

**QUARTERLY UPDATE
TO THE
51st EDITION
OF THE
SASKATCHEWAN FORMULARY**

NEW LISTINGS**NEW EXCEPTION DRUG STATUS AGENTS**

Effective April 1, 2002 the following products are available under Exception Drug Status subject to the indicated criteria.

- **Abacavir SO₄/lamivudine/zidovudine, tablet, 300mg/150mg/300mg (Trizivir-GSK)**
Exception Drug Status Criteria: For management of HIV disease. *This drug, as with other antivirals in treatment of HIV, should be used under the direction of an infectious disease specialist.*
- **Bosentan, tablet, 62.5mg, 125mg (Tracleer-ACT)**
Exception Drug Status Criteria: For patients with pulmonary arterial hypertension on the recommendation of a specialist.
- **Doxercalciferol, capsule, 2.5ug (Hectorol-DPY)**
Exception Drug Status Criteria: For the management of hypocalcemia, osteodystrophy, and secondary hyperparathyroidism in chronic renal disease patients prior to initiation of dialysis. *Coverage for dialysis patients is provided under the Saskatchewan Aids to Independent Living (S.A.I.L.) Program. Exception Drug Status coverage is not required for S.A.I.L. patients.*
- **Fusidic acid, ophthalmic drops (preservative free) 1%; ophthalmic drops 1% (Fucithalamic-LEO)**
Exception Drug Status Criteria: For patients not responding to listed alternatives.

- **Pamidronate disodium injection, 30mg, 90mg (Aredia-NVR)**
Exception Drug Status Criteria: For treatment of osteoporosis in patients unable to tolerate oral bisphosphonates.
- **Tacrolimus, topical ointment, 0.03%, 0.1% (Protopic-FUJ)**
Exception Drug Status Criteria: For treatment of moderate to severe atopic dermatitis in patients who are unresponsive or intolerant to topical steroids.

FIRST ENTRY GENERIC

- Amoxicillin trihydrate/potassium clavulanate, oral suspension, 25mg/6.25mg/mL, 50mg/12.5mg/mL (Apo-Amoxi Clav-APX)
- Floctafenine, tablet, 200mg, 400mg (Apo-Floctafenine-APX)
- Fluorometholone, ophthalmic suspension, 0.1% (pms-Fluorometholone-PMS)
- Gentamicin SO₄/betamethasone sodium phosphate, otic/ophthalmic solution, 0.3%/0.1% (SAB-Pentason-SAB)

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

Covered under the same Exception Drug Status criteria published in this bulletin for the other listed strengths (effective April 1, 2002).

- Montelukast sodium, chewable tablet, 4mg (Singulair-MSD)
- Quetiapine, tablet, 300mg (Seroquel-AST)

**MODIFICATIONS TO CURRENT
EXCEPTION DRUG STATUS
CRITERIA**

Effective April 1, 2002 the Exception Drug status criteria for the following products will be as indicated.

- **Calcitriol, capsule, 0.25ug, 0.5ug; oral solution, 1ug/mL (Rocaltrol-HLR)**
Exception Drug Status criteria has been revised to:
 - (a) For the management of hypocalcemia and osteodystrophy in patients with chronic renal failure undergoing renal dialysis. *Coverage for dialysis patients is provided under the Saskatchewan Aids to Independent Living (S.A.I.L.) Program. Exception Drug Status coverage is not required for S.A.I.L. patients.*
 - (b) For the management of hypocalcemia and clinical manifestations associated with post-surgical hypoparathyroidism, idiopathic hypoparathyroidism, pseudohypoparathyroidism, or Vitamin D resistant rickets.
- **Fentanyl, transdermal system, 25ug/hr., 50ug/hr., 75ug/hr., 100ug/hr. (Duragesic-JAN)**
Exception Drug Status criteria has been revised to:
For treatment of patients who cannot tolerate, or are unable to take oral sustained-release strong opioids, or as an alternative to subcutaneous narcotic infusion therapy.
In non-palliative patients, coverage will only be approved for a 6 month course of therapy.

