Saskatchewan Health

Drug Plan and Extended Benefits Branch

January, 2003
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SASKATCHEWAN FORMULARY COMMITTEE UPDATE BULLETIN 52nd Edition

NEW EXCEPTION DRUG STATUS AGENTS

Effective January 1, 2003 the following product is available under Exception Drug Status subject to the indicated criteria.

- **Darbepoetin alfa, pre-filled syringe, 25ug/mL (0.4mL), 40ug/mL (0.5mL), 100ug/mL (0.3mL, 0.4mL, 0.5mL), 200ug/mL (0.3mL, 0.4mL, 0.5mL), 500ug/mL (0.3mL) (Aranesp-AMG)**
  Exception Drug Status Criteria:
  For treatment of anemia in chronic renal disease patients prior to initiation of dialysis.
  Note: Coverage for dialysis patients is provided under the Saskatchewan Aids to Independent Living (S.A.I.L.) Program. EDS coverage is not required for S.A.I.L. patients.

NEW DOSAGE FORMS/ STRENGTHS OF EXCEPTION DRUG STATUS AGENTS

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

- Enoxaparin, syringe, 150mg/mL (0.8mL, 1mL) (Lovenox HP-AVT)

NEW FULL FORMULARY LISTINGS

- Bimatoprost, ophthalmic solution, 0.03% (Lumigan-ALL)
- Methazolamide, tablet, 50mg (Apo-Methazolamide-APX)
- Metoprolol tartrate, tablet, 25mg (Apo-Metoprolol-APX)

FIRST ENTRY GENERIC

- Amoxicillin trihydrate/potassium clavulanate, tablet, 875mg/125mg (Apo-Amoxi Clav-APX)
- Flunarizine HCl, capsule, 5mg (Apo-Flunarizine-APX)
- Ipratropium bromide/salbutamol SO4, inhalation solution (2.5mL), 0.5mg/2.5mg (ratio-IPRA SAL UDV-RTP)
- Ipratropium bromide/salbutamol SO4, inhalation solution (2.5mL), 0.5mg/2.5mg (Gen-Combo Sterinebs-GPM)

MODIFICATIONS TO CURRENT EXCEPTION DRUG STATUS CRITERIA

Effective November 20, 2002 the Exception Drug status criteria for the following product was modified as indicated.

- **Alendronate sodium, tablet, 70mg (Fosamax-MSD)**
  Exception Drug Status criteria was revised to include:
  Treatment of osteoporosis in patients who have fresh fractures.
  Note: Patients who currently have EDS coverage for Fosamax 10mg have been automatically approved for Fosamax 70mg EDS coverage.

Effective January 1, 2003 the Exception Drug status criteria for the following products will be as indicated.

- **Celecoxib, capsule, 200mg (Celebrex-PHU)**
  Exception Drug Status criteria has been revised to include:
  Treatment of Familial Adenomatous Polyposis.

- **Clopidogrel bisulfate, tablet, 75mg (Plavix-SAW)**
  Exception Drug Status criteria has been revised to include:
  Concurrent use of clopidogrel and acetylsalicylic acid for up to 4 weeks for reduction of atherothrombotic events in patients with acute coronary syndrome (i.e. unstable angina or non-Q-wave myocardial infarction without ST segment elevation).

- **Cyclobenzaprine HCl, tablet, 10mg (Flexeril-JAN) (Apo-Cyclobenzaprine-APX) (Novo-Cycloprine-NOP) (Nu-Cyclobenzaprine-NXP) (pms-Cyclobenzaprine-PMS) (Gen-Cyclobenzaprine-GPM) (Med-Cyclobenzaprine-MED) (Flexitec-TCH) (Dom-Cyclobenzaprine-DOM)**
  Exception Drug Status criteria has been revised to:
  As an adjunct to rest and physical therapy for relief of muscle spasm associated with acute, painful musculoskeletal conditions not responding or experiencing severe adverse reactions to alternative therapy. *Coverage will be provided for up to a 3-week period. Coverage can be renewed for a 3-week period every 3 months.*

- **Modafinil, tablet, 100mg (Alertec-DPY)**
  Exception Drug Status criteria has been revised to:
  For treatment in patients with sleep-laboratory confirmed diagnosis of narcolepsy or idiopathic CNS hypersomnia.

