

**QUARTERLY UPDATE
TO THE
50th EDITION
OF THE
SASKATCHEWAN FORMULARY**

NEW LISTINGS

**NEW EXCEPTION DRUG
STATUS AGENTS**

Effective April 1, 2001 the following products will be available under Exception Drug Status subject to the indicated criteria.

• **Rivastigmine, capsule, 1.5mg, 3mg, 4.5mg, 6mg (Exelon-NVR)
Exception Drug Status
Criteria :**

- (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) A Functional Activities Questionnaire (FAQ) must be completed.
- (d) Patients must discontinue all drugs with anticholinergic activity at least 14 days before the MMSE and FAQ are administered. Drugs with anticholinergic activity are not to be used concurrently with rivastigmine therapy. List all current medications patient was taking at the time of assessment.
- (e) Patients **intolerant** to one drug may be switched to another drug in this class. Intolerance should be observed within the first month of treatment.

✧ **Eligible patients currently taking rivastigmine** would require assessment at 6 month intervals. To continue receiving rivastigmine, 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.

✧ **Eligible new patients** will enter a 3 month treatment period with rivastigmine. During the 3 month trial, patients must exhibit an improvement from the initial MMSE or FAQ to continue treatment with rivastigmine. The improvement must be at least 2 MMSE points or -1 FAQ. Patients who meet these requirements will be re-evaluated at 6 month intervals. To continue receiving rivastigmine, 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.

✧ 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 rivastigmine can be re-evaluated within 3 months to confirm deterioration before coverage is discontinued.
- ✧ Rivastigmine does not need to be discontinued prior to MMSE or FAQ testing.
- ✧ A patient intolerant of one drug in this class and switching to a second will be considered a "new" patient and will be assessed as such.
- ✧ Coverage will not be considered for patients who have **failed** on other drugs in this class.

Application for EDS and EDS renewals for Aricept and Exelon will only be accepted from physicians on the Aricept/Exelon EDS application form. A new and improved form has been included with this mailing. Please discard old forms.

- **Bisoprolol fumarate, tablet, 5mg, 10mg (Monacor-BVL)
Exception Drug Status Criteria:** For the treatment of patients with stable symptomatic congestive heart failure taking diuretics and ACE inhibitors, with or without digoxin.

See inside for more info
on Exelon and Aricept

- **Deferoxamine mesylate, powder for solution, 500mg/vial (pms-Deferoxamine) (Desferal-NVR); 2g/vial (Desferal-NVR)**
Exception Drug Status Criteria: For the treatment of iron overload in patients with transfusion-dependent anemias.
- **Moxifloxacin HCl, tablet, 400mg (Avelox-BAY)**
Exception Drug Status Criteria:
 - (a) For treatment of infections in patients with underlying lung disease not responding to first-line antibiotics.
 - (b) For treatment of infections caused by organisms known to be resistant to alternative antibiotics.
 - (c) For treatment of infections in patients allergic to alternative antibiotics.
- **Pioglitazone HCl, tablet, 15mg, 30mg, 45mg (Actos-LIL)**
Exception Drug Status Criteria: For treatment of diabetes in patients who are not adequately controlled on or are intolerant to metformin and sulfonylureas.

**NEW DOSAGE FORMS/
STRENGTHS OF EXCEPTION
DRUG STATUS AGENTS**

Covered under the same Exception Drug Status criteria as the currently listed forms (effective April 1, 2001).

- Somatropin, injection, 5mg (Saizen-SRO)

**MODIFICATIONS TO CURRENT
EXCEPTION DRUG STATUS
CRITERIA**

Effective April 1, 2001 the Exception Drug status criteria for the following products will be as indicated.

- **Azithromycin, tablet, 250mg; oral suspension, 20mg/mL, 40mg/mL (Zithromax-PFI)**
In addition to the criteria listed in Appendix A of the Saskatchewan Formulary:
For step down care following hospital separation in patients treated with intravenous

macrolides (guided by culture and sensitivity results).

