Saskatchewan Ministry of Health

Drug Plan and Extended Benefits Branch

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SASKATCHEWAN FORMULARY COMMITTEE BULLETIN TO THE 58th EDITION OF THE SASKATCHEWAN FORMULARY

The following listings are effective **July 1, 2008**, unless otherwise indicated.

NEW FULL FORMULARY LISTINGS:

- Blood glucose test strip, (FreeStyle Lite-ABB)
- Amiodarone tablet, 100mg (pms-Amiodarone-PMS)

NEW EXCEPTION DRUG STATUS LISTINGS:

- **Efalizumab, powder for solution, 150mg/vial (Raptiva-SRO)**

  For the treatment of patients with severe, debilitating plaque psoriasis who meet all of the following criteria as outlined in the Canadian Expert Drug Advisory Committee (CEDAC) recommendation:

  1) Body surface area (BSA) involvement of >10% and/or significant involvement of the face, hands, feet or genital region;
  2) Failure to respond to, contraindications to, or intolerant of methotrexate and cyclosporine;
  3) Failure to respond to, intolerant to or unable to access phototherapy.

  Coverage will be approved initially for 12 weeks. Continued coverage can be approved in patients who have responded to therapy. A response is defined as patients who have achieved a ≥75% reduction in Psoriasis Area Severity Index (PASI) score, or a ≥50% reduction with a ≥5 point improvement in Dermatology Life Quality Index (DLQI) or a quantitative reduction in BSA affected with qualitative consideration of specific regions such as face, hands, feet or genital region.

  Entry into a registry, known as RESTORE, maintained by the manufacturer is encouraged. This RESTORE registry is designed to collect effectiveness and harm outcome information. This process will be managed between the patient's specialist and the manufacturer of the drug.

  The following two drugs were recommended by the Saskatchewan review committees for plaque psoriasis according to the following Exception Drug Status criteria:

- **Etanercept, powder for injection (vial), 25mg/vial; pre-filled syringe, 50mg/ml Enbrel-AMG)**

  AND

- **Infliximab, injection, 100mg/vial (Remicade-SCH)**

  For the treatment of adult patients with severe debilitating plaque psoriasis who meet all of the following criteria:

  1) failure to respond, contraindications to, or intolerant of methotrexate and cyclosporine; AND,
  2) failure to respond to, intolerant to or unable to access phototherapy.

  These drugs should be used in consultation with a specialist in this area.

DRUGS CURRENTLY UNDER REVIEW BY THE SASKATCHEWAN REVIEW COMMITTEES:

Atripla, Campral, Invega, Isentress, Lucentis, Ralivia, Tridural

NEW FULL FORMULARY NON-INTERCHANGEABLE LISTING EFFECTIVE FEBRUARY 15, 2008:

- Hydromorphone, suppository, 3mg (pms-Hydromorphone-PMS)

NEW INTERCHANGEABLE LISTINGS EFFECTIVE MAY 1, 2008:

- Etidronate disodium/calcium carbonate, tablet, 400mg/1250mg (package) (CO Etidrocal-COB)
- Etidronate disodium/calcium carbonate, tablet, 400mg/1250mg (package) (Gen-Eti-Cal Carepac-GPM)
- Lisinopril, tablet, 5mg, 10mg, 20mg (Dom-Lisinopril-DOM)
- Metoprolol tartate, sustained release tablet, 100mg, 200mg (Sandoz Metoprol SR-SDZ)
- Morphine sulfate, sustained release tablet, 100mg, 200mg (pms-Morphine Sulfate SR-PMS)
- Propafenone HCl, tablet, 150mg, 300mg (pms-Propafenone-PMS)
- Ramipril, capsule, 1.5mg, 2.5mg, 5mg, 10mg (Ramipril-PMS)
- Risperidone, tablet, 0.25mg, 0.5mg (Sandoz Risperidone-SDZ)
- Sodium Sulamyd, ophthalmic solution, 10% (Sodium Sulamyd-SDZ)
- Venlafaxine HCl, capsule, 37.5mg, 75mg, 150mg (CO Venlafaxine XR-COB)

