Saskatchewan Health

Drug Plan and Extended Benefits Branch

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SASKATCHEWAN FORMULARY COMMITTEE UPDATE BULLETIN 51st Edition

NEW LISTINGS

NEW EXCEPTION DRUG STATUS AGENT

Effective July 1, 2002 the following product is available under Exception Drug Status subject to the indicated criteria.

- **Formoterol fumarate dihydrate/budesonide, powder for inhalation (package), 6ug/100ug, 6ug/200ug (Symbicort Turbuhaler-AST)**
  Exception Drug Status Criteria:
  (a) For treatment of asthma in patients not adequately controlled on inhaled steroid therapy. *It is important that these patients also have access to a short-acting beta-2 agonist for symptomatic relief.*
  (b) For treatment of chronic obstructive pulmonary disease (COPD) in patients who are not adequately controlled on a long-acting beta-2 agonist alone.

NEW FULL FORMULARY LISTINGS

- Alfuzosin HCl, prolonged release tablet, 10mg (Xatral-SAW)
- Glucose oxidase/peroxidase reagent, strip (Freestyle-THS)
- Metronidazole, topical cream, 1% (Rosasol-STI)

SPECIAL REVIEW COMMITTEE ON ANTIBIOTICS

A special subcommittee of the Drug Quality Assessment Committee has been convened to review and make recommendations regarding the antibiotics currently covered under the Drug Plan. The committee will also be updating the *Chart of Antibiotic Choices for Common Infectious Diseases* previously published in 1999.

The committee members include a family physician, a pediatrician, a pharmacologist, internal medicine specialists in infectious disease and respirology, and clinical pharmacists with expertise in infectious disease. Recommendations from this committee will be forwarded to the Saskatchewan Formulary Committee, who advises the Minister of Health on changes to the Formulary.

ANNUAL FORMULARY

Due to the work of the Special Review Committee on Antibiotics, it is anticipated there will be changes to the criteria of many of the EDS listed antibiotics. In order to have the most current information published in the Formulary, the printing of the 52nd Edition of the Saskatchewan Formulary will be delayed until fall. The July update is provided in sticker format.

Fenofibrate, capsule, 100mg (Apo-Fenofibrate-APX, Nu-Fenofibrate-NXP)

As previously notified in the January 2002 bulletin, the 100mg strength of fenofibrate has been delisted from the Formulary effective July 1, 2002. However, patients who currently have Exception Drug Status for this strength will continue to be covered.

NEW DOSAGE FORMS/ STRENGTHS OF EXCEPTION DRUG STATUS AGENTS

Effective July 1, 2002 the following products will be covered under the same Exception Drug Status criteria as the currently listed forms/strengths.

- Didanosine, capsule (enteric coated beadlet), 125mg, 200mg, 250mg, 400mg (Videx EC-BMY)
- Glatiramer acetate, 20mg injection (pre-filled syringe) (Copaxone-TVM)
  - *see Appendix J of the Formulary for information on the Saskatchewan MS Drugs Program.*
- Salmeterol xinafoate/fluticasone propionate, inhaler aerosol (package) 25ug/125ug, 25ug/250ug (Advair-GSK)

FIRST ENTRY GENERIC

- Lamotrigine, tablet, 25mg, 100mg, 150mg (Apo-Lamotrigine-APX)

MODIFICATIONS TO CURRENT EXCEPTION DRUG STATUS CRITERIA

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

- **Leflunomide, tablet, 10mg, 20mg (Arava-AVT)**
  Exception Drug Status criteria has been revised to:
  For treatment of active rheumatoid arthritis in patients who have failed or are intolerant to methotrexate and at least one other DMARD (e.g. sulfasalazine, azathioprine, or hydroxychloroquine).
  Note: Leflunomide is contraindicated in patients with pre-existing impairment of liver function.

- **Etanercept, powder for injection, 25mg/vial (Enbrel-WYA)**
  Exception Drug Status criteria has been revised to:
  For treatment of patients with active rheumatoid arthritis who have failed or are intolerant to methotrexate, leflunomide, and at least one other DMARD.
  This product should be used in consultation with a specialist in this area.

- **Infliximab, injection (mg), 100mg/vial (Remicade-SCH)**
  Exception Drug Status criteria for Rheumatoid Arthritis has been revised to:
  For treatment of patients with active rheumatoid arthritis who have failed or are intolerant to methotrexate, leflunomide, and at least one other DMARD.
  Treatment should be combined with an immunosuppressant.
  This product should be used in consultation with a specialist in this area.
  Note: Remicade EDS criteria for Crohn's Disease is unchanged.

- **Linezolid, tablet, 600mg (Zyvoxam-PHU)**
  Exception Drug Status criteria has been revised to:
  Following consultation with an infectious disease specialist for:
  (a) Treatment of gram-positive infections resistant to vancomycin.
  (b) Treatment of gram-positive infections in patients unable to tolerate or who are experiencing severe adverse effects from vancomycin.
  (c) For completion of therapy initiated in hospital with intravenous vancomycin, quinupristin/dalfopristin, or linezolid for patients who can be discharged on oral therapy.

