#85 **December, 2000**

QUARTERLY UPDATE TO THE 50th EDITION OF THE SASKATCHEWAN FORMULARY

NEW LISTINGS

NEW EXCEPTION DRUG STATUS AGENTS

Effective December 6, 2000, donepezil will be available under Exception Drug Status subject to the indicated criteria.

- **Donepezil HCl, tablet, 5mg, 10mg (Aricept-PFI)**
  Exception Drug Status Criteria:
  1. A diagnosis of probable Alzheimer disease as per DSM-IV criteria.
  2. A mild to moderate stage of the disease with a MMSE score of 10-26 established within 60 days prior to application for coverage by a clinician.
  3. An initial Functional Activities Questionnaire (FAQ) must be completed.
  4. Patients must discontinue all drugs with anticholinergic activity at least 14 days before the initial MMSE & FAQ are administered (list all current medications patient was taking at the time of assessment).

Eligible new patients will enter a 3 month treatment period with donepezil. During the 3 month trial, patients must exhibit an improvement from the initial MMSE or FAQ to continue treatment with donepezil. The improvement must be at least 2 MMSE points or -1 FAQ.

Eligible patients currently taking donepezil would require assessment at 6 months, based on the following criteria: complete an initial MMSE & FAQ, and not have both a greater than 2 point reduction in MMSE and 1 point increase in FAQ in a 6 month evaluation period.

Patients will be re-evaluated at 6 month intervals. To continue receiving donepezil patients must not have both a greater than 2 point reduction in MMSE and a 1 point increase in FAQ in a 6 month evaluation period. Scores are compared to the most recent test results.

In addition, the MMSE score must remain at 10 or greater at all times to be eligible for coverage.

Patients who do not meet criteria to continue donepezil can be re-evaluated within 3 months to confirm deterioration before coverage is discontinued.

Drugs with anticholinergic activity are not to be used concurrently with Aricept therapy.

Application for EDS and EDS renewals for Aricept will only be accepted from physicians on the Aricept EDS application form.

Modifications have been made to the criteria and EDS form since the last mailing to physicians and pharmacies. The updated criteria is published in this bulletin and an updated EDS form has been included. Please discard old forms.

Effective December 1, 2000 the following products will be available under Exception Drug Status subject to the indicated criteria.

- **Cabergoline, tablet, 0.5mg (Dostinex-PHU)**
  Exception Drug Status Criteria:
  For treatment of hyperprolactinemic disorders in patients not responding to or intolerant to bromocriptine.

- **Dipyridamole/acetylsalicylic acid, capsule, 200mg/25mg (Aggrenox-BOE)**
  Exception Drug Status Criteria:
  For patients who have had a stroke or transient ischemic attack while on ASA.

- **Estradiol/norethindrone acetate, transdermal therapeutic system (8), 50ug/140ug, 50ug/250ug (Estalis-NVR)**
  Exception Drug Status Criteria:
  For treatment in patients who are unable to tolerate oral hormone replacement therapy (i.e. either estrogen or progesterone).

New EDS agents (continued):

- **Fosfomycin tromethamine, oral powder (sachet), 3g (Monurol-PFR)**
  Exception Drug Status Criteria:
  a) for the treatment of urinary tract infection with organisms resistant to first line therapy.
  b) for the treatment of urinary tract infection in patients allergic to first line agents.
  c) for the treatment of urinary tract infection in pregnancy when first line agents are inappropriate.

- **Modafinil, tablet, 100mg (Alertec-DPY)**
  Exception Drug Status Criteria:
  For the treatment of narcolepsy in patients where other standard therapy such as methylphenidate or dextroamphetamine have failed.

- **Pivmecillinam HCl, tablet, 200mg (Selexid-LEO)**
  Exception Drug Status Criteria:
  a) for the treatment of urinary tract infection with organisms resistant to first line therapy.
  b) for the treatment of urinary tract infection in patients allergic to first line agents.
  c) for the treatment of urinary tract infection in pregnancy when first line agents are inappropriate.

- **Risedronate sodium, tablet, 5mg (Actonel-PGA)**
  Exception Drug Status Criteria:
  For the treatment of osteoporosis in patients unable to tolerate or who do not respond to etidronate disodium/calcium (Didrocal) after receiving it for 1 year.

