Saskatchewan
Ministry of
Health

Drug Plan and Extended Benefits Branch

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SASKATCHEWAN FORMULARY BULLETIN

Update to the 62nd Edition of the Saskatchewan Formulary

New Full Formulary Listing Effective January 1, 2014:

- **clindamycin phosphate/benzoyl peroxide, topical gel, 1 %/3 % (Clindoxyl ADV Gel-GSK)**

New Exception Drug Status (EDS) Listings Effective January 1, 2014:

- **certolizumab pegol, solution for injection, 200mg/ml (Cimzia-UCB)**
  For treatment of active rheumatoid arthritis in patients who have failed or are intolerant to methotrexate and leflunomide.
  Note: Exceptions can be considered in cases where methotrexate or leflunomide are contraindicated. Treatment should be combined with an immunosuppressant. This product should be used in consultation with a specialist in this area.

- **methylphenidate hydrochloride, extended release capsule, 10, 15, 20, 30, 40, 50, 60, 80mg (Biphentin-PFR)**
  For the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients:
  (a) Where the use of an alternative long-acting methylphenidate has not properly controlled the symptoms of the disease; or
  (b) Who cannot swallow tablets /capsules whole and require a long-acting ADHD medication.

Additional Formulations of current Exception Drug Status (EDS) Listing Effective January 1, 2014 according to the following criteria:

- **somatropin, solution for injection, 5mg/2mL, 20mg/2 mL (Nutropin AQ NuSpin Pen-HLR)**
  For treatment of:
  (a) Children who have growth failure due to inadequate secretion of normal endogenous growth hormone.
  (b) Children who have growth failure associated with chronic renal insufficiency.
  Note Exception Drug Status coverage is not required for S.A.I.L. patients. Coverage is provided under Saskatchewan Aids to Independent Living (S.A.I.L.) Program.

Revised Exception Drug Status Criteria:

Exception Drug Status criteria was revised to remove the exclusion regarding HIV co-infection:

- **boceprevir, capsule, 200mg (Victrelis-MRK)**
  For the treatment of chronic hepatitis C genotype 1 infection in patients with compensated liver disease, in combination with peginterferon alpha/ribavirin when all of the following criteria are met:
  a) detectable levels of hepatitis C virus (HCV) RNA in the last six months
  b) a fibrosis stage of F2, F3, or F4.
  c) one-course of treatment only (up to 44 weeks)
  Note: This product should be used in consultation with a specialist in this area.

- **boceprevir/ribavirin plus peginterferon alfa 2b,combination kit, 200mg/200mg capsule/80mcg/0.5ml powder for solution, 200mg/200mg capsule/100mcg/0.5ml powder for solution, 200mg/200mg capsule/120mcg/0.5ml powder for solution, 200mg/200mg capsule/150mcg/0.5ml powder for solution (Victrelis Triple – MRK)**
  For the treatment of chronic hepatitis C genotype 1 infection in patients with compensated liver disease, in combination with peginterferon alpha/ribavirin when all of the following criteria are met:
  a) detectable levels of hepatitis C virus (HCV) RNA in the last six months
  b) a fibrosis stage of F2, F3, or F4.
  c) one-course of treatment only (up to 44 weeks)
  Note: This product should be used in consultation with a specialist in this area.

- **telaprevir, tablet, 375mg (Incivek-VER)**
  For the treatment of chronic hepatitis C genotype 1 infection in patients with compensated liver disease, in combination with peginterferon alpha/ribavirin when all of the following criteria are met:
  a) detectable levels of hepatitis C virus (HCV) RNA in the last six months
  b) a fibrosis stage of F2, F3, or F4.
  c) one-course of treatment only (up to 12 weeks)
  Note: This product should be used in consultation with a specialist in this area.

Revised Exception Drug Status Criteria (see bold italicized portion):

- **progesterone, capsule, 100mg (Prometrium-MRK)**
  For treatment of patients:
  (a) Intolerant to medroxyprogesterone acetate (Provera).
  (b) Having low high-density lipoproteins.
  (c) For women with a singleton gestation, who are greater than 20 weeks gestation, and identified as being high-risk for pre-term birth (cervix less than 15 mm, or past history of pre-term birth).

- **calcitonin salmon, injection, 200 IU/mL (2mL) (Calcimar-AVT)**
  For treatment of:
  (a) Osteoporosis with bone pain due to crush fracture.
  (b) For symptomatic treatment of Paget's disease of the bone.
  Coverage will be provided for both indications for a maximum of three months.

- **alendronate sodium, tablet, 10mg (Apo-Alendronate-APX) (Novo-Alendronate-NOP) (Mylan-Alendronate-MYL) (Sandoz Alendronate-SDZ) (Alendronate Sodium Tablets-AHI) (Ran-Alendronate-RAN) (Auro-Alendronate-API) (Mint-Alendronate-MNT); tablet, 70mg (Fosamax-MSD) (CO Alendronate-COB) (pms-Alendronate-PMS) (Apo-Alendronate-APX) (Novo-Alendronate-NOP) (ratio-Alendronate-RPH) (Mylan-Alendronate-MYL) (pms-Alendronate-FC-PMS) (Alendronate-SAN) (Alendronate Sodium Tablets-AHI) (Ran-Alendronate-RAN) (Jamp-Alendronate-JPC) (Auro-Alendronate-API) (Mint-Alendronate-MNT)**
  (a) For the treatment of osteoporosis with a 20% or greater 10-year fracture risk.
  Note: The fracture risk can be determined by the World Health Organization's risk assessment tool, FRAX, or the most recent (2010) version of the Canadian Association of Radiologist and Osteoporosis Canada (CAROC) table.
  The links to the tools are available at:
  http://www.shef.ac.uk/FRAX/tool.jsp?country=19
  http://www.osteoporosis.ca/multimedia/pdf/CAROC.pdf
  The Drug Plan will not require FRAX or CAROC documentation to be included with EDS applications for oral bisphosphonates.
  (b) For treatment of osteogenesis imperfecta.