- **Clarithromycin, tablet, 250mg, 500mg; oral suspension, 25mg/mL (Biaxin-ABB)**
In addition to the criteria listed in Appendix A of the Saskatchewan Formulary:
For step-down care following hospital separation in patients treated with intravenous macrolides (guided by culture and sensitivity results).
- **Donepezil HCl, tablet, 5mg, 10mg (Aricept-PFI)**
Same Exception Drug Status criteria as for rivastigmine, (Exelon-NVR) published in this bulletin.
- **Mycophenolate mofetil, capsule, 250mg; tablet, 500mg (CellCept-HLR)**
Exception Drug Status criteria has been revised to:
Prevention of acute rejection in renal and cardiac transplant patients. *This is renewable on a yearly basis.*
- **Risedronate sodium, tablet, 5mg (Actonel-PGA)**
Exception Drug Status criteria has been revised to:
 - (a) For treatment of osteoporosis in patients who do not respond to etidronate disodium/calcium (Didrocal) after receiving it for one year.
 - (b) For treatment of osteoporosis in patients unable to tolerate etidronate disodium/calcium (Didrocal).
 - (c) For treatment of osteoporosis in patients unable to tolerate alendronate sodium (Fosamax).

FIRST ENTRY GENERIC

- Nefazodone HCl, tablet, 50mg, 100mg, 150mg, 200mg (Apo-Nefazodone-APX)
- Gabapentin, capsule, 100mg, 300mg, 400mg (pms-Gabapentin-PMS)

**NEW FULL FORMULARY
LISTINGS**

- Adapalene, cream, 0.1% (Differin-GAC)
- Beclomethasone dipropionate, inhalation aerosol (package), 50ug, 100ug (QVAR-MDA)
Note: this product will be listed as not **interchangeable** with currently listed beclomethasone inhalers and should be treated as a new medication. The dose must be titrated for each individual patient.
- Conjugated estrogens/medroxyprogesterone acetate, tablet (package), 0.625mg/2.5mg (Premplus-WYA)
- Diazepam, rectal gel, 5mg/mL Diastat-DPY)
- Eprosartan mesylate, tablet, 300mg, 400mg (Teveten-SLV)

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

- Etanercept, powder for injection, 25mg/vial (Enbrel-WYA)
- Infliximab, lyophilized concentrate for iv injection, 100mg/20mL vial (Remicade-SCH)
- Glucose oxidase/peroxidase reagent, strip (One Touch Ultra-LSN)
- Glucose oxidase/peroxidase reagent, strip (Precision Xtra-MDS)
- Riluzole, tablet, 50mg (Rilutek-AVT)
- Sevelamer HCl, capsule, 403mg (Renagel-GZY)
- Verteporfin, injection, 2mg/ml (15mg/vial) (Visudyne-CBV)
- 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)

PRODUCTS REVIEWED AND NOT RECOMMENDED FOR LISTING

- **Delta-9-tetrahydrocannabinol, capsule, 2.5mg, 5mg, 10mg (Marinol-SAW)**
The submitted clinical information did not demonstrate any advantage over available alternatives.
- **Gliclazide, tablet, 80mg (Diamicron-SEV)**
This product offers no advantage over listed products.
- **Loxapine succinate, tablet, 2.5mg (pms-Loxapine-PMS)**
There is no demonstrated need for this strength.
- **Meloxicam, tablet, 7.5mg, 15mg (Mobicox-BOE)**
This product offers no advantage over currently listed NSAIDS and is more expensive.

HOSPITAL BENEFIT DRUG LIST UPDATE – March 2001

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.

AZITHROMYCIN

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

AMPHOTERICIN B LIPID COMPLEX INJECTION

Restricted Coverage: when used in consultation with an infectious disease specialist under the following guidelines:

- failure of Amphotericin B deoxycholate. For adults, this is normally defined as poor clinical response to >500mg cumulative doses;
- nephrotoxicity due to conventional Amphotericin B therapy as evidenced by doubling of baseline serum creatinine or a significant rise from baseline plus concomitant use of other potential nephrotoxins;
- significant pre-existing renal failure – creatinine >220umol/L or CrCl <25mL/minute or special renal condition (eg. transplant or single kidney);
- severe dose-related toxicities which do not resolve with premedication (eg. fever, rigors, hypotension)

Common Questions About Aricept and Exelon Coverage

1. I have a patient who has been taking Aricept or Exelon for the past year. Does this patient have to stop taking the Aricept or Exelon before I do the MMSE and FAQ tests?

