Government of Saskatchewan

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SASKATCHEWAN FORMULARY BULLETIN

Update to the 62nd Edition of the Saskatchewan Formulary

New Exception Drug Status (EDS) Listings Effective April 1, 2015 according to the following criteria:

- **vilanterol trifenatate/fluticasone furoate, powder for inhalation, 25mcg/100mcg (Breo Ellipta-GSK)**

  For treatment of COPD in patients where there has been concurrent or past use of a long-acting muscarinic receptor antagonist (LAMA) or a long-acting beta-2 agonist (LABA).

Additional Formulations of a Current Exception Drug Status (EDS) Listing effective April 1, 2015 according to the following criteria:

- **abatacept, pre-filled syringe, 125mg/ml (Orencia-BMY)**

  For the treatment of active rheumatoid arthritis in patients who have failed or are intolerant to methotrexate and leflunomide.
  Note: This drug should NOT be used in combination with anti-TNF agents.

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

- **buprenorphine/naloxone, sublingual tablet, 2mg/0.5mg, 8mg/2mg (Suboxone-SCH)**

  For treatment of opioid dependency in patients for whom methadone is contraindicated, (e.g. patients at high risk of, or with QT prolongation, or hypersensitivity to methadone).
  OR
  For treatment of opioid dependence when methadone is not accessible, or when methadone is not appropriate.

- **rivaroxaban, tablet, 15 mg, 20 mg (Xarelto-BAY)**

  a) At-risk patients with non-valvular atrial fibrillation who require rivaroxaban for the prevention of stroke and systemic embolism **AND** in whom:
     - Anticoagulation is inadequate following a reasonable trial on warfarin;

     OR
     - Anticoagulation with warfarin is contraindicated or not possible due to inability to regularly monitor via International Normalized Ratio (INR) testing (i.e. no access to INR testing services at a laboratory, clinic, pharmacy, and at home).

Exclusion Criteria:
Patients with impaired renal function (creatinine clearance or estimated glomerular filtration rate <30 mL/min) **OR** ≥ 75 years of age and **without** documented stable renal function **OR** hemodynamically significant rheumatic valvular heart disease, especially mitral stenosis; **OR** prosthetic heart valves.

Notes:
(i) Documented stable renal function is defined as creatinine clearance or estimated glomerular filtration rate of 30-49 mL/min for 15 mg once daily dosing or ≥ 50 mL/min for 20 mg once daily dosing that is maintained for at least 3 months.
(ii) At-risk patients with atrial fibrillation are defined as those with a CHADS2 score of ≥ 1. Although the ROCKET-AF trial included patients with higher CHADS2 scores (≥ 2), other landmark studies with the other newer oral anticoagulants demonstrated a therapeutic benefit in patients with a CHADS2 score of 1. Prescribers may consider an antiplatelet regimen or oral anticoagulation for patients with a CHADS2 score of 1.
(iii) Inadequate anticoagulation is defined as INR testing results that are outside the desired INR range for at least 35% of the tests during the monitoring period(i.e. adequate anticoagulation is defined as INR test results that are within the desired INR range for at least 65% of the tests during the monitoring period).
(iv) A reasonable trial on warfarin is defined as at least 2 months of therapy.
(v) Since renal impairment can increase bleeding risk, renal function should be regularly monitored. Other factors that increase bleeding risk should also be assessed and monitored (see rivaroxaban product monograph).
(vi) Patients starting rivaroxaban should have ready access to appropriate medical services to manage a major bleeding event.
(vii) There is currently no data to support that rivaroxaban provides adequate anticoagulation in patients with rheumatic valvular disease or those with prosthetic heart valves, so rivaroxaban is not recommended in these populations.

(b) Treatment of deep vein thrombosis (DVT) ***or pulmonary embolism (PE).***

Approval Period: Up to six (6) months

Notes:
(i) The recommended dose of rivaroxaban for patients initiating DVT or ***PE treatment*** is 15 mg twice daily for 3 weeks, followed by 20 mg once daily.
(ii) Drug plan coverage for rivaroxaban is an alternative to heparin/warfarin for up to 6 months. When used for greater than 6 months, rivaroxaban is more costly than heparin/warfarin. As such, patients with an intended duration of therapy greater than 6 months should be considered for initiation on heparin/warfarin.
(iii) Since renal impairment can increase bleeding risk, it is important to monitor renal function regularly. Other factors that increase bleeding risks should also be assessed and monitored (see product monograph).

Revised Exception Drug Status Criteria:

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

For treatment of Acute Coronary Syndrome (ACS), defined as unstable angina or myocardial infarction when initiated in hospital and prescribed by a specialist in cardiology, cardiac surgery, or other physician with experience managing ACS as identified by the Drug Plan.

Treatment must be in combination with low dose ASA.

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

- **algoliptin benzoate, tablet, 6.25mg, 12.5mg, 25mg (Nesina-TAK)**
- **algoliptin benzoate/metformin HCL, tablet, 12.5/500 mg, 12.5/850 mg, 12.5/1000 mg (Kazano-TAK)**
- **ethinyl estradiol/norethindrone acetate, 10mcg/ 1mg tablet (LoLo-WCI)**
- **vitamin D3, 10,000 IU tablet (Vidextra- ORI)**

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