MODIFICATIONS TO CURRENT EXCEPTION DRUG STATUS CRITERIA (continued)

- **Lansoprazole, delayed release capsule, 15mg, 30mg (Prevacid-ABB)**
  Exception Drug Status criteria has been revised to include:
  Treatment for 8 weeks in patients discharged from hospital on a proton pump inhibitor following a gastroduodenal bleed.

- **Omeprazole, delayed release tablet, 20mg (Losec-AST)**
  Same Exception Drug Status criteria revision as for lansoprazole (Prevacid-ABB) published in this bulletin.

- **Pantoprazole, enteric coated tablet, 40mg (Pantoloc-SLV)**
  Same Exception Drug Status criteria revision as for lansoprazole (Prevacid-ABB) published in this bulletin.

- **Rabeprazole sodium, tablet, 10mg (Pariet-JAN)**
  Same Exception Drug Status criteria revision as for lansoprazole (Prevacid-ABB) published in this bulletin.

PRODUCTS TO BE DELISTED

As previously noted in the October 2002 bulletin:

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

CHANGE IN STATUS FROM NON-INTERCHANGEABLE TO INTERCHANGEABLE

The following products are now listed as interchangeable:

- Salbutamol SO4, inhaler aerosol (package) (CFC-free), 100ug/dose (Airomir)
- Salbutamol SO4, inhaler aerosol (package) (CFC-free), 100ug/dose (Ratio-Salbutamol HFA)

Note: Apo-Salvent CFC-Free, a new listing for January 1/03, is also interchangeable with these two products.

Chart of Antibiotic Choices for Common Infectious Diseases

Please note that in the new chart, sent to pharmacies and physicians in October, the treatment of Acute Otitis Media should include azithromycin as an alternative in pediatric cases.

SOME OF THE PRODUCTS CURRENTLY UNDER REVIEW BY THE FORMULARY COMMITTEE

- Fondaparinux sodium, injection solution (pre-filled syringe), 2.5mg/0.5mL (Arixtra-OSS)
- Glucose oxidase/peroxidase reagent, strip (BD Latitude-BDC)
- Latanoprost/timolol maleate, ophthalmic solution (2.5mL), 50ug/mL/5mg/mL (Xalacom-PHU)
- Metronidazole, extended-release tablet, 750mg (Florazole ER-FEI)
- Peginterferon alfa-2b/ribavirin, powder for solution/capsule (weekly injection/daily capsules), 50ug/800mg, 80ug/800mg, 100ug/1000mg, 120ug/1000mg, 150ug/1200mg (Pegetron-SCH)
- Tegaserod hydrogen maleate, tablet, 6mg (Zelnorm-NVR)
- Thyrotropin alfa, powder for injection, 0.9mg/mL (Thyrogen-GZY)
- Valganciclovir HCl, tablet, 450mg (Valcyte-HLR)

Unoprostone isopropyl, ophthalmic solution, 0.15% (Rescula-NVO)

It was noted in the October bulletin that this product was "under review" by the Formulary Committee, however the manufacturer has since decided not to market Rescula in Canada.

Apo-Zidovudine 100mg capsules

Apotex is discontinuing the sale of Apo-Zidovudine 100mg capsules due to a Supreme Court of Canada ruling. Any Apo-Zidovudine currently in the marketplace can be distributed by wholesalers and dispensed by pharmacies but Apotex will no longer be able to offer this product for sale.

PRODUCTS REVIEWED AND NOT RECOMMENDED FOR LISTING

- **Anakinra, subcutaneous injection (pre-filled syringe), 100mg/0.67mL (Kineret-AMG)**
  It was noted that definitive data from joint damage studies is not yet available.

- **Gliclazide, modified release tablet, 30 mg (Diamicron MR-SEV)**
  This product offers no advantage over listed products.