NEW INTERCHANGEABLE EDS LISTINGS EFFECTIVE MAY 1, 2008 ACCORDING TO CURRENT EDS CRITERIA:

- Ciprofloxacin, tablet, 250mg, 500mg, 750mg (Ran-Ciproflox-RAN)
- Pantoprazole, tablet, 40mg (Novo-Pantoprazole-NOP)

NEW INTERCHANGEABLE LISTING EFFECTIVE JUNE 1, 2008:

- Valacyclovir, caplet, 500mg (pms-Valacyclovir-PMS)

NEW INTERCHANGEABLE LISTINGS EFFECTIVE JULY 1, 2008:

- Doxycycline, capsule, 100mg, tablet, 100mg (Dom-Doxycycline-DOM)
- Levetiracetam, tablet, 250mg, 500mg, 750mg (Dom-Levetiracetam-DOM)

NEW INTERCHANGEABLE EDS LISTINGS EFFECTIVE JULY 1, 2008 ACCORDING TO CURRENT EDS CRITERIA:

- Azithromycin, tablet, 250mg, 500mg (Dom-Azithromycin-DOM)
- Fluconazole, tablet, 50mg, 100mg (CO Fluconazole-COB)
- Modafinil, tablet, 100mg (Apo-Modafinil-APX)

Saskatchewan Formulary Committee
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FORMULARY AND EDS UPDATES EFFECTIVE JULY 1, 2008

GENERIC & TRADE NAME	*STRENGTH & FORM*	*DIN*	*UNIT PRICE*	*LEGEND*
Valacyclovir				
pms-Valacyclovir	500mg tablet	02298457	2.7606	I/C
Atomoxetine HCl				
Strattera	10mg capsule	02262800	4.3183	EDS
Strattera	18mg capsule	02262819	4.3183	EDS
Strattera	25mg capsule	02262827	4.3183	EDS
Strattera	40mg capsule	02262835	4.3183	EDS
Strattera	60mg capsule	02262843	4.3183	EDS
***Citalopram Hydrobromide**				
Citalopram Odan	20mg tablet	2306239	0.9494	I/C
Citalopram Odan	40mg tablet	2306247	0.9494	I/C
***Clarithromycin**				
Sandoz Clarithromycin	250mg tablet	2266539	1.1941	I/C EDS
Sandoz Clarithromycin	500mg tablet	2266547	2.388	I/C EDS
***Clonidine HCl**				
Novo-Clonidine	0.025mg tablet	2304163	0.1972	I/C EDS
Methylphenidate HCl				
Concerta	18mg XR tablet	2247732	2.1483	
Concerta	27mg XR tablet	2250241	2.4847	
Concerta	36mg XR tablet	2247733	2.8102	
Concerta	54mg XR tablet	2247734	3.472	
***Pantoprazole (MAC)**				
CO Pantoprazole	40mg EC tablet	2300486	1.4864	I/C EDS
Gen-Pantoprazole	40mg ECtablet	2299585	1.4864	I/C EDS
pms-Pantoprazole	40mg EC tablet	2307871	1.4864	I/C EDS
ratio-Pantoprazole	40mg EC tablet	2308681	1.4864	I/C EDS
Sandoz Pantoprazole	40mg EC tablet	2301083	1.4864	I/C EDS
***Paroxetine HCl**				
Sandoz Paroxetine	10mg tablet	2269422	1.1317	I/C
Sandoz Paroxetine	20mg tablet	2269430	1.0869	I/C
Sanodz Paroxetine	30mg tablet	2269449	1.1552	I/C
***Rabeprazole (MAC)**				
pms-Rabeprazole EC	10mg EC tablet	2310805	0.4937	I/C EDS
pms-Rabeprazole EC	20mg EC tablet	2310813	0.9874	I/C EDS
***Valacyclovir**				
Apo-Valacyclovir	500mg tablet	2295822	2.7606	I/C
***Venlafaxine HCl**				
Gen-Venlafaxine XR	37.5mg XR capsule	2310279	0.6379	I/C
Gen-Venlafaxine XR	75mg XR capsule	2310287	1.2758	I/C
Gen-Venlafaxine XR	150mgXR capsule	2310295	1.347	I/C
Sandoz Venlafaxine XR	37.5mg XR capsule	2310317	0.6379	I/C
Sandoz Venlafaxine XR	75mg XR capsule	2310325	1.2758	I/C