*No, neither Aricept nor Exelon need to be discontinued before **any** MMSE or FAQ test. It is only drugs with anticholinergic effects that need to be discontinued before testing and are not to be used concurrently with Aricept or Exelon. Aricept and Exelon are in essence cholinergic drugs that work by preventing the enzyme acetyl-cholinesterase from breaking down acetylcholine. This increased acetylcholine level may improve cognitive function in Alzheimer patients.*

2. Why does the criteria indicate that anticholinergic drugs are not to be used concurrently with Aricept or Exelon?

Using a concurrent drug with moderate to high anticholinergic effects can reduce or negate the enhancement of cholinergic function resulting from the Aricept or Exelon. In addition, anticholinergic drugs are known to cause cognitive disorders in the elderly such as disorientation, confusion, and memory impairment. This can make it difficult to assess the efficacy of Aricept or Exelon, especially when the overall clinical improvement seen in most patients is modest. On the back page of this Bulletin is the list of drugs with moderate to high anticholinergic effects which is used to assess Aricept or Exelon requests. Coverage cannot be approved if a patient is using a drug on this list concurrently with Aricept or Exelon.

3. Why do two tests, the Mini Mental State Exam (MMSE) and the Functional Activities Questionnaire (FAQ), have to be completed to get coverage?

The MMSE test has been included in the criteria to show any change in mental status. The FAQ test has been included in the criteria to show any change in functional activity. The specialists in Alzheimer disease consulted by the Formulary Committee suggested requiring the FAQ in addition to the MMSE to allow coverage to be granted for a patient who does not show an improvement on the MMSE but who does show a functional improvement on the FAQ.

Reference List of Drugs with Anticholinergic Effects

Aricept (donepezil) and Exelon (rivastigmine) are reversible inhibitors of the enzyme acetylcholinesterase. Because of their mechanism of action, anticholinergic medications can interfere with the activity of Aricept and Exelon. The following is a list of drugs with anticholinergic effects with emphasis on those with moderate to high activity. This list has been reviewed by DQAC and SFC and will be used for assessing Aricept and Exelon requests. Coverage cannot be approved if a patient is using a drug on this list concurrently with Aricept or Exelon.

Antidepressants with moderate to high anticholinergic effects

amitriptyline (Elavil)
clomipramine (Anafranil)
doxepin (Sinequan)
imipramine (Tofranil)
nortriptyline (Aventyl)
protriptyline (Triptil)
trimipramine (Surmontil)

Antiparkinsonian

benztropine mesylate (Cogentin)
biperiden HCl (Akineton)*
ethopropazine (Parsitan)
orphenadrine (Disipal)
procyclidine (Kemadrin)
trihexyphenidyl (Novo-Hexidyl, Apo-Trihex)

Antiemetics/Antivertigo with moderate to high anticholinergic effects

dimenhydrinate (Gravol)
meclizine (Antivert)
promethazine (Phenergan)*
scopolamine (Transderm V)

Antipsychotics with moderate to high anticholinergic effects

chlorpromazine (Largactil)
clozapine (Clozaril)
flupenthixol (Fluanxol)
loxapine (Loxapac)
mesoridazine (Serentil)
methotrimeprazine (Nozinan)
olanzapine (Zyprexa)
pericyazine (Neuleptil)
pimozide (Orap)
thiopropazine (Majeptil)*
thioridazine (Mellaril)
zuclopenthixol (Clopixol)

Antispasmodics

dicyclomine (Formulex, Bentylol)
flavoxate (Urispas)
glycopyrrolate (Robinul)
hyoscine butylbromide (Buscopan)
hyoscyamine/atropine/hyoscyne/
phenobarbital (Donnatal)
oxybutynin (Ditropan)
pinaverium bromide (Dicetel)*
propantheline bromide (Pro-Banthine, Propanthel)
tolterodine 1-tartrate (Detrol)

Antihistamines/Antipruritics with moderate to high anticholinergic effects

chlorpheniramine (Chlor-Triplon)*
cycloheptadine (Periactin)*
diphenhydramine (Benadryl)*
trimeprazine (Panectyl)

Miscellaneous

cyclobenzaprine (Flexeril) - moderate
diphenoxylate/atropine (Lomotil) – moderate
disopyramide (Norpace) – moderate