NEW DOSAGE FORMS/STRENGTHS OF EXCEPTION DRUG STATUS AGENTS

Covered under the same Exception Drug Status criteria as the currently listed forms (effective December 1, 2000).

- Rizatriptan benzoate, wafer, 5mg (Maxalt RPD-MSD)
- Ganciclovir SO4, capsule, 500mg (Cytovene-HLR)

MODIFICATIONS TO CURRENT EXCEPTION DRUG STATUS CRITERIA

Effective December 1, 2000 the Exception Drug status criteria for the following product will be as indicated.

- **Ciprofloxacin/hydrocortisone, otic suspension, 0.2%/1% (Cipro HC-ALC)**
  In addition to the criteria listed in Appendix A of the Sask Formulary:
  For the treatment of patients with perforation of the tympanic membrane.

NEW FULL FORMULARY LISTINGS

- 5-Aminosalicylic acid, suppository, 1g (Salofalk-AXC)
  - not interchangeable with Quintasa 1g suppository
- Oxycodone HCl, tablet, 5mg, 10mg, 20mg (Oxy-IR-PFR)
- Pancrelipase (lipase/amylase/protease), tablet, 16000U/60000U/60000U (Viokase-AXC)
- Valsartan/HCTZ tablets, 80mg/12.5mg, 160mg/12.5mg (Diovan-HCT-NVR)

CHANGE IN STATUS FROM EDS TO FULL FORMULARY

Effective December 1, 2000:

- Ipratropium bromide/salbutamol SO4, inhalation solution, 0.5mg/3.0mg (2.5mL) (Combivent-BOE)
- Oxycodone HCl, controlled release tablet, 10mg, 20mg, 40mg, 80mg (OxyContin-PFR)

FIRST ENTRY GENERIC

- Desmopressin, intranasal solution (spray pump), 10ug/dose (Apo-Desmopressin-APX)

CORRECTION

Please note the following change to page 73 of the 50th Edition of the Saskatchewan Formulary. The correct price for telmisartan 40mg and 80mg tablets (Micardis) is $1.1610.

SOME OF THE PRODUCTS CURRENTLY UNDER REVIEW BY THE FORMULARY COMMITTEE

- Rivastigmine, capsule, 1.5mg, 3mg, 4.5mg, 6mg (Exelon-NVR)
- Warfarin, tablet, 1mg, 2mg, 2.5mg, 3mg, 4mg, 5mg, 6mg, 7.5mg, 10mg (Taro-Warfarin-TAR)
- Warfarin, tablet, 1mg, 2mg, 2.5mg, 4mg, 5mg, 10mg (Apo-Warfarin-APX)
- Etanercept, powder for injection, 25mg/vial (Enbrel-WYA)
- Infliximab, lyophilized concentrate for iv injection, 100mg/20mL vial (Remicade-SCH)
- Verteporfin, injection, 2mg/ml (15mg/vial) (Visudyne-CBV)

PRODUCTS REVIEWED AND NOT RECOMMENDED FOR LISTING

- **Fenofibrate (micronized), capsule, 67mg (Lipidil Micro-FFR)**
  This formulation offers no advantage over the listed 200mg strength of micronized fenofibrate. The 67mg strength is less convenient than the 200mg strength as it is administered two to three times daily compared with once daily for the 200mg strength.

- **Fenofibrate, tablet, 100mg, 160mg (Lipidil Supra-FFR)**
  This formulation offers no significant clinical or cost advantage over the other formulations of fenofibrate.

- **Oseltamivir phosphate, capsule, 75mg (Tamiflu-HLR)**
  The submitted documentation did not demonstrate significant clinical benefit in relation to the incremental cost. The clinical significance of a 1.3 day reduction in flu symptoms was unclear. It was noted that studies have yet to be completed in high-risk patients who have the potential to benefit the most.

- **Raloxifene HCl, tablet, 60mg (Evista-LIL)**
  It was noted that this product is less effective than hormone replacement therapy and bisphosphonates for the treatment of osteoporosis. The Committee awaits further evidence to establish the beneficial effects of the drug on the cardiovascular system and breast.

Airomir (CFC-Free)-MDA (salbutamol SO4 100ug/dose inhaler aerosol)
Effective December 1, 2000, this product will be considered **NON-interchangeable** with other brands of salbutamol SO4 100ug/dose inhaler aerosols.

