Saskatchewan Health | **Drug Plan and Extended Benefits Branch** | **October 2006 Bulletin #108**
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SASKATCHEWAN FORMULARY COMMITTEE BULLETIN FOR THE 56th EDITION OF THE SASKATCHEWAN FORMULARY

The following two products became a full Formulary benefit **August 1, 2006**:

- Insulin, regular pork, injection solution, 100U/ml (10ml) (Hypurin Regular Insulin Pork-WCK)
- Insulin NPH Isophane, pork, injection suspension (Hypurin NPH Insulin Isophane Pork-WCK)

The remaining listings are effective **October 1, 2006** unless otherwise indicated.

NEW FULL FORMULARY LISTINGS:

- Amlodipine besylate/atorvastatin calcium, tablet, 5mg/10mg, 5mg/20mg, 5mg/40mg, 5mg/80mg, 10mg/10mg, 10mg/20mg, 10mg/40mg, 10mg/80mg (Caduet-PFI)

NEW FULL FORMULARY INTERCHANGEABLE LISTINGS:

- Domperidone maleate, tablet, 10mg (Gen-Domperidone-GPM)
- Mirtazapine, tablet, 30mg (CO Mirtazapine-COB)
- Mirtazapine, orally disintegrating tablet, 15mg, 30mg, 45mg (Novo-Mirtazapine-NOP)
- Methylphenidate HCl, tablet, 5mg (Apo-Methylphenidate-APX)
- Terbinafine HCl, tablet, 250mg (Sandoz Terbinafine-SDZ)
- Pindolol, tablet, 5mg, 10mg, 15mg (Sandoz Pindolol-SDZ)
- Carbamazepine, chewable tablet, 100mg (Sandoz Carbamazepine Chewtabs-SDZ)
- Carbamazepine, controlled release tablet, 200mg, 400mg (Sandoz Carbamazepine CR-SDZ)
- Diclofenac sodium, enteric tablet, 25mg, 50mg (Sandoz Diclofenac-SDZ)
- Cilazapril, tablet, 1mg, 2.5mg, 5mg (pms-Cilazapril-PMS)
- Diclofenac sodium, sustained release tablet, 75mg, 100mg (Sandoz Diclofenac SR-SDZ)
- Trazodone, tablet, 50mg, 100mg (ratio-Trazodone-RPH)
- Topiramate, tablet, 25mg, 100mg, 200mg (Apo-Topiramate-APX)
- Paroxetine HCl, tablet, 10mg (Gen-Paroxetine-GPM)
- Betahistine dihydrochloride, tablet, 16mg, 24mg, (Novo-Betahistine-NOP)

NEW EXCEPTION DRUG STATUS (EDS) LISTINGS:

- Tipranavir, capsule, 250mg (Aptivus-BOE)
  For the management of HIV disease in patients who have been shown to be non-responsive or resistant to all currently listed protease inhibitors.
  This drug, as with other antivirals in the treatment of HIV, should be used under the direction of an infectious disease specialist.
- Quinagolide HCl, tablet, 0.075mg, 0.150mg (Norprolac-FEI)
  For the treatment of hyperprolactinemia in patients who have failed or are intolerant to bromocriptine.

NEW STRENGTHS/FORMS OF CURRENTLY LISTED EDS PRODUCTS SUBJECT TO CURRENT CRITERIA:

- Saquinavir mesylate, tablet, 500mg (Invirase-HLR)

NEW INTERCHANGEABLE EDS LISTINGS SUBJECT TO CURRENT CRITERIA:

- Tizanidine HCL, tablet, 4mg (Gen-Tizanidine-GPM)
- Calcitonin salmon, nasal spray (bottle), 200IU/dose (Sandoz Calcitonin NS-SDZ)
- Azithromycin, tablet, 250mg (Gen-Azithromycin-GPM)
- Azithromycin, oral suspension, 20mg/mL, 40mg/mL (pms-Azithromycin-PMS)