*not on the Sask Rx Drug Plan

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SASKATCHEWAN HEALTH

DRUG PLAN & EXTENDED BENEFITS BRANCH

FORMULARY AND EDS UPDATES EFFECTIVE APRIL 1, 2001

<u>GENERIC & TRADE NAME</u>	<u>STRENGTH & FORM</u>	<u>DIN</u>	<u>UNIT PRICE</u>	<u>LEGEND</u>
Adapalene				
<i>Differin</i>	0.1% topical cream	02231592	0.6272	
Beclomethasone dipropionate				
<i>Qvar</i>	50ug inh aer (CFC-Free)	02242029	30.7600	<i>not I/C</i>
<i>Qvar</i>	100ug inh aer (CFC-Free)	02242030	61.5200	<i>not I/C</i>
Bisoprolol fumarate				
<i>Monocor</i>	5mg tablet	02241148	0.3798	<i>EDS</i>
<i>Monocor</i>	10mg tablet	02241149	0.6293	<i>EDS</i>
Captopril				
<i>Captopril (Zymcan)</i>	12.5mg tablet	02242788	0.2301	<i>I/C</i>
<i>Captopril (Zymcan)</i>	25mg tablet	02242789	0.3255	<i>I/C</i>
<i>Captopril (Zymcan)</i>	50mg tablet	02242790	0.6066	<i>I/C</i>
<i>Captopril (Zymcan)</i>	100mg tablet	02242791	1.1279	<i>I/C</i>
Carbamazepine				
<i>Apo-Carbamazepine CR</i>	200mg CR tablet	02242908	0.2048	<i>I/C EDS</i>
<i>Apo-Carbamazepine CR</i>	400mg CR tablet	02242909	0.4095	<i>I/C EDS</i>
Conjugated estrogens/medroxyprogesterone acetate				
<i>Premplus</i>	0.625mg/2.5mg tablet (pkg)	02242878	7.6000	
Deferoxamine mesylate				
<i>pms-Deferoxamine</i>	500mg/vial pwdr for sol	02242055	8.8700	<i>I/C EDS</i>
<i>Desferal</i>	500mg/vial pwdr for sol	01981242	14.1800	<i>EDS</i>
<i>Desferal</i>	2g/vial pwdr for sol	01981250	56.9700	<i>EDS</i>
Diazepam				
<i>Diastat</i>	5mg/mL rectal gel (delivery system)	02238162	72.9700	
Diltiazem HCl				
<i>Novo-Diltazem CD</i>	120mg CD capsule	02242538	0.9324	<i>I/C</i>
<i>Novo-Diltazem CD</i>	180mg CD capsule	02242539	1.2377	<i>I/C</i>
<i>Novo-Diltazem CD</i>	240mg CD capsule	02242540	1.6416	<i>I/C</i>
<i>Novo-Diltazem CD</i>	300mg CD capsule	02242541	2.1608	<i>I/C</i>
Eprosartan mesylate				
<i>Teveten</i>	300mg tablet	02240431	0.5534	
<i>Teveten</i>	400mg tablet	02240432	1.1067	
Etodolac				
<i>Taro-Etodolac</i>	200mg capsule	02242914	0.6510	<i>I/C EDS</i>
<i>Taro-Etodolac</i>	300mg capsule	02242915	0.6510	<i>I/C EDS</i>
Fluphenazine decanoate				
<i>pms-Fluphenazine Decanoate</i>	100mg/mL inj sol	02241928	32.3200	<i>I/C</i>
Gabapentin				
<i>pms-Gabapentin</i>	100mg capsule	02243446	0.3038	<i>I/C</i>
<i>pms-Gabapentin</i>	300mg capsule	02243447	0.7390	<i>I/C</i>
<i>pms-Gabapentin</i>	400mg capsule	02243448	0.8802	<i>I/C</i>
Lisinopril				
<i>Apo-Lisinopril</i>	20mg tablet	02217511	0.9917	<i>I/C</i>