Cimetidine, tablet, 200mg (Peptol-TCH, Novo-Cimetine-NOP, Apo-Cimetidine-APX, Nu-Cimet-NXP, Gen-Cimetidine-GPM, PMS-Cimetidine-PMS)
The 200mg strength of all cimetidine brands has been recommended for delisting effective July 1, 2001.

HOSPITAL BENEFIT DRUG LIST UPDATE – November 2000

See Appendix B of the Formulary for the Hospital Benefit Drug List. The following are revisions to the published criteria and additions to the list.

CEFTRIAXONE
Restricted Coverage: Benefit status is automatic for first 72 hours in severe infections. Long term use is covered when supported by sensitivity tests.
Injection 250mg, 1g, 2g

CLIMACTERON
Restricted Coverage: When used in hospital for post-hysterectomy patients.
Injection

TISSUE PLASMINOGEN ACTIVATOR (tPA)
For the treatment of strokes when all the following circumstances are present:
- within three (3) hours of the onset of symptoms;
- under the guidance of a neurologist and a neuro-radiologist;
- after a CT scan to rule out hemorrhage; and
- in conjunction with established treatment protocols.

AZITHROMYCIN
Restricted Coverage: as per the Exceptional Drug Status (EDS) criteria listed in Appendix A of the Saskatchewan Formulary when a patient cannot tolerate oral dosage forms.

DALTEPARIN
Restricted Coverage: for in-hospital treatment of acute coronary syndrome to a maximum of eight (8) days.
Injection

ENOXAPARIN
Restricted Coverage: for in-hospital treatment of acute coronary syndrome to a maximum of eight (8) days.
Injection

NADROPARIN
Restricted Coverage: for in-hospital treatment of acute coronary syndrome to a maximum of eight (8) days.
Injection

QUINUPRISTIN/DALFOPRISTIN (Synercid™)
Restricted Coverage: reserved for use against multi-resistant gram positive organisms, including methicillin resistant *Staph. aureus* (MRSA) and vancomycin resistant *E. faecium*, on the recommendation of an infectious disease specialist.

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

FORMULARY AND EDS UPDATES EFFECTIVE DECEMBER 1, 2000

GENERIC & TRADE NAME	STRENGTH & FORM	DIN	UNIT PRICE	LEGEND
Acyclovir				
Gen-Acyclovir	200mg tablet	02242784	0.9530	*I/C*
Gen-Acyclovir	400mg tablet	02242463	1.8758	*I/C*
Gen-Acyclovir	800mg tablet	02242464	3.0985	*I/C*
Amoxicillin (Amoxycillin)				
Scheinpharm Amoxicillin	250mg capsule	02241826	0.1120	*I/C*
Scheinpharm Amoxicillin	500mg capsule	02241827	0.2181	*I/C*
Cabergoline				
Dostinex	0.5mg tablet	02242471	13.7253	*EDS*
Desmopressin				
Apo-Desmopressin	10ug/dose intranasal sol (spray pump)	02242465	71.7000	*I/C EDS*
Dipivefrin HCl				
Apo-Dipivefrin	0.1% ophth sol	02242232	1.0807	*I/C*
Dipyridamole/acetylsalicylic acid				
Aggrenox	200mg/25mg capsule	02242119	0.8409	*EDS*
Doxazosin mesylate				
Novo-Doxazosin	1mg tablet	02242728	0.4178	*I/C*
Novo-Doxazosin	2mg tablet	02242729	0.5013	*I/C*
Novo-Doxazosin	4mg tablet	02242730	0.6516	*I/C*
Estradiol/norethindrone acetate				
Estalis	50ug/140ug (pkg)	02241835	23.6600	*EDS*
Estalis	50ug/250ug (pkg)	02241837	23.6600	*EDS*
Famotidine				
Alti-Famotidine	20mg tablet	02242327	0.6398	*I/C*
Alti-Famotidine	40mg tablet	02242328	1.1514	*I/C*
Flunisolide				
Rhinaris-F	0.025% nasal sol (pkg)	01927167	15.0400	*I/C*
Fluoxetine				
Scheinpharm Fluoxetine	10mg capsule	02242177	1.2774	*I/C*
Scheinpharm Fluoxetine	20mg capsule	02242178	1.0972	*I/C*
Fosfomycin tromethamine				
Monurol	3g oral powder (sachet)	02240335	21.7000	*EDS*
Ganciclovir SO4				
Cytovene	500mg capsule	02240362	8.6334	*EDS*
Gemfibrozil				
Scheinpharm Gemfibrozil	300mg capsule	02242390	0.3216	*I/C*
Haloperidol decanoate				
Apo-Haloperidol LA	50mg/mL inj sol (5mL)	02242361	32.0100	*I/C*
Apo-Haloperidol LA	100mg/mL inj sol (5mL)	02242362	63.2600	*I/C*
Levobunolol HCl				
SAB-Levobunolol	0.25% ophth sol	02241715	1.2760	*I/C*
SAB-Levobunolol	0.5% ophth sol	02241716	1.6883	*I/C*