- **Glimepiride, tablet, 1mg, 2mg, 4mg (Amaryl-AVT)**
  The clinical benefit of this product, over listed alternatives, does not justify the incremental cost.

- **Iron Dextran, injection solution, 50mg/mL (2mL) (DexIron-GPM)**
  There are no comparative studies of this product to the iron dextran product (Infufer-SAB) listed in the formulary.

- **Quinine SO4, tablet, 300mg (Quinine-Odan-ODN)**
  This product does not offer a clinical benefit in relation to the incremental cost.

- **Testosterone transdermal delivery system, 12.2mg (2.5mg/day) (Androderm-PAL)**
  The clinical benefit does not justify the significantly higher cost over the listed alternatives.

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 378. These index stickers will assist in locating products on the update stickers.

CFC SALBUTAMOL METERED-DOSE INHALERS

Just a reminder, effective January 1, 2003, all salbutamol metered-dose inhalers (MDI) containing chlorofluorocarbon (CFC) propellant will no longer be available for sale in Canada. This is a result of an international agreement to eliminate the use of CFC propellant in pharmaceutical products to protect the ozone layer and help the environment.

Apo-Salvent, Ratio-Salbutamol, Novo-Salmol, and Ventolin MDIs, which are currently listed in the Saskatchewan Formulary, will no longer be a Drug Plan benefit effective January 1, 2003.

Those individuals who are using a CFC salbutamol MDI will need to switch to a CFC-free product. The Saskatchewan Formulary currently lists several CFC-free salbutamol alternatives, including drug powder formulations and two CFC-free salbutamol MDIs (Airomir and Ratio-Salbutamol HFA). A third CFC-free MDI, Apo-Salvent CFC-Free, will be listed in the Formulary on January 1, 2003. While all three CFC-free MDI products are interchangeable with each other, they are not interchangeable with CFC salbutamol MDIs.

Patients should be informed that they may notice a difference in the taste and sound of their new inhaler or they may perceive that the spray is softer and warmer than that of their CFC-containing MDI.

Other products that contain CFCs will also be gradually phased out. Beginning January 1, 2004 there will be a ban on the importation and manufacturing of CFC metered dose inhalers containing inhaled corticosteroids.

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

FORMULARY AND EDS UPDATES EFFECTIVE JANUARY 1, 2003

GENERIC & TRADE NAME	*STRENGTH & FORM*	*DIN*	*UNIT PRICE*	*LEGEND*
Amoxicillin				
pms-Amoxicillin	250mg capsule	02230243	0.1120	*I/C*
pms-Amoxicillin	500mg capsule	02230244	0.2181	*I/C*
pms-Amoxicillin	25mg/mL oral suspension	02230245	0.0217	*I/C*
pms-Amoxicillin	50mg/mL oral suspension	02230246	0.0326	*I/C*
Amoxicillin trihydrate/potassium clavulanate				
Apo-Amoxi Clav	875mg/125mg tablet	02245623	1.5205	*I/C EDS*
Bimatoprost				
Lumigan	0.03% ophthalmic solution	02245860	11.5100	
Brimonidine tartrate				
pms-Brimonidine	0.2% ophthalmic solution	02246284	2.5064	*I/C*
Carbamazepine				
pms-Carbamazepine Chewtabs	100mg chewable tablet	02231542	0.0929	*I/C*
Clobazam				
pms-Clobazam	10mg tablet	02244474	0.2338	*I/C*
Darbepoetin alfa				
Aranesp	25ug/mL (0.4mL) pre-filled syringe	02246354	29.0800	*EDS*
Aranesp	40ug/mL (0.5mL) pre-filled syringe	02246355	58.1600	*EDS*
Aranesp	100ug/mL (0.3mL) pre-filled syringe	02246357	87.2400	*EDS*
Aranesp	100ug/mL (0.4mL) pre-filled syringe	02246357	114.7000	*EDS*
Aranesp	100ug/mL (0.5mL) pre-filled syringe	02246357	141.5000	*EDS*
Aranesp	200ug/mL (0.3mL) pre-filled syringe	02246358	168.3000	*EDS*
Aranesp	200ug/mL (0.4mL) pre-filled syringe	02246358	221.9000	*EDS*
Aranesp	200ug/mL (0.5mL) pre-filled syringe	02246358	275.5000	*EDS*
Aranesp	500ug/mL (0.3mL) pre-filled syringe	02246360	409.5000	*EDS*
Enoxaparin sodium				
Lovenox HP	120mg/mL (0.8mL) pre-filled syringe	02242692	26.0400	*EDS*
Lovenox HP	150mg/mL (1mL) pre-filled syringe	02242692	32.5500	*EDS*
Flavoxate HCl				
pms-Flavoxate	200mg tablet	02245480	0.3752	*I/C EDS*
Fluconazole				
Dom-Fluconazole	50mg tablet	02246108	3.9579	*I/C EDS*
Dom-Fluconazole	100mg tablet	02246109	7.0211	*I/C EDS*
Novo-Fluconazole	50mg tablet	02236978	3.7693	*I/C EDS*
Novo-Fluconazole	100mg tablet	02236979	6.6867	*I/C EDS*
Novo-Fluconazole	150mg capsule	02243645	11.0779	*I/C*
Flunarizine HCl				
Apo-Flunarizine	5mg capsule	02246082	0.5760	*I/C EDS*
Ipratropium bromide				
Apo-Ipravent	21ug/dose nasal spray (package)	02246083	19.0300	*I/C*
Ipratropium bromide/salbutamol SO4				
Gen-Combo Sterinebs	0.5mg/2.5mg inhalation sol. (2.5mL)	02246066	1.2744	*I/C*
ratio-Ipra Sal UDV	0.5mg/2.5mg inhalation sol. (2.5mL)	02243789	1.1150	*I/C*

