glimepiride-SDZ)

These two generic brands of glimerpiride were not recommended as the innovator brand is not listed.

- Niacin, extended release tablet, 500mg, 750mg, 1000mg (Niaspan-ORX)

This product was not recommended as the convenience of once-a-day dosing and possibility of less flushing does not justify the incremental cost.

FROM THE ADVISORY COMMITTEE ON INSTITUTIONAL PHARMACY PRACTICE:

There were no additions to the Hospital Benefit Drug List for this update.

RECOMMENDED FOR DELISTING FROM THE FORMULARY:

- Enoxaparin, injection, 30mg/0.3mL, 40mg/0.4mL, 60mg/0.6mL, 80mg/0.8mL, 100mg/mL (Novo-enoxaparin-NOP)

Health Canada has withdrawn the Notice of Compliance on this product and therefore it has been removed from the market and will be delisted effective April 1, 2006.

The Health Quality Council of Saskatchewan recently addressed the issue of wet nebulization in "Breathing Easier: Opportunities to improve the quality of asthma care in Saskatchewan." The Health Quality Council stated, "the Canadian Asthma Consensus Guidelines discourage the use of wet nebulized drugs because more effective and less expensive drug-powdered forms of the same medications are available." The Saskatchewan drug review committees support these findings and following a discussion of the literature, a review of initiatives in other provinces and a review of utilization data for wet nebulization in the province have concluded that:

- wet nebulization offers no therapeutic advantage over metered-dose or dry powder inhalers
- wet nebulization is more costly, less efficient and less convenient than dry delivery methods
- use of wet nebulization in the province is relatively low.

REQUIREMENTS FOR DRUGS FOR NON-APPROVED INDICATIONS

Occasionally drugs are required for non-approved indications on a case by case basis. In order to conduct a timely review of these requests the drug review committees request the following information be provided by the prescriber:

- the disease or problem being treated
- list of previous therapies tried and the response achieved
- other non-exception options available and why not appropriate
- name of the drug being requested
- clinical evidence available to support use of the drug with provision of such evidence
- outcome measures that will be followed to assess the effect of the drug
- dose of the drug and length of time to be used

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FORMULARY AND EDS UPDATES EFFECTIVE FEBRUARY 1, 2006

GENERIC & TRADE NAME	*STRENGTH & FORM*	*DIN*	*UNIT PRICE*	*LEGEND*
Alendronate sodium				
pms-Alendronate	70mg tablet	02273179	5.5750	I/C EDS
Azithromycin				
CO Azithromycin	250mg tablet	02255340	3.4533	I/C EDS
pms-Azithromycin	250mg tablet	02261634	3.4533	I/C EDS
Sandoz Azithromycin	250mg tablet	02265826	3.4533	I/C EDS
CO Azithromycin	600mg tablet	02256088	7.6250	I/C EDS
pms-Azithromycin	600mg tablet	02261642	7.6250	I/C EDS
Buspirone				
CO Buspirone	10mg tablet	02262916	0.6521	I/C
Clindamycin phosphate				
Taro-Clindamycin	1% topical solution	02266938	0.2260	I/C
Deferoxamine mesylate				
Desferrioxamine Mesilate	500mg/vial injection	02241600	8.8800	I/C
Desferrioxamine Mesilate	2g/vial injection	02247022	38.1400	I/C
Levetiracetam				
CO Levetiracetam	250mg tablet	02274183	1.2125	I/C
CO Levetiracetam	500mg tablet	02274191	1.4811	I/C
CO Levetiracetam	750mg tablet	02274205	2.1077	I/C
Mirtazapine				
pms-Mirtazapine	15mg tablet	02273942	0.3750	I/C
ratio-Mirtazapine	30mg tablet	02270927	0.7812	I/C
Sumatriptan				
Dom-Sumatriptan	25mg tablet	02270749	10.2419	I/C EDS
Dom-Sumatriptan	50mg tablet	02270757	10.3274	I/C EDS
ratio-Sumatriptan	50mg tablet	02271583	9.8356	I/C EDS
Dom-Sumatriptan	100mg tablet	02270765	11.3774	I/C EDS
ratio-Sumatriptan	100mg tablet	02271591	10.8356	I/C EDS
Topiramate				
Dom-Topiramate	25mg tablet	02271141	0.8374	I/C
Dom-Topiramate	100mg tablet	02271168	1.5871	I/C
Dom-Topiramate	200mg tablet	02271176	2.5121	I/C
Sandoz Topiramate	25mg tablet	02260050	0.7975	I/C
Sandoz Topiramate	100mg tablet	02260069	1.5114	I/C
Sandoz Topiramate	200mg tablet	02267837	2.3925	I/C