- **Montelukast sodium, chewable tablet, 5mg; tablet, 10mg (Singulair-MSD)**
Exception Drug Status criteria has been revised to:
For adjunctive treatment of asthma in patients not well controlled on inhaled corticosteroids.
- **Mycophenolate mofetil, capsule, 250mg; tablet, 500mg (CellCept-HLR)**
Exception Drug Status criteria has been revised to:
For prevention of acute rejection in transplant patients.
- **Olanzapine, tablet, 2.5mg, 5mg, 7.5mg, 10mg (Zyprexa-LIL); orally disintegrating tablet, 5mg, 10mg (Zyprexa Zydis-LIL)**
Exception Drug Status criteria has been revised to:
 - (a) For treatment of schizophrenia.
 - (b) For treatment of other psychotic conditions where there has been treatment failure or intolerance to other atypical anti-psychotic agents.
 EDS criteria (c) has been deleted.
- **Quetiapine, tablet, 25mg, 100mg, 150mg, 200mg (Seroquel-AST)**
Exception Drug Status criteria (a) and (c) unchanged. Exception Drug Status criteria (b) has been revised to:
For treatment of other psychotic conditions where there has been treatment failure or intolerance to other atypical anti-psychotic agents.
- **Repaglinide, tablet, 0.5mg, 1mg, 2mg (Gluconorm-NOO)**
Exception Drug Status criteria has been revised to:
For the treatment of diabetes in patients who are not adequately controlled on or are intolerant to sulfonylureas.

- **Ursodiol, tablet, 250mg (Urso-AXC)**
Exception Drug Status criteria has been revised to:
For management of cholestatic liver diseases such as primary biliary cirrhosis.

Salbutamol SO4, inhaler aerosol (package) (CFC- free), 100ug/dose (Alti-Salbutamol HFA-ALT)
This product has been added to the Formulary and will be listed as not interchangeable with other salbutamol metered dose inhalers.
Patients may notice differences in the taste and sound of this new inhaler, or may perceive that the spray is softer and warmer than that of their CFC-containing MDI.

NEW FULL FORMULARY LISTINGS

- Epinephrine, injection solution (package), 0.15mg/dose (EpiPen Jr.-ALX)
- Epinephrine, injection solution (package), 0.3mg/dose (EpiPen-ALX)
- Glucose oxidase/peroxidase reagent, strip (Sof-Tact-MDS)
- Levonorgestrel, tablet, 0.75mg (Plan B-PAL)
- Morphine, sustained-release tablet, 15mg, 30mg, 60mg (Alti-morphine SR-ALT) *Note: interchangeable with MS Contin.*
- Tazarotene, topical cream, 0.05%, 0.1% (Tazorac-ALL)
- Travoprost, ophthalmic solution 0.004% (Travatan-ALC)

Discontinued Products

The following products have been discontinued by the manufacturer and will not be listed in the next edition of the Saskatchewan Formulary.

- Iron sorbitol, injection, 50mg/mL (Jectofer-AST)
- Tolmetin, tablet, 600mg (Tolectin-JAN)

PRODUCTS REVIEWED AND NOT RECOMMENDED FOR LISTING

- **Gliclazide, modified release tablet, 30mg (Diamicon MR-SEV)**
This product offers no advantage over listed products and the clinical benefit does not justify the incremental cost.
- **Levocarnitine, injection solution, 200mg/mL (Carnitor-SIG)**
There is insufficient clinical evidence to support the use of this product.