SOME OF THE PRODUCTS CURRENTLY UNDER REVIEW BY THE FORMULARY COMMITTEE

- Alendronate sodium, tablet, 70mg (Fosamax-MSD)
- Clindamycin phosphate/benzoyl peroxide, topical gel, 1%/5% (Clindoxyl-STI)
- Esomeprazole magnesium trihydrate, delayed release tablet, 20mg, 40mg (Nexium-AST)
- Glucagon (rDNA origin), injection powder, 1mg (Glucagon-LIL)
- Insulin (Regular) Aspart, injection solution (5x3ml), 100u/mL (NovoRapid-NOO)
- Nateglinide, tablet, 60mg, 120mg, 180mg (Starlix-NVR)
- Sibutramine hydrochloride monohydrate, capsule, 10mg 15mg (Meridia-ABB)
- Testosterone, gel (2.5g packet), gel (5.0g packet), 1% (Androgel-SLV)
- Tolterodine L-tartrate, extended release capsules, 2mg, 4mg (Unidet-PHU)

PRODUCT REVIEWED AND NOT RECOMMENDED FOR LISTING

- **Morphine, sustained release capsule, 10mg (Kadian-ABB)**
  It was noted there is little need for or benefit from this strength of morphine.

Fluticasone propionate, inhalation aerosol (package), 50ug, 125ug, 250ug (Flovent HFA-GSK)
Flovent HFA has been added to the Formulary and will be listed as non interchangeable with other fluticasone metered dose inhalers. Flovent HFA inhaler uses an alternative propellant called hydrofluoroalkane, which is safer for the environment. 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.

As a result of an international agreement to eliminate the use of CFC propellant in pharmaceutical products, there will be a gradual phasing out of CFC inhalers in Canada. Whenever possible, newly diagnosed patients should be started on a CFC-free product, as the currently listed CFC inhalers will eventually be delisted from the Formulary.

Saskatchewan Formulary Committee
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FORMULARY AND EDS UPDATES EFFECTIVE JULY 1, 2002

GENERIC & TRADE NAME	***STRENGTH & FORM***	***DIN***	***UNIT PRICE***	***LEGEND***
Alfuzosin HCl				
Xatral	10mg prolonged-release tablet	02245565	1.0308	
Clindamycin HCl				
Apo-Clindamycin	150mg capsule	02245232	0.5306	*I/C*
Apo-Clindamycin	300mg capsule	02245233	1.0612	*I/C*
Didanosine				
Videx EC	125mg capsule (enteric coated beadlet)	02244596	3.3635	*EDS*
Videx EC	200mg capsule (enteric coated beadlet)	02244597	5.3816	*EDS*
Videx EC	250mg capsule (enteric coated beadlet)	02244598	6.7270	*EDS*
Videx EC	400mg capsule (enteric coated beadlet)	02244599	10.7849	*EDS*
Fluticasose propionate				
Flovent HFA	50ug/inhalation aerosol (package)	02244291	23.7700	*Not I/C*
Flovent HFA	125ug/inhalation aerosol (package)	02244292	39.0600	*Not I/C*
Flovent HFA	250ug/inhalation aerosol (package)	02244293	78.1200	*Not I/C*
Formoterol fumarate dihydrate/budesonide				
Symbicort Turbuhaler	6ug/100ug powder for inhalation (package)	02245385	65.1000	*EDS*
Symbicort Turbuhaler	6ug/200ug powder for inhalation (package)	02245386	84.6300	*EDS*
Gabapentin				
Dom-Gabapentin	100mg capsule	02243743	0.3190	*I/C*
Dom-Gabapentin	300mg capsule	02243744	0.7760	*I/C*
Dom-Gabapentin	400mg capsule	02243745	0.9248	*I/C*
Glatiramer acetate				
Copaxone	20mg injection (pre-filled syringe)	02245619	37.0000	*EDS*
Glucose oxidase/peroxidase reagent				
Freestyle	strip	00950907	0.8029	*Not I/C*
Lamotrigine				
Apo-Lamotrigine	25mg tablet	02245208	0.2519	*I/C*
Apo-Lamotrigine	100mg tablet	02245209	1.0071	*I/C*
Apo-Lamotrigine	150mg tablet	02245210	1.5107	*I/C*
Metronidazole				
Rosasol	1% topical cream	02242919	0.5357	
Misoprostol				
pms-Misoprostol	200ug tablet	02244125	0.3440	*I/C*
Nefazodone				
Dom-Nefazodone	50mg tablet	02245754	0.5849	*I/C*
Dom-Nefazodone	**100mg tablet**	**02245755**	**0.4809***	***I/C***
Dom-Nefazodone	**150mg tablet**	**02245756**	**0.4809***	***I/C***
Dom-Nefazodone	**200mg tablet**	**02245757**	**0.5610***	***I/C***
pms-Nefazodone	50mg tablet	02245101	0.5570	*I/C*
pms-Nefazodone	100mg tablet	02245102	0.6076	*I/C*
pms-Nefazodone	150mg tablet	02245103	0.6076	*I/C*
pms-Nefazodone	200mg tablet	02245111	0.7089	*I/C*
Salmeterol xinafoate/fluticasone propionate				
Advair	25ug/125ug inhaler aerosol (package)	02245126	93.1000	*EDS*
Advair	25ug/250ug inhaler aerosol (package)	02245127	132.1600	*EDS*