FORMULARY AND EDS UPDATES EFFECTIVE APRIL 1, 2006

GENERIC & TRADE NAME	***STRENGTH & FORM***	***DIN***	***UNIT PRICE***	***LEGEND***
Abacavir SO4/Lamivudine				
Kivexa	600mg/300mg tablet	02269341	22.3000	EDS
Anagrelide HCl				
pms-Anagrelide	0.5mg capsule	02274949	3.6338	
Dalteparin sodium				
Fragmin	25,000IU/mL pre-filled syringe	02132648	16.0800	EDS
Diltiazem HCl				
Novo-Diltiazem HCl ER	120mg sustained release capsule	02271605	0.5527	I/C
Sandoz Diltiazem T	120mg sustained release capsule	02245918	0.5527	I/C
Novo-Diltiazem HCl ER	180mg sustained release capsule	02271613	0.7336	I/C
Sandoz Diltiazem T	180mg sustained release capsule	02245919	0.7336	I/C
Novo-Diltiazem HCl ER	240mg sustained release capsule	02271621	0.9731	I/C
Sandoz Diltiazem T	240mg sustained release capsule	02245920	0.9731	I/C
Novo-Diltiazem HCl ER	300mg sustained release capsule	02271648	1.2163	I/C
Sandoz Diltiazem T	300mg sustained release capsule	02245921	1.2163	I/C
Novo-Diltiazem HCl ER	360mg sustained release capsule	02271656	1.4672	I/C
Sandoz Diltiazem T	360mg sustained release capsule	02245922	1.4672	I/C
Epinephrine				
Twinject	0.15mg/dose inj. sol. (package)	02268205	85.7200	Not I/C
Twinject	0.3mg/dose inj. sol. (package)	02247310	85.7200	Not I/C
Etanercept				
Enbrel	50mg/mL pre-filled syringe	02274728	361.1100	EDS
Hydrochlorothiazide				
pms-Hydrochlorothiazide	12.5mg tablet	02274086	0.0343	
Isotretinoin				
Clarus	10mg capsule	02257955	1.4822	I/C
Clarus	40mg capsule	02257963	3.0247	I/C
Risperidone				
Risperdal M-Tab	3mg orally disintegrating tablet	02268086	3.1194	
Risperdal M-Tab	4mg orally disintegrating tablet	02268094	4.1592	
Somatropin				
Saizen	8.8mg injection (vial)	02272083	377.62	EDS
Tamsulosin HCl				
Flomax CR	0.4mg controlled release tablet	02270102	0.6510	
Valsartan				
Diovan	40mg tablet	02270528	1.1971	
Zoledronic acid				
Aclasta	5mg/100mL inj. sol. (vial)	02269198	675.0000	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 **February 1, 2006,** the following products will be available for coverage under Exception Drug Status subject to the indicated criteria.*

***alendronate sodium, tablet, 70mg (pms-Alendronate-PMS)**
New interchangeable - same criteria as other brands listed in Appendix A, page 221.

***azithromycin, tablet, 250mg (CO Azitromycin-COB) (pms-Azithromycin-PMS) (Sandoz Azithromycin-SDZ); 600mg (CO Azithromycin-COB) (pms-Azithromycin-PMS)**
New interchangeable - same criteria as other brands listed in Appendix A, page 223.

***deferoxamine mesylate, injection, 500mg/vial; 2g/vial (Desferrioxamine Mesilate-DBU)**
New interchangeable - same criteria as other brand listed in Appendix A, page 229.

***sumatriptan, tablet, 25mg (Dom-Sumatriptan-DOM); 50mg, 100mg (ratio-Sumatriptan-RPH) (Dom-Sumatriptan-DOM)**
New interchangeable - same criteria as other brands listed in Appendix A, page 251.

*Effective **April 1, 2006,** the following products will be available for coverage under Exception Drug Status subject to the indicated criteria.*

abacavir SO4/lamivudine, tablet, 600mg/300mg (Kivexa-GSK)
For the 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.*

etanercept, pre-filled syringe, 50mg/mL (Enbrel-AMG)
New strength - same criteria as other strength listed in Appendix A, page 233.

somatropin, injection, 8.8mg (vial) (5.83mg) (Saizen-SRO)
New strength - same criteria as other strength listed in Appendix A, page 251.

zoledronic acid, injection solution, 5mg/100mL (Aclasta-NVR)
For symptomatic treatment of Paget's disease of the bone.
Note: Only one treatment per year is required.

MODIFICATIONS TO CURRENT EXCEPTION DRUG STATUS (EDS) CRITERIA

*Effective **April 1, 2006** criteria for the following product is modified as indicated:*
dalteparin sodium, pre-filled syringe, 25,000IU/mL (0.3mL) (Fragmin-PFI)
New strength - same criteria as other strengths listed in Appendix A, page 229 with the addition of:
(f) For prophylaxis in patients undergoing total hip replacement or following hip fracture surgery for up to 25 days following the procedure.

mycophenolate mofetil, capsule, 250mg; tablet, 500mg; powder for oral suspension, 200mg/mL (CellCept-HLR)
(b) For treatment of proliferative lupus nephritis in patients refractory or intolerant to standard therapy such as cyclophosphamide and cyclosporine.

peginterferon alfa-2a, pre-filled syringe, 180ug/0.5mL; injection (vial), 180ug/1mL (Pegasys-HLR)
b) For the management of hepatitis B for up to 48 weeks.