SOME OF THE PRODUCTS CURRENTLY UNDER REVIEW BY THE FORMULARY COMMITTEE

- Alfuzosin HCl, prolonged release tablet, 10mg (Xatral-SAW)
- Esomeprazole magnesium trihydrate, delayed release tablet, 20mg, 40mg (Nexium-AST)
- Fluticasone propionate, inhalation aerosol (package), 50ug, 125ug, 250ug (Flovent HFA-GSK)
- Formoterol fumarate dihydrate/budesonide, powder for inhalation (package), 6ug/100ug, 6ug/200ug (Symbicort Turbuhaler-AST)
- Insulin (Regular) Aspart, injection solution (5x3ml), 100u/mL (NovoRapid-NOO)
- Metronidazole, topical cream, 1% (Rosasol-STI)
- Salmeterol xinafoate/fluticasone propionate, inhaler aerosol (package) 25ug/125ug, 25ug/250ug, (Advair-GSK)
- Sibutramine hydrochloride monohydrate, capsule, 10mg 15mg (Meridia-ABB)

HOSPITAL BENEFIT DRUG LIST UPDATE

April 2002

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.

LINEZOLID INJECTION (Zyvoxam™)

Restricted Coverage: When used according to the current Exceptional Drug Status criteria for the agent.

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

This Bulletin is not to be reproduced or republished except with the approval of the Saskatchewan Formulary Committee. Inquiries should be directed to the address shown at left.

FORMULARY AND EDS UPDATES EFFECTIVE APRIL 1, 2002

<u>GENERIC & TRADE NAME</u>	<u>STRENGTH & FORM</u>	<u>DIN</u>	<u>UNIT PRICE</u>	<u>LEGEND</u>
Abacavir SO4/lamivudine/zidovudine				
Trizivir	300mg/150mg/300mg tablet	02244757	16.2500	EDS
Acetylcysteine				
Acetylcysteine Solution	20% solution (30mL)	02243098	15.4400	I/C
Amoxicillin trihydrate/ potassium clavulanate				
Apo-Amoxi Clav	25mg/6.25mg/mL oral suspension	02243986	0.0786	I/C EDS
Apo-Amoxi Clav	50mg/12.5mg/mL oral suspension	02243987	0.1322	I/C EDS
Amethopterin				
Alti-Methotrexate	2.5mg tablet	02244798	0.7636	I/C
Bosentan				
Tracleer	62.5mg tablet	02244981	60.4000	EDS
Tracleer	125mg tablet	02244982	60.4000	EDS
Bromocriptine mesylate				
Dom-Bromocriptine	2.5mg tablet	02238636	0.6213	I/C
Doxazosin mesylate				
pms-Doxazosin	1mg tablet	02244527	0.3760	I/C
pms-Doxazosin	2mg tablet	02244528	0.4512	I/C
pms-Doxazosin	4mg tablet	02244529	0.5865	I/C
Doxercalciferol				
Hectorol	2.5ug capsule	02243790	1.8445	EDS
Epinephrine				
EpiPen Jr.	0.15mg/dose injection solution (package)	00578657	81.3800	
EpiPen	0.3mg/dose injection solution (package)	00509558	81.3800	
Floctafenine				
Apo-Floctafenine	200mg tablet	02244680	0.3151	I/C
Apo-Floctafenine	400mg tablet	02244681	0.5487	I/C
Fluorometholone				
pms-Fluorometholone	0.1% ophthalmic suspension	02238568	1.7556	I/C
Fusidic acid				
Fucithalmic	1% ophthalmic drops (preservative free)	02243861	0.8190	EDS
Fucithalmic	1% ophthalmic drops (g)	02243862	1.7580	EDS
Gentamicin SO4/betamethasone sodium phosphate				
Sab-Pentason	0.3%/0.1% otic/ophthalmic solution	02244999	1.5904	I/C
Glucose oxidase/peroxidase reagent				
Sof-Tact	strip	00950902	0.8626	
Lactulose				
Apo-Lactulose	667mg/mL solution	02242814	0.0158	EDS I/C to Acilac
Levonorgestrel				
Plan B	0.75mg tablet	02241674	8.6600	
Loperamide HCl				
Dom-Loperamide	2mg caplet	02239535	0.2810	I/C

