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

Product	DIN	Pre-Markup ($)

New Exception Drug Status (EDS) Listings Effective January 1, 2013:

Saphris (asenapine) (LUD)		
5mg sublingual tablet	02374803	1.4300
10mg sublingual tablet	02374811	1.4300

(a) For the treatment of patients with bipolar disorder in combination with lithium or divalproex after trials of less expensive atypical antipsychotic agents (i.e. risperidone and quetiapine) have failed due to intolerance or lack of response.
(b) For the treatment of bipolar disorder as monotherapy for patients who have failed lithium or divalproex **AND** have failed trials of less expensive atypical antipsychotic agents (i.e. risperidone and quetiapine) due to intolerance or lack of response.

Toviaz (fesoterodine fumarate) (PFI)		
4mg extended release tablet	02380021	1.5000
8mg extended release tablet	02380048	1.5000

For treatment of patients intolerant to oxybutynin chloride.

Revised Exception Drug Status (EDS) Criteria Effective November 1, 2012:

- **ticagrelor, tablet, 90mg (Brilinta-AST)**

Inclusion:
To be taken in combination with ASA 75mg to 150mg daily[a] for patients with acute coronary syndrome (i.e., ST elevation myocardial infarction [STEMI], non-ST elevation myocardial infarction [NSTEMI], or unstable angina [UA]) with ONE of the following:

1. Failure on optimal clopidogrel and ASA therapy as defined by definite stent thrombosis,[b] **or** recurrent STEMI, **or** NSTEMI **or** UA after prior revascularization via percutaneous coronary intervention (PCI).
OR
2. STEMI and undergoing revascularization via PCI.
OR
3. NSTEMI or UA and high risk angiographic anatomy[c] and undergoing revascularization via PCI.

Notes:
(a) Co-administration of ticagrelor with high maintenance dose ASA (>150mg daily) is not recommended.

(b) Definite stent thrombosis, according to the American Research Consortium, is a total occlusion originating in or within 5mm of the stent, **or** is a visible thrombus within the stent, **or** is within 5mm of the stent in the presence of an acute ischemic clinical syndrome within 48 hours. Definite stent thrombosis must be confirmed by angiography or by pathologic confirmation of acute thrombosis.

(c) High risk angiographic anatomy is defined as any of the following: left main stenting, high risk bifurcation stenting (i.e., two-stent techniques), long stents ≥ 38mm or overlapping stents, small stents ≤ 2.5mm in patients with diabetes.

(d) Ticagrelor is contraindicated in patients with active pathological bleeding, in those with a history of intracranial hemorrhage and moderate to severe hepatic impairment.

Requests for patients with a clearly demonstrated allergy or intolerance to ASA may be considered. (Allergy will be as manifested by asthma or nasal polyps. Intolerance will be as manifested by gastrointestinal hemorrhage.)

Requests meeting the above inclusion criteria will be eligible for an approval period of 12 months.

Revised Exception Drug Status Criteria (see italicized portion) Effective January 1, 2013:

- **rituximab, injection solution, 10mg/ml (Rituxan-HLR)**
  (a) For treatment of severe rheumatoid arthritis when used in combination with methotrexate in adult patients who have failed to respond to an adequate trial of an anti-TNF agent. Rituxan should not be used concomitantly with anti-TNF agents.
  (b) For induction of remission in patients with severely active granulomatosis with polyangiitis (GPA), also known as Wegener's Granulomatosis, or microscopic polyangiitis (MPA) who have a severe intolerance or other contraindication to cyclophosphamide, or who have failed an adequate trial of cyclophosphamide.

- **tocilizumab, concentrate solution for infusion, 80mg in 4ml, 200mg in 10ml, 400mg in 20ml, (20mg /ml) (Actemra-HLR)**
  (a) For treatment of moderate to severe active rheumatoid arthritis, in combination with methotrexate or other disease-modifying antirheumatic drugs (DMARDS), who have failed to respond to an adequate trial of both DMARDs and a tumour necrosis factor (TNF) alpha inhibitor.
  Patients should be assessed after 16 weeks of treatment and therapy continued only if there is a clinical response to treatment.
  Actemra should not be used concomitantly with TNF alpha inhibitors.
  This product should be used in consultation with a specialist in this area.
  (b) For the treatment of active systemic juvenile idiopathic arthritis (sJIA) in patients two years of age and older who have responded inadequately to non-steroidal anti-inflammatory drugs (NSAIDs) and systemic corticosteroids (with or without methotrexate), due to intolerance or lack of efficacy.
  Actemra should not be used concomitantly with TNF alpha inhibitors. This product should be used in consultation with a specialist in this area.

Additional Formulations of current Exception Drug Status (EDS) Listings Effective January 1, 2013:

- **dalteparin sodium, solution for injection, 2,500 IU (anti-factor Xa)/mL (Fragmin-PFI)**
  (a) For treatment of venous thromboembolism for up to 10 days.
  (b) For prophylaxis following total knee arthroplasty for up to 35 days.
  (c) For major orthopedic trauma for up to10 days (treatment duration may be reassessed).
  (d) For long-term outpatient prophylaxis in patients who are pregnant.
  (e) For long-term outpatient prophylaxis in patients who have a contraindication to, are intolerant to, or have failed, warfarin therapy.
  (f) For long-term outpatient prophylaxis in patients who have lupus anticoagulant syndrome.
  (g) Prophylaxis in patients undergoing total hip replacement or following hip fracture surgery for up to 35 days following the procedure.

- **darunavir, tablet, 150 mg (Prezista-JAN)**
  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.

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

- **Byetta, injection, 250ug/ml (exenatide) (LIL)**
- **Resotran, tablet, 1mg, 2mg (prucalopride succinate) (JAN)**
- **Saphris, sublingual tablet, 5mg, 10mg (asenapine) (LUD) – for schizophrenia**

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