<u>GENERIC & TRADE NAME</u>	<u>STRENGTH & FORM</u>	<u>DIN</u>	<u>UNIT PRICE</u>	<u>LEGEND</u>
Metformin				
<i>Metformin (Zymcan)</i>	500mg tablet	02242794	0.1320	<i>I/C</i>
<i>Metformin (Zymcan)</i>	850mg tablet	02242793	0.2268	<i>I/C</i>
<i>pms-Metformin</i>	850mg tablet	02242589	0.2268	<i>I/C</i>
<i>Dom-Metformin</i>	850mg tablet	02242726	0.2382	<i>I/C</i>
Minocycline HCl				
<i>pms-Minocycline</i>	50mg capsule	02239238	0.5805	<i>I/C EDS</i>
<i>Rhoxal-Minocycline</i>	50mg capsule	02237313	0.5805	<i>I/C EDS</i>
<i>Dom-Minocycline</i>	50mg capsule	02239667	0.6131	<i>I/C EDS</i>
<i>pms-Minocycline</i>	100mg capsule	02239239	1.1211	<i>I/C EDS</i>
<i>Rhoxal-Minocycline</i>	100mg capsule	02237314	1.1211	<i>I/C EDS</i>
<i>Dom-Minocycline</i>	100mg capsule	02239668	1.1769	<i>I/C EDS</i>
Moclobemide				
<i>pms-Moclobemide</i>	150mg tablet	02243218	0.3965	<i>I/C</i>
<i>pms-Moclobemide</i>	300mg tablet	02243219	0.8651	<i>I/C</i>
Moxifloxacin HCl				
<i>Avelox</i>	400mg tablet	02242965	5.4359	<i>EDS</i>
Nefazodone				
<i>Apo-Nefazodone</i>	50mg tablet	02242822	0.5570	
<i>Apo-Nefazodone</i>	100mg tablet	02242823	0.6076	<i>I/C</i>
<i>Apo-Nefazodone</i>	150mg tablet	02242824	0.6076	<i>I/C</i>
<i>Apo-Nefazodone</i>	200mg tablet	02242825	0.7089	<i>I/C</i>
Pioglitazone HCl				
<i>Actos</i>	15mg tablet	02242572	2.6691	<i>EDS</i>
<i>Actos</i>	30mg tablet	02242573	2.9946	<i>EDS</i>
<i>Actos</i>	45mg tablet	02242574	4.4834	<i>EDS</i>
Prochlorperazine				
<i>Apo-Prochlorazine</i>	5mg tablet	00886440	0.1145	<i>I/C</i>
<i>Apo-Prochlorazine</i>	10mg tablet	00886432	0.1400	<i>I/C</i>
Ranitidine				
<i>pms-Ranitidine</i>	150mg tablet	02242453	0.4386	<i>I/C</i>
<i>pms-Ranitidine</i>	300mg tablet	02242454	0.8449	<i>I/C</i>
Rivastigmine				
<i>Exelon</i>	1.5mg capsule	02242115	2.4901	<i>EDS</i>
<i>Exelon</i>	3mg capsule	02242116	2.4901	<i>EDS</i>
<i>Exelon</i>	4.5mg capsule	02242117	2.4901	<i>EDS</i>
<i>Exelon</i>	6mg capsule	02242118	2.4901	<i>EDS</i>
Somatropin				
<i>Saizen</i>	5mg inj (vial)	02237971	208.8700	<i>not I/C EDS</i>
Terbinafine HCl				
<i>Gen-Terbinafine</i>	250mg tablet	02242503	2.7393	<i>I/C</i>
Vancomycin HCl				
<i>pms-Vancomycin</i>	500mg injection	02241820	24.2000	<i>I/C EDS</i>
<i>pms-Vancomycin</i>	1g injection	02241821	48.3700	<i>I/C EDS</i>

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

CRITERIA FOR NEW EXCEPTION DRUG STATUS (EDS) ADDITIONS

Effective April 1, 2001, the following products will be available for coverage subject to the indicated criteria.

bisoprolol fumarate, tablet, 5mg, 10mg (Monacor-BVL)

For treatment of patients with stable symptomatic congestive heart failure taking diuretics and ACE inhibitors, with or without digoxin.

carbamazepine, controlled release tablet, 200mg, 400mg (Apo-Carbamazepine CR-APX)

New interchangeable - same criteria as other brands listed in Appendix A, page 235.

deferoxamine mesylate, powder for solution, 500mg/vial (pms-Deferoxamine) (Desferal-NVR); 2g/vial (Desferal-NVR)

For treatment of iron overload in patients with transfusion-dependent anemias.

etodolac, capsule, 200mg, 300mg (Taro-Etodolac-TAR)

New interchangeable - same criteria as other brands listed in Appendix A, page 242.

minocycline HCl, capsule, 50mg, 100mg (Dom-Minocycline-DOM) (RhoXal-Minocycline-RHO) (pms-Minocycline-PMS)

New interchangeables - same criteria as other brands listed in Appendix A, page 248.

moxifloxacin HCl, tablet, 400mg (Avelox-BAY)