GENERIC & TRADE NAME	***STRENGTH & FORM***	***DIN***	***UNIT PRICE***	***LEGEND***
Modafinil				
Alertec	100mg tablet	02239665	1.3020	*EDS*
Nabumetone				
Novo-Nabumetone	750mg tablet	02240868	0.7406	*EDS*
Oxycodone HCl				
Oxy-IR	5mg IR tablet	02231934	0.2561	
Oxy-IR	10mg IR tablet	02240131	0.3776	
Oxy-IR	20mg IR tablet	02240132	0.6554	
Pancrelipase (lipase/amylase/protease)				
Viokase	16000U/60000U/60000U tablet	02241933	0.3470	
Pivmecillinam HCl				
Selexid	200mg tablet	00657212	0.9402	*EDS*
Risedronate sodium				
Actonel	5mg tablet	02242518	1.8011	*EDS*
Rizatriptan benzoate				
Maxalt RPD	5mg wafer	02240518	14.0508	*EDS*
Sertraline hydrochloride				
Gen-Sertraline	25mg capsule	02242519	0.6076	*I/C*
Gen-Sertraline	50mg capsule	02242520	1.2152	*I/C*
Gen-Sertraline	100mg capsule	02242521	1.3292	*I/C*
Terbinafine HCl				
Apo-Terbinafine	250mg tablet	02239893	2.5576	*I/C*
Timolol maleate				
Rhoxal-Timolol	0.25% ophth sol	02241731	1.6818	*I/C*
Rhoxal-Timolol	0.5% ophth sol	02241732	2.0181	*I/C*
Tobramycin				
SAB-Tobramycin	0.3% ophth sol	02241755	1.1393	*I/C EDS*
Trazodone				
Scheinpharm Trazodone	50mg tablet	02242392	0.2403	*I/C*
Scheinpharm Trazodone	100mg tablet	02242391	0.4293	*I/C*
Valsartan/hydrochlorothiazide				
Diovan-HCT	80mg/12.5mg tablet	02241900	1.1393	
Diovan-HCT	160mg/12.5mg tablet	02241901	1.1393	
5-Aminosalicylic acid				
Salofalk	1g suppository	02242146	1.7360	*not I/C*

EDS UPDATE EFFECTIVE DECEMBER 6, 2000

Donepezil HCl				
Aricept	5mg tablet	02232043	4.9842	*EDS*
Aricept	10mg tablet	02232044	4.9842	*EDS*

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

CHANGE IN STATUS FOR THE FOLLOWING PRODUCTS

Effective December 1, 2000, the following product will ***not be interchangeable*** *with currently listed brands:*

- **Airomir 100ug/dose inhaler aerosol (package) (CFC-Free)**
  DIN: 02232570

Effective December 1, 2000, the following products will ***not require*** *Exception Drug Status (EDS) coverage and are to be considered full formulary benefits:*

- **Combivent nebules 0.5mg/2.5mg inhalation solution (2.5mL)**
  DIN: 02231675

- **Oxycontin 10mg, 20mg, 40mg, 80mg controlled release tablets**
  DIN: 02202441 (10mg) DIN: 02202476 (40mg)
  DIN: 02202468 (20mg) DIN: 02202484 (80mg)

CRITERIA FOR NEW EXCEPTION DRUG STATUS (EDS) ADDITIONS

Effective ***December 1, 2000****, the following products will be available for coverage subject to the indicated criteria.*

Cabergoline, tablet, 0.5mg (Dostinex-PHU)
For treatment of hyperprolactinemic disorders in patients not responding to, or intolerant to, bromocriptine.

Desmopressin, intranasal solution (spray pump), 10ug/dose (Apo-Desmopressin-APX)
New interchangeable – same criteria as DDAVP 10ug/dose intranasal solution listed in Appendix A, page 240.