FORMULARY AND EDS UPDATES EFFECTIVE JANUARY 1, 2003

GENERIC & TRADE NAME	*STRENGTH & FORM*	*DIN*	*UNIT PRICE*	*LEGEND*
Lamotrigine				
ratio-Lamotrigine	25mg tablet	02243352	0.2519	*I/C*
ratio-Lamotrigine	100mg tablet	02243353	1.0071	*I/C*
Lovastatin				
Nu-Lovastatin	20mg tablet	02231434	1.5028	*I/C*
Nu-Lovastatin	40mg tablet	02231435	2.7717	*I/C*
Methazolamide				
Apo-Methazolamide	50mg tablet	02245882	0.3385	
Metoprolol tartrate				
Apo-Metoprolol	25mg tablet	02246010	0.0698	
Nefazodone				
Novo-Nefazodone-5HT2	100mg tablet	02245435	0.5469	*I/C*
Novo-Nefazodone-5HT2	150mg tablet	02245436	0.5469	*I/C*
Novo-Nefazodone-5HT2	200mg tablet	02245437	0.6380	*I/C*
Nitrazepam				
Apo-Nitrazepam	5mg tablet	02245230	0.0930	*I/C*
Apo-Nitrazepam	10mg tablet	02245231	0.1391	*I/C*
Norfloxacin				
pms-Norfloxacin	400mg tablet	02246596	1.6554	*I/C EDS*
Salbutamol SO4				
Apo-Salvent CFC Free	100ug/dose inh. aer. (pkg) (CFC FREE)	02245669	5.0400	*I/C**
	* I/C with Ratio-Salbutamol HFA and Airomir			
Temazepam				
Co-Temazepam	15mg capsule	02244814	0.1196	*I/C*
Co-Temazepam	30mg capsule	02244815	0.1439	*I/C*
Thiamine HCl				
Thiamiject	100mg/mL inj. sol. (10mL)	02193221	12.8900	*I/C*
Ticlopidine				
Novo-Ticlopidine	250mg tablet	02236848	0.7471	*I/C EDS*
Tobramycin				
Apo-Tobramycin	0.3% ophthalmic solution	02245698	1.1371	*I/C EDS*