- (a) For treatment of infections in patients with underlying lung disease not responding to first-line antibiotics.
- (b) For treatment of infections caused by organisms known to be resistant to alternative antibiotics.
- (c) For treatment of infections in patients allergic to alternative antibiotics.

pioglitazone HCl, tablet, 15mg, 30mg, 45mg (Actos-LIL)

For treatment of diabetes in patients who are not adequately controlled on or are intolerant to metformin and sulfonylureas.

rivastigmine, capsule, 1.5mg, 3mg, 4.5mg, 6mg (Exelon-NVR)

- (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) A Functional Activities Questionnaire (FAQ) must be completed.
 - (d) Patients must discontinue all drugs with anticholinergic activity at least 14 days before the MMSE and FAQ are administered. Drugs with anticholinergic activity are not to be used concurrently with rivastigmine therapy. List all current medications patient was taking at the time of assessment.
 - (e) Patients intolerant to one drug may be switched to another drug in this class. Intolerance should be observed within the first month of treatment.
- **Eligible patients currently taking rivastigmine** would require assessment at 6 month intervals. To continue receiving rivastigmine, 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.

- **Eligible new patients** will enter a 3 month treatment period with rivastigmine. During the 3 month trial, patients must exhibit an improvement from the initial MMSE or FAQ to continue treatment with rivastigmine. The improvement must be at least 2 MMSE points or -1 FAQ. Patients who meet these requirements will be re-evaluated at 6 month intervals. To continue receiving rivastigmine, 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.
- 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 rivastigmine can be re-evaluated within 3 months to confirm deterioration before coverage is discontinued.
- Rivastigmine does not need to be discontinued prior to MMSE or FAQ testing.
- A patient intolerant of one drug and switching to a second will be considered a "new" patient and will be assessed as such.
- Coverage will not be considered for patients who have failed on other drugs in this class.

somatropin, injection, 5mg (Saizen-SRO)

For treatment of children who have growth failure due to inadequate secretion of normal endogenous growth hormone.

vancomycin HCl, injection, 500mg, 1g (pms-Vancomycin-PMS)

New interchangeable - same criteria as Vancocin listed in Appendix A, page 257.

MODIFICATIONS TO CURRENT EXCEPTION DRUG STATUS (EDS) CRITERIA

Effective April 1, 2001, the EDS criteria for the following products will be as indicated.

azithromycin, tablet, 250mg; oral suspension, 20mg/mL, 40mg/mL (Zithromax-PFI)

Note: criteria (a) to (f) unchanged. Modification of (g) from August 1, 2000 update, Sticker #3 as follows:

- (g) For step-down care following hospital separation in patients treated with intravenous macrolides (guided by culture and sensitivity results).

clarithromycin, tablet, 250mg, 500mg; oral suspension, 25mg/mL (Biaxin-ABB)

Note: criteria (a) to (g) unchanged. Addition of (h) as follows:

- (h) For step-down care following hospital separation in patients treated with intravenous macrolides (guided by culture and sensitivity results).

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) A Functional Activities Questionnaire (FAQ) must be completed.
- (d) Patients must discontinue all drugs with anticholinergic activity at least 14 days before the MMSE and FAQ are administered. Drugs with anticholinergic activity are not to be used concurrently with donepezil therapy. List all current medications patient was taking at the time of assessment.
- (e) Patients intolerant to one drug may be switched to another drug in this class. Intolerance should be observed within the first month of treatment.

- **Eligible patients currently taking donepezil** would require assessment 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.
- **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. Patients who meet these requirements 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.
- 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.
- Donepezil does not need to be discontinued prior to MMSE or FAQ testing.
- A patient intolerant of one drug and switching to a second will be considered a "new" patient and will be assessed as such.

- Coverage will not be considered for patients who have failed on other drugs in this class.

mycophenolate mofetil, capsule, 250mg; tablet, 500mg (CellCept-HLR)

For prevention of acute rejection in renal and cardiac transplant patients. *This is renewable on a yearly basis.*

risedronate sodium, tablet, 5mg (Actonel-PGA)

- (a) For treatment of osteoporosis in patients who do not respond to etidronate disodium/calcium (Didrocal) after receiving it for one year.
- (b) For treatment of osteoporosis in patients unable to tolerate etidronate disodium/calcium (Didrocal).
- (c) For treatment of osteoporosis in patients unable to tolerate alendronate sodium (Fosamax).