Dipyridamole/acetylsalicylic acid, capsule, 200mg/25mg (Aggrenox-BOE)
For treatment of patients who have had a stroke or transient ischemic attack while on acetylsalicylic acid.

Estradiol/norethindrone acetate, transdermal therapeutic system (8), 50ug/140ug, 50ug/250ug (Estalis-NVR)
For treatment in patients who are unable to tolerate oral hormone replacement therapy (either estrogen or progesterone).

Fosfomycin tromethamine, oral powder (sachet), 3g (Monurol-PFR)
(a) For treatment of urinary tract infections with organisms resistant to first line therapy.
(b) For treatment of urinary tract infections in patients allergic to first line agents.
(c) For treatment of urinary tract infections in pregnancy when first line agents are inappropriate.

Ganciclovir SO4, capsule, 500mg (Cytovene-HLR)
New strength – same criteria as 250mg capsule listed in Appendix A, page 243.

Modafinil, tablet, 100mg (Alertec-DPY)
For treatment of narcolepsy in patients where other standard therapy such as methylphenidate or dextroamphetamine have failed.

Nabumetone, tablet, 750mg (Novo-Nabumetone-NOP)
New strength – same criteria as 500mg tablet listed in Appendix A, page 249.

Pivmecillinam HCl, tablet, 200mg (Selexid-LEO)
(a) For treatment of urinary tract infections with organisms resistant to first line therapy.
(b) For treatment of urinary tract infections in patients allergic to first line agents.
(c) For treatment of urinary tract infections in pregnancy when first line agents are inappropriate.

Risedronate sodium, tablet, 5mg (Actonel-PGA)
For treatment of osteoporosis in patients unable to tolerate or who do not respond to etidronate disodium/calcium (Didrocal) after receiving it for one year.

Rizatriptan benzoate, wafer, 5mg (Maxalt RPD-MSD)
New strength – same criteria as other forms/strengths listed in Appendix A, page 254.

Tobramycin, ophthalmic solution, 0.3% (SAB-Tobramycin-SAB)
New interchangeable – same criteria as other brands listed in Appendix A, page 257.

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*Effective **December 6, 2000**, the following product will be available for coverage subject to the indicated criteria*

Donepezil HCl, tablet, 5mg, 10mg (Aricept-PFI)
(a) A diagnosis of probable Alzheimer's Disease as per DSM-IV criteria.
(b) A mild to moderate stage of the disease with a MMSE score of 10-26 established within 60 days prior to application for coverage by a clinician.
(c) An initial Functional Activities Questionnaire (FAQ) must be completed.
(d) Patients must discontinue all drugs with anticholinergic activity at least 14 days before the initial MMSE and FAQ are administered (list all current medications patient was taking at the time of assessment).

- **Eligible new patients** will enter a 3 month treatment period with donepezil. During the 3 month trial, patients must exhibit an improvement from the initial MMSE or FAQ to continue treatment with donepezil. The improvement must be at least 2 MMSE points or -1 FAQ.
- **Eligible patients currently taking donepezil** would require assessment at 6 month intervals, based on the same criteria: complete a initial MMSE and FAQ, and not have both a greater than 2 point reduction in MMSE and 1 point increase in FAQ in a 6 month evaluation period.
- Patients will be re-evaluated at 6 month intervals. To continue receiving donepezil patients must not have both a greater than 2 point reduction in MMSE and a 1 point increase in FAQ in a 6 month evaluation period. Scores are compared to the most recent test results.
- In addition, the MMSE score must remain at 10 or greater at all times to be eligible for coverage.
- Patients who do not meet criteria to continue donepezil can be re-evaluated within 3 months to confirm deterioration before coverage is discontinued.
- Drugs with anticholinergic activity are not to be used concurrently with Aricept therapy.

MODIFICATIONS TO CURRENT EXCEPTION DRUG STATUS (EDS) CRITERIA

*Effective **December 1, 2000**, the EDS criteria for the following product will be as indicated.*

ciprofloxacin/hydrocortisone, otic suspension, 0.2%/1% (Cipro HC-ALC)
(a) For treatment of otitis externa in patients who have failed previous treatment with listed combination anti-infective/anti-inflammatory agents.
(b) For treatment of patients with perforation of the tympanic membrane.