- **risedronate sodium, tablet, 5mg, 150mg (Actonel-WCI) (Novo-Risedronate-NOP); 35mg (Apo-Risedronate-APX) (pms-Risedronate-PMS) (ratio-Risedronate-RPH) (Sandoz Risedronate-SDZ) (Mylan-Risedronate-MYL) (Risedronate-SAN) (Jamp-Risedronate-JPC) (Auro-Risedronate-API) (Risedronate-35-SIV); delayed release tablet, 35mg (Actonel DR-WCI)**
  (a) For the treatment of osteoporosis with a 20% or greater 10-year fracture risk.
  Note: The fracture risk can be determined by the World Health Organization's fracture risk assessment tool, FRAX, or the most recent (2010) version of the Canadian Association of Radiologist and Osteoporosis Canada (CAROC) table. The links to the tools are available at:
  http://www.shef.ac.uk/FRAX/tool.jsp?country=19
  http://www.osteoporosis.ca/multimedia/pdf/CAROC.pdf
  The Drug Plan will not require FRAX or CAROC documentation to be included with EDS applications for oral bisphosphonates.
  (b) For treatment of osteogenesis imperfecta.

HIV Post-Exposure Prophylaxis Regimens

Human immunodeficiency virus (HIV) post-exposure prophylaxis (PEP) starter kits are provided by the Saskatchewan Ministry of Health and located in a variety of health care facilities throughout Saskatchewan. The starter kits contain 3 to 5 days of treatment. Patients may then be prescribed a further course of HIV PEP medications upon consultation with an Infectious Disease (ID) specialist. Alternate regimens for the remainder treatment have been approved effective January 1, 2014.

Information regarding HIV PEP treatment is now available on the Formulary website at:
http://formulary.drugplan.health.gov.sk.ca/FormularyAppxIndOther.aspx

Exception Drug Status criteria for the following products was revised to include HIV PEP criteria, ***(see bold italicized portion):***

- **lamivudine/zidovudine, tablet, 150mg/300mg (Combivir-VII)**
  a) For 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.*
  b) When prescribed by, or on the advice of an Infectious Disease specialist familiar with HIV treatment for post-exposure prophylaxis (PEP). Please refer to the HIV PEP Treatment document on the Formulary website.

- **lopinavir/ritonavir, tablet, 200mg/50mg (Kaletra-ABB)**
  a) For 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.*
  b) When prescribed by, or on the advice of an Infectious Disease specialist familiar with HIV treatment for post-exposure prophylaxis (PEP). Please refer to the HIV PEP Treatment document on the Formulary website.

- **darunavir, tablet, 800mg (Prezista-JAN)**
  a) For 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.*
  b) When prescribed by, or on the advice of an Infectious Disease specialist familiar with HIV treatment for post-exposure prophylaxis (PEP). Please refer to the HIV PEP Treatment document on the Formulary website.

- **ritonavir, tablet, 100mg (Norvir-ABB)**
  a) 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.*
  b) When prescribed by, or on the advice of an Infectious Disease specialist familiar with HIV treatment for post-exposure prophylaxis (PEP). Please refer to the HIV PEP Treatment document on the Formulary website.

- **emtricitabine/tenofovir disoproxil fumarate, tablet, 200mg/300mg (Truvada-GSI)**
  a) For treatment of HIV patients where:
  i. The virus is susceptible to tenofovir and emtricitabine, **AND**
  ii. Efavirenz is not indicated due to adverse effects or antiretroviral resistance.
  This drug as with other antivirals in the treatment of HIV, should be used under the direction of an infectious disease specialist.
  b) When prescribed by, or on the advice of an Infectious Disease specialist familiar with HIV treatment for post-exposure prophylaxis (PEP). Please refer to the HIV PEP Treatment document on the Formulary website.

- **raltegravir, tablet, 400mg (Isentress-MSD)**
  a) For the treatment of HIV-1 infection in treatment-experienced patients who have evidence of viral replication and HIV-1 strains resistant to three classes of HIV agents. *This drug, as with other antivirals in the treatment of HIV, should be used under the direction of an infectious disease specialist.*
  b) When prescribed by, or on the advice of an Infectious Disease specialist familiar with HIV treatment for post-exposure prophylaxis (PEP). Please refer to the HIV PEP Treatment document on the Formulary website.

- **atazanavir SO4, capsule, 300mg (Reyataz-BMY)**
  a) For 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.*
  b) When prescribed by, or on the advice of an Infectious Disease specialist familiar with HIV treatment for post-exposure prophylaxis (PEP). Please refer to the HIV PEP Treatment document on the Formulary website.

Drugs Reviewed and Not Approved for Listing in the Saskatchewan Formulary:

- **azilsartan, tablet, 40mg, 80mg (Edarbi-TAK)**
- **azilsartan medoxomil/chlorthalidone, tablet, 40/12.5mg, 80/12.5mg, 40/25mg (Edarbyclor – TAK)**
- **collagenase clostridium histolyticum, powder for injection, 0.9mg/vial (Xiaflex-ACT)**
- **grass pollen allergen extract, sublingual tablet, 100IR, 300IR (Oralair-PAL)**
- **interferon beta-1a, pre-filled syringe, 44ug/0.5ml (Rebif-SRO)** for clinically isolated syndrome (CIS)
- **zolpidem tartrate, tablet, 5mg, 10mg (Sublinox-MVC)**

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