FORMULARY AND EDS UPDATES EFFECTIVE APRIL 1, 2002

<u>GENERIC & TRADE NAME</u>	<u>STRENGTH & FORM</u>	<u>DIN</u>	<u>UNIT PRICE</u>	<u>LEGEND</u>
Misoprostol				
<i>Novo-Misoprostol</i>	100ug tablet	02240754	0.2066	I/C
<i>Novo-Misoprostol</i>	200ug tablet	02240755	0.3440	I/C
Montelukast sodium				
<i>Singulair</i>	4mg chewable tablet	02243602	1.3758	EDS
Morphine				
<i>Alti-Morphine SR</i>	15mg sustained release tablet	02244790	0.4523	I/C to MS Contin
<i>Alti-Morphine SR</i>	30mg sustained release tablet	02244791	0.6828	I/C to MS Contin
<i>Alti-Morphine SR</i>	60mg sustained release tablet	02244792	1.2037	I/C to MS Contin
Nabumetone				
<i>Relafen</i>	750mg tablet	02083558	1.0170	I/C EDS
Nizatidine				
<i>Dom-Nizatidine</i>	150mg capsule	02185814	0.6023	I/C
Pamidronate disodium				
<i>Aredia</i>	30mg injection	02059762	170.8900	EDS
<i>Aredia</i>	90mg injection	02059789	502.5000	EDS
Quetiapine				
<i>Seroquel</i>	300mg tablet	02244107	4.0500	EDS
Salbutamol SO4				
<i>Alti-Salbutamol HFA</i>	100ug/dose inhaler aerosol (package) (CFC-free)	02244914	5.0400	Non I/C
Salbutamol SO4				
<i>Apo-Salvent</i>	0.5mg/mL inhalation solution preservative free (2.5mL)	02243828	0.4047	I/C
Tacrolimus				
<i>Protopic</i>	0.03% topical ointment	02244149	2.3330	EDS
<i>Protopic</i>	0.1% topical ointment	02244148	2.4960	EDS
Tazarotene				
<i>Tazorac</i>	0.05% topical cream	02243894	1.3961	
<i>Tazorac</i>	0.1% topical cream	02243895	1.3961	
Terazosin HCl				
<i>Dom-Terazosin</i>	1mg tablet	02243746	0.3977	I/C
<i>Dom-Terazosin</i>	2mg tablet	02243747	0.5054	I/C
<i>Dom-Terazosin</i>	5mg tablet	02243748	0.6864	I/C
<i>Dom-Terazosin</i>	10mg tablet	02243749	1.0049	I/C
Timolol Maleate				
<i>Alti-Timolol Maleate</i>	0.25% ophthalmic solution	02240248	1.6818	I/C
<i>Alti-Timolol Maleate</i>	0.5% ophthalmic solution	02240249	2.0181	I/C
Travoprost				
<i>Travatan</i>	0.004% ophthalmic solution (2.5mL)	02244896	28.7600	

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

EDS UPDATE EFFECTIVE APRIL 1, 2002

CRITERIA FOR NEW EXCEPTION DRUG STATUS (EDS) ADDITIONS

Effective **April 1, 2002**, the following products will be available for coverage subject to the indicated criteria.

abacavir SO₄/lamivudine/zidovudine, tablet, 300mg/150mg/300mg (Trizivir-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.*

amoxicillin trihydrate/potassium clavulanate, oral suspension, 25mg/6.25mg/mL, 50mg/12.5mg/mL (Apo-Amoxi Clav-APX)

New interchangeable – same criteria as other brands listed in Appendix A, page 207.

bosentan, tablet, 62.5mg, 125mg (Tracleer-ACT)

For patients with pulmonary arterial hypertension on the recommendation of a specialist.

doxercalciferol, capsule, 2.5ug (Hectorol-DPY)

For the management of hypocalcemia, osteodystrophy and secondary hyperparathyroidism in chronic renal disease patients prior to initiation of dialysis.