EDS REVISED CRITERIA:

- Olanzapine tablet 2.5, 5, 7.5, 10, & 15mg and orally disintegrating tablet 5, 10, 15mg (Zyprexa & Zyprexa Zidis-LIL)
  Criteria (d) has been revised to:
  (d) For maintenance treatment of bipolar disorder in patients who are unresponsive to other first line agents (lithium, divalproex and lamotrigine).
- Etanercept, powder for injection (vial), 25mg/vial; pre-filled syringe, 50mg/mL (Enbrel-AMG)
  Criteria (c) has been revised to:
  (c) For treatment of psoriatic arthritis in patients who have failed or are intolerant to methotrexate and one other DMARD.

CURRENTLY UNDER REVIEW WITH THE COMMON DRUG REVIEW PROCESS (as of the printing of this Bulletin):

Altace plus Felodipine, Amevive, Cipralex, Enablex, Fosavance, Hepsera, Humira (psoriatic arthritis), Lantus, Nuvaring, Prezista, Rituxan (rheumatoid arthritis), Truvada, Vesicare

OTHER PRODUCTS CURRENTLY UNDER REVIEW IN SASKATCHEWAN INCLUDE:
Duo Trav, Levemir, Pantoloc M, Raptiva, Somavert, Trosec, Vfend

PRODUCTS NOT RECOMMENDED FOR COVERAGE VIA THE COMMON DRUG REVIEW (CDR) PROCESS:
Saskatchewan supports the CDR process. The following products were reviewed by the Canadian Expert Drug Advisory Committee (CEDAC) under the national Common Drug Review (CDR) process. The CEDAC recommendations to participating provinces were that the following products not be listed under provincial drug plans:

- Insulin soluble aspart/insulin aspart protamine crystal, injection suspension, 30%/70% (NovoMix 30-NOO). Based on the CEDAC review the Saskatchewan review committees have not recommended coverage for this product noting that this product offers no clinical advantage over alternative listed combinations.
- Pegaptanib sodium, injection solution, 0.3mg/90uL (pre-filled syringe) (Macugen-PFI)
  This product also was not recommended by CEDAC. The Saskatchewan review committees support the CEDAC recommendation and note that the clinical benefit does not justify the incremental cost of the product.

  For more information on the CDR recommendations please visit the website: www.cadth.ca/index.php/en/cdr/recommendations/search.

OTHER PRODUCTS NOT RECOMMENDED FOR COVERAGE BY THE SASKATCHEWAN REVIEW COMMITTEES ARE:

- Niacin/Lovastatin, tablet (sustained-release niacin/IR lovastatin) 500mg/20mg & 1000mg/20mg (Advicor-ORX)
  Saskatchewan review committees have not recommended this product for listing noting that this product offers no clinical advantage and is more expensive than individual prescriptions of the components due to the Standing Offer Contract price for lovastatin.
- Fenofibrate, tablet, 100mg, 160mg (Apo-Feno-Supra-APX)
  AND
- Glimepiride, tablet, 1mg, 2mg, 3mg, 4mg (Co Glimepiride-COB)
  were not recommended for listing as the innovator brands of these products are not listed.

NOT RECOMMENDED-NEW INDICATIONS FOR CURRENTLY LISTED PRODUCTS

- Etanercept, powder for injection (vial), 25mg/vial, pre-filled syringe, 50mg/mL (Enbrel-AMG)
  AND
- Infliximab, injection, 100mg/vial (Remicade-SCH)
  The Saskatchewan review committees have not recommended the above products as a benefit for ankylosing spondylitis. The committees have suggested that the clinical benefit does not justify the incremental cost.