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

EDS UPDATE EFFECTIVE JANUARY 1, 2003

CRITERIA FOR NEW EXCEPTION DRUG STATUS (EDS) ADDITIONS

*Effective **January 1, 2003** the following product is available under Exception Drug Status subject to the indicated criteria.*

darbepoetin alfa, pre-filled syringe, 25ug/mL (0.4mL), 40ug/mL (0.5mL), 100ug/mL (0.3mL, 0.4mL, 0.5mL), 200ug/mL (0.3mL, 0.4mL, 0.5mL), 500ug/mL (0.3mL) (Aranesp-AMG)

For treatment of anemia in chronic renal disease patients prior to initiation of dialysis.
Note: Coverage for dialysis patients is provided under the Saskatchewan Aids to Independent Living (S.A.I.L.) Program. EDS coverage is not required for S.A.I.L. patients.

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

enoxaparin, syringe, 150mg/mL (0.8mL, 1mL) (Lovenox HP-AVT)

MODIFICATIONS TO CURRENT EXCEPTION DRUG STATUS CRITERIA

*Effective **November 20, 2002** the Exception Drug status criteria for the following product was modified as indicated.*

alendronate sodium, tablet, 70mg (Fosamax-MSD)

Exception Drug Status criteria was revised to include:

(b) For treatment of osteoporosis in patients who have fresh fractures.
Note: Patients who currently have EDS coverage for Fosamax 10mg have been automatically approved for Fosamax 70mg EDS coverage.

*Effective **January 1, 2003** the Exception Drug status criteria for the following products will be as indicated.*

celecoxib, capsule, 200mg (Celebrex-PHU)

Exception Drug Status criteria has been revised to include:

(d) For treatment of Familial Adenomatous Polyposis.

clopidogrel bisulfate, tablet, 75mg (Plavix-SAW)

Exception Drug Status criteria has been revised to include:

(e) Concurrent use of clopidogrel and acetylsalicylic acid for up to 4 weeks for reduction of atherothrombotic events in patients with acute coronary syndrome (i.e. unstable angina or non-Q-wave myocardial infarction without ST segment elevation).

cyclobenzaprine HCl, tablet, 10mg (Flexeril-JAN) (Apo-Cyclobenzaprine-APX) (Novo-Cycloprine-NOP) (Nu-Cyclobenzaprine-NXP) (pms-Cyclobenzaprine-PMS) (Gen-Cyclobenzaprine-GPM) (Med-Cyclobenzaprine-MED) (Flexitec-TCH) (Dom-Cyclobenzaprine-DOM)

Exception Drug Status criteria has been revised to:

As an adjunct to rest and physical therapy for relief of muscle spasm associated with acute, painful musculoskeletal conditions not responding or experiencing severe adverse reactions to alternative therapy. *Coverage will be provided for up to a 3-week period. Coverage can be renewed for a 3-week period every 3 months.*

modafinil, tablet, 100mg (Alertec-DPY)

Exception Drug Status criteria has been revised to:

For treatment in patients with sleep-laboratory confirmed diagnosis of narcolepsy or idiopathic CNS hypersomnia.

lansoprazole, delayed release capsule, 15mg, 30mg (Prevacid-ABB)

Exception Drug Status criteria has been revised to include:

(f) Treatment for 8 weeks in patients discharged from hospital on a proton pump inhibitor following a gastroduodenal bleed.

omeprazole, delayed release tablet, 20mg (Losec-AST)

Same Exception Drug Status criteria revision as for lansoprazole (Prevacid-ABB) published in this bulletin.

pantoprazole, enteric coated tablet, 40mg (Pantoloc-SLV)

Same Exception Drug Status criteria revision as for lansoprazole (Prevacid-ABB) published in this bulletin.

rabeprazole sodium, tablet, 10mg (Pariet-JAN)

Same Exception Drug Status criteria revision as for lansoprazole (Prevacid-ABB) published in this bulletin.

CHANGE IN STATUS FOR THE FOLLOWING PRODUCTS

Effective ***January 1, 2003*** the following products will be ***interchangeable:***
Salbutamol SO4, 100ug/dose inhaler aerosol (package) (CFC Free) (Apo-Salvent CFC Free-APX, Ratio-Salbutamol HFA-RTP, Airomir-MDA)