Sandoz Venlafaxine XR	150mg XR capsule	2310333	1.347 I/C

(MAC) - Maximum Allowable Cost Policy in effect.

Due to supply issues, the manufacturer has asked to immediately de-list the following products:

Nitrazepam

Nitrazadon	5mg tablet	2229654	0.0738 I/C
Nitrazadon	10mg tablet	2229655	0.1104 I/C

Claims will still adjudicate while inventory is being depleted.

Exception Drug Status Criteria

Effective ***July 1, 2008*** the following products will be available for coverage under (EDS):

Atomoxetine HCl, capsule, 10mg, 18mg, 25mg, 40mg, 60mg (Strattera-LIL)

For treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients who meet all the following criteria:

- have failed or are intolerant to treatment with methylphenidate and dextroamphetamine.
- treatment with Strattera must be recommended by or in consultation with a specialist in psychiatry, pediatrics or a general practitioner with expertise in ADHD.
- Evidence of benefit from a one-month trial with Strattera (provided by the manufacturer).

***Clarithromycin, tablet, 250mg, 500mg (Sandoz Clarithromcyin-SDZ)**

New interchangeable, same criteria as other brands listed in Appendix A, page 221.

***Clonidine HCl, tablet, 0.025mg (Novo-Clonidine-NOP)**

New interchangeable, same criteria as other brands listed in Appendix A, page 222.

Infliximab, injection (mg) 100mg/vial (Remicade-SCH)

Additional criteria:

(f) Psoriatic arthritis in patients who have failed or are intolerant to methotrexate and one other DMARD.

Note: Exceptions can be considered in cases where methotrexate or leflunomide are contraindicated. Treatment should be combined with an immunosuppressant.

(g) For treatment of ankylosing spondylitis (A.S.) according to the following criteria:

1) For patients who have already been treated conventionally with two or more NSAIDs taken sequentially at maximum tolerated or recommended doses for four weeks without symptom control. AND

2) Satisfy New York diagnostic criteria: a score $\geq$ 4 on the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) AND a score of > 4 cm on the 0-10cm spinal pain VAS on two occasions at least 12 weeks apart without any change of treatment. AND

3) Adequate response to treatment assessed at 12 weeks defined as at least 50% reduction in pre-treatment baseline BASDAI score or by > 2 units AND a reduction of > 2 cm in the spinal pain VAS.

NOTE:

Coverage will not be provided when a patient switches to another anti-TNF agent if the patient

fails to respond or if there is loss of response to the first agent.
Requests for coverage for this indication must be made by the rheumatologist.
A second application would also be required after 12 weeks to assess and would need to show an improvement to the patient's condition on either of these medications.
Please refer to the Formulary website for the application form.

For all of the above indications this product should be used in consultation with a specialist in this area.

PRICE CHANGES

At the manufacturers request, please amend the price in the 58th edition of the formulary as follows:

Renagel	800mg tablet	02244310	1.6692	EDS
Flovent HFA	125ug/inhalation aerosol	02244292	43.75	

ADDITIONS/DELETIONS SUMMARY

The Additions/Deletions Summary (a comprehensive summary of all products added or deleted from the previous formulary) is available online at: **http://formulary.drugplan.health.gov.sk.ca**