Sertraline HCl				
Dom-Sertraline	**25mg capsule**	**02245748**	**0.4327***	***I/C***
Dom-Sertraline	**50mg capsule**	**02245749**	**0.8655***	***I/C***
Dom-Sertraline	**100mg capsule**	**02245750**	**0.9466***	***I/C***
pms-Sertraline	25mg capsule	02244838	0.5469	*I/C*
pms-Sertraline	50mg capsule	02244839	1.0937	*I/C*
pms-Sertraline	100mg capsule	02244840	1.1963	*I/C*
Warfarin				
Gen-Warfarin	1mg tablet	02244462	0.2149	*I/C*
Gen-Warfarin	2mg tablet	02244463	0.2272	*I/C*
Gen-Warfarin	2.5mg tablet	02244464	0.1819	*I/C*
Gen-Warfarin	4mg tablet	02244465	0.2817	*I/C*
Gen-Warfarin	5mg tablet	02244466	0.1823	*I/C*
Gen-Warfarin	10mg tablet	02244467	0.3271	*I/C*

LEGEND: EDS = Exception Drug Status
I/C = interchangeable
not I/C = not interchangeable
* This product is a Standing Offer Contract (SOC)

EDS UPDATE EFFECTIVE JULY 1, 2002

CRITERIA FOR NEW EXCEPTION DRUG STATUS (EDS) ADDITIONS

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

didanosine, capsule (enteric coated beadlet), 125mg, 200mg, 250mg, 400mg (Videx EC-BMY)
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.*

formoterol fumarate dihydrate/budesonide, powder for inhalation (package), 6ug/100ug, 6ug/200ug (Symbicort Turbuhaler-AST)
(a) For treatment of asthma in patients not adequately controlled on inhaled steroid therapy. *It is important that these patients also have access to a short-acting beta-2 agonist for symptomatic relief.*
(b) For treatment of chronic obstructive pulmonary disease (COPD) in patients who are not adequately controlled on a long-acting beta-2 agonist alone.

glatiramer acetate, injection (pre-filled syringe), 20mg (Copaxone-TVM)
See Appendix J of the Formulary for information on the Saskatchewan MS Drugs Program.

salmeterol xinafoate/fluticasone propionate, inhaler aerosol (package), 25ug/125ug, 25ug/250ug (Advair-GSK)
(a) for treatment of asthma in patients not adequately controlled on inhaled steroid therapy. *It is important that these patients also have access to a short-acting beta-2 agonist for symptomatic relief.*
(b) for treatment of chronic obstructive pulmonary disease (COPD) in patients who are not adequately controlled on a long-acting beta-2 agonist alone.

MODIFICATIONS TO CURRENT EXCEPTION DRUG STATUS (EDS) CRITERIA

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

etanercept, powder for injection, 25mg/vial (Enbrel-WYA)
For treatment of patients with active rheumatoid arthritis who have failed or are intolerant to methotrexate, leflunomide and at least one other DMARD. The product should be used in consultation with a specialist in this area.

infliximab, injection (mg), 100mg/vial (Remicade-SCH)
Rheumatoid Arthritis:
For treatment of patients with active rheumatoid arthritis who have failed or are intolerant to methotrexate, leflunomide and at least one other DMARD. Treatment should be combined with an immunosuppressant. The product should be used in consultation with a specialist in this area.
Note: criteria for Crohn's Disease remains unchanged.

leflunomide, tablet, 10mg, 20mg (Arava-AVT)
For treatment of active rheumatoid arthritis in patients who have failed or are intolerant to methotrexate and at least one other DMARD (e.g. sulfasalazine, azathioprine or hydroxychloroquine).
Note: leflunomide is contraindicated in patients with pre-existing impairment of liver function.

linezolid, tablet, 600mg (Zyvoxam-PHU)
Following consultation with an infectious disease specialist for:
(a) treatment of gram-positive infections resistant to vancomycin.
(b) treatment of gram-positive infections in patients unable to tolerate or who are experiencing severe adverse effects from vancomycin,
(c) for completion of therapy initiated in hospital with intravenous vancomycin, quinupristin/dalfopristin or linezolid for patients who can be discharged on oral therapy.