Note: Coverage for dialysis patients is provided under the Saskatchewan Aids to Independent Living (SAIL) Program. Exception Drug Status coverage is NOT required for SAIL patients.

fusidic acid, ophthalmic drops (preservative free), 1%; ophthalmic drops 1% (Fucithalmic-LEO)

For patients not responding to listed alternatives.

lactulose, solution, 667mg/mL (Apo-Lactulose-APX)

New interchangeable (with Acilac-TCH) – same criteria as other brands listed in Appendix A, page 221.

montelukast sodium, chewable tablet, 4mg, (Singulair-MSD)

For adjunctive treatment of asthma in patients not well controlled on inhaled corticosteroids.

nabumetone, tablet, 750mg (Relafen-GSK)

New interchangeable – same criteria as other brands listed in Appendix A, page 224.

pamidronate disodium injection, 30mg, 90mg (Aredia-NVR)

For the treatment of osteoporosis in patients unable to tolerate oral bisphosphonates.

quetiapine, tablet, 300mg (Seroquel-AST)

New strength - criteria same as other strengths of quetiapine (Seroquel) below.

tacrolimus, topical ointment, 0.03%, 0.1% (Protopic-FUJ)

For the treatment of moderate to severe atopic dermatitis in patients who are unresponsive or intolerant to topical steroids.

MODIFICATIONS TO CURRENT EXCEPTION DRUG STATUS (EDS) CRITERIA

Effective **April 1, 2002**, the EDS criteria for the following products will be as indicated.

calcitriol, solution 1ug/mL; capsule, 0.25ug, 0.5ug (Rocaltrol-HLR)

(a) For management of hypocalcemia and osteodystrophy in patients with chronic renal failure undergoing renal dialysis. *Note: Coverage for dialysis patients is provided under the Saskatchewan Aids to Independent Living (SAIL) Program. Exception Drug Status coverage is NOT required for SAIL patients.*

(b) For management of hypocalcemia and clinical manifestations associated with post-surgical hypoparathyroidism, idiopathic hypoparathyroidism, pseudohypoparathyroidism, vitamin D resistant rickets.

fentanyl, transdermal system, 25ug/hr., 50ug/hr., 75ug/hr., 100ug/hr. (Duragesic-JAN)

For treatment of patients who cannot tolerate, or are unable to take, oral sustained-released strong opioids, or as an alternative to subcutaneous narcotic infusion therapy. *In non-palliative patients, coverage will only be approved for a 6-month course of therapy.*

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

Crohn's Disease:

Note: criteria (a) remains unchanged.

(b) Fistulizing Crohn's Disease:

- For treatment of patients with symptomatic enterocutaneous or perineal fistulae, enterovaginal fistulae or enterovesical fistulae, (i.e. any type of fistulizing Crohn's Disease).

Note: This product should be used in consultation with a specialist in this area.

montelukast sodium, chewable tablet, 5mg; tablet, 10mg (Singulair-MSD)

Note: criteria (a) and (b) deleted. Revised criteria as follows:

For adjunctive treatment of asthma in patients not well controlled on inhaled corticosteroids.

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

For the prevention of acute rejection in transplant patients.

olanzapine, tablet, 2.5mg, 5mg, 7.5mg, 10mg (Zyprexa-LIL); orally disintegrating tablet, 5mg, 10mg, (Zyprexa Zydis-LIL)

Note: criteria (a) unchanged. Criteria (b) modified as follows. Criteria (c) deleted.

(b) For treatment of other psychotic conditions where there has been treatment failure or intolerance to other atypical anti-psychotic agents.

quetiapine, tablet, 25mg, 100mg, 150mg, 200mg (Seroquel-AST)

Note: criteria (a) and (c) unchanged. Criteria (b) modified as follows:

(b) For treatment of other psychotic conditions where there has been treatment failure or intolerance to other atypical anti-psychotic agents.

repaglinide, tablet, 0.5mg, 1mg, 2mg (Gluconorm-NOO)

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

ursodiol, tablet, 250mg (Urso-AXC)

Note: criteria (a) deleted.

For the management of cholestatic liver diseases such as primary biliary cirrhosis.