RECOMMENDED FOR DELISTING EFFECTIVE JANUARY 1, 2007:

- **Insulin (regular/protamine) lispro, injection suspension, 100U/mL, 25%/75% (5x3mL) (Humalog Mix 25-LIL). For those patients currently taking the drug, coverage will continue i.e. they will be GRANDFATHERED.** CEDAC recommended that participating provincial drug plans review their listing decisions on insulin (regular insulin/protamine) lispro (Humalog Mix 25-LIL). The Saskatchewan Formulary Committee (SFC) have recommended that Humalog Mix 25 be delisted from the Formulary as new clinical evidence indicates this product offers no advantage over listed alternative insulin combination products.

FROM THE ADVISORY COMMITTEE ON INSTITUTIONAL PHARMACY PRACTICE:
There are no new products recommended for listing.

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

FORMULARY AND EDS UPDATES EFFECTIVE OCTOBER 1, 2006

GENERIC & TRADE NAME	STRENGTH & FORM	DIN	UNIT PRICE	LEGEND
Amlodipine besylate/atorvastatin calcium				
Caduet	5mg/10mg tablet	02273233	2.6583	
Caduet	5mg/20mg tablet	02273241	3.4720	
Caduet	5mg/40mg tablet	02273268	3.4720	
Caduet	5mg/80mg tablet	02273276	3.4720	
Caduet	10mg/10mg tablet	02276284	2.6548	
Caduet	10mg/20mg tablet	02273292	3.4720	
Caduet	10mg/40mg tablet	02273306	3.4720	
Caduet	10mg/80mg tablet	02273314	3.4720	
Azithromycin				
Gen-Azithromycin	250mg tablet	02278359	3.3727	I/C EDS
Azithromycin				
pms-Azithromycin	20mg/mL oral suspension	02274388	0.8102	I/C EDS
pms-Azithromycin	40mg/mL oral suspension	02274396	1.1478	I/C EDS
Betahistine dihydrochloride				
Novo-Betahistine	16mg tablet	02280191	0.3190	I/C
Novo-Betahistine	24mg tablet	02280205	0.4785	I/C
Calcitonin salmon				
Sandoz Calcitonin NS	200IU/actuation	02261766	26.2200	I/C EDS
Carbamazepine				
Sandoz Carb. Chewtabs	100mg chewable tablet	02261855	0.0836	I/C
Carbamazepine				
Sandoz Carbamazepine CR	200mg controlled release tablet	02261839	0.2048	I/C EDS
Sandoz Carbamazepine CR	400mg controlled release tablet	02261847	0.4095	I/C EDS
Cilazapril				
pms-Cilazapril	1mg tablet	02280442	0.4033	I/C
pms-Cilazapril	2.5mg tablet	02280450	0.4649	I/C
pms-Cilazapril	5mg tablet	02280469	0.5400	I/C
Diclofenac sodium				
Sandoz Diclofenac	25mg enteric coated tablet	02261952	0.2064	I/C
Sandoz Diclofenac	50mg enteric coated tablet	02261960	0.4272	I/C
Diclofenac sodium				
Sandoz Diclofenac SR	75mg sustained release tablet	02261901	0.6191	I/C
Sandoz Diclofenac SR	100mg sustained release tablet	02261944	0.8544	I/C
Domperidone maleate				
Gen-Domperidone	10mg tablet	02278669	0.1624	I/C
Methylphenidate HCl				
Apo-Methlyphenidate	5mg tablet	02273950	0.1028	I/C
Mirtazapine				
Novo-Mirtazapine OD	15mg orally disintegrating tablet	02279894	0.2962	I/C
Novo-Mirtazapine OD	30mg orally disintegrating tablet	02279908	0.5925	I/C
Novo-Mirtazapine OD	45mg orally disintegrating tablet	02279916	0.8887	I/C
CO Mirtazapine	30mg tablet	02274361	0.8463	I/C
Paroxetine HCl				
Gen-Paroxetine	10mg tablet	02248012	1.1317	I/C

FORMULARY AND EDS UPDATES EFFECTIVE OCT 1, 2006 CON'T.

GENERIC & TRADE NAME	*STRENGTH & FORM*	*DIN*	*UNIT PRICE*	*LEGEND*
Pindolol				
Sandoz Pindolol	5mg tablet	02261782	0.2477	I/C
Sandoz Pindolol	10mg tablet	02261790	0.4302	I/C
Sandoz Pindolol	15mg tablet	02261804	0.6321	I/C
Quinagolide HCl				
Norprolac	0.075mg tablet	02223767	1.1827	EDS
Norprolac	0.150mg tablet	02223775	1.7686	EDS
Saquinavir mesylate				
Invirase	500mg tablet	02279320	4.4500	EDS
Terbinafine HCl				
Sandoz Terbinafine	250mg tablet	02262177	2.7389	I/C
Tipranavir				
Aptivus	250mg capsule	02273322	8.5000	EDS
Tizanidine HCl				
Gen-Tizanidine	4mg tablet	02272059	0.5540	I/C EDS
Topiramate				
Apo-Topiramate	25mg tablet	02279614	0.7178	I/C
Apo-Topiramate	100mg tablet	02279630	1.3603	I/C
Apo-Topiramate	200mg tablet	02279649	2.1532	I/C
Trazodone				
ratio-Trazodone	50mg tablet	02277344	0.2403	I/C
ratio-Trazodone	100mg tablet	02277360	0.4293	I/C

LEGEND: EDS-Exception Drug Status; I/C-Interchangeable; Not I/C-Not Interchangeable

CRITERIA FOR NEW EXCEPTION DRUG STATUS (EDS) ADDITIONS

EDS UPDATE EFFECTIVE AUGUST 1, 2006

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

***midodrine HCl, tablet, 70mg (Apo-Midodrine-APX)**
New interchangeable - same criteria as other brand listed in Appendix A, page 241.

EDS UPDATE EFFECTIVE OCTOBER 1, 2006

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

***azithromycin, tablet, 250mg (Gen-Azithromycin-GPM); oral suspension, 20mg/mL, 40mg/mL (pms-Azithromycin-PMS)**
New interchangeable - same criteria as other brands listed in Appendix A, page 222.

***calcitonin salmon, nasal spray, 200iu/mL (Sandoz Calcitonin NS-SDZ)**
New interchangeable - same criteria as other brands listed in Appendix A, page 223.

***carbamazepine, controlled release tablet, 200mg, 400mg (Sandoz Carbamazepine CR-SDZ)**
New interchangeable - same criteria as other brands listed in Appendix A, page 224.

quinagolide HCl, tablet, 0.25mg, 0.50mg, 0.75mg, 0.150mg (Norprolac-FEI)
For patients with hyperprolactineamia who have failed or are intolerant to bromocriptine.

saquinavir mesylate, tablet, 500mg (Invirase-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.*

tipranavir, capsule 250mg (Aptivus-BOE)
For the management of HIV disease in patients who have been shown to be non-responsive or resistant to all currently listed protease inhibitors. *This drug, as with all antivirals in the treatment of HIV, should be used under the direction of an infectious disease specialist.*

***tizanidine HCl, tablet, 4mg (Gen-Tizanidine-GPM)**
New interchangeable - same criteria as other brands listed in Appendix A, page 253.

MODIFICATIONS TO CURRENT EXCEPTION DRUG STATUS (EDS) CRITERIA

*Effective **October 1, 2006** criteria for the following product is modified as indicated:*

etanercept, powder for injection (vial), 25mg/vial; pre-filled syringe, 50mg/mL (Enbrel-AMG)
(c) For treatment of psoriatic arthritis in patients who have failed or are intolerant to methotrexate and one other DMARD.

olanzapine, tablet, 2.5mg, 5mg, 7.5mg, 10mg, 15mg (Zyprexa-LIL); orally disintegrating tablet, 5mg, 10mg, 15mg (Zyprexa Zydis-LIL)
(d) For maintenance treatment of bipolar disorder in patients who are unresponsive to other first line agents (lithium, divalproex and lamotrigine).