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Drug Plan and Extended Benefits Branch

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# SASKATCHEWAN FORMULARY BULLETIN

## Update to the 62nd Edition of the Saskatchewan Formulary

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

- **apixaban tablet, 2.5 mg, 5 mg (Eliquis - BMY)**

  For at-risk patients with non-valvular atrial fibrillation, for the prevention of stroke and systemic embolism **AND** in whom:

  a) Anticoagulation is inadequate following at least a 2-month trial of warfarin;
  **OR**
  b) Anticoagulation using warfarin is contraindicated or not possible due to inability to regularly monitor the patient via International Normalized Ratio (INR) testing (i.e. no access to INR testing services at a laboratory, clinic, pharmacy, and at home).

  **Exclusion:**

  a) Patients with impaired renal function (creatinine clearance or estimated glomerular filtration rate < 25 mL/min) **OR**
  b) Patients who are ≥75 years of age and who **do not** have documented stable renal function **OR**
  c) Patients who have hemodynamically significant rheumatic valvular heart disease (especially mitral stenosis) **OR**
  d) Patients who have prosthetic heart valves.

  **Notes:**

  a) At-risk patients with atrial fibrillation are defined as those with a $CHADS_2$ score of ≥1. Prescribers may consider an antiplatelet regimen or oral anticoagulation for patients with a $CHADS_2$ score of 1.
  b) 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).
  c) Documented stable renal function is defined as creatinine clearance or estimated glomerular filtration rate maintained for at least 3 months.
  d) Dosing: the usual recommended dose is 5 mg twice daily; a reduced dose of apixaban 2.5 mg twice daily is recommended for patients with at least two [2] of the following: age ≥80 years, body weight ≤60 kg, or serum creatinine ≥133 micromole/litre.
  e) 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 apixaban product monograph).
  f) Patients starting apixaban should have ready access to appropriate medical services to manage a bleeding event.
  g) There is currently no data to support that apixaban provides adequate anticoagulation in patients with rheumatic valvular disease or those with prosthetic heart valves. As a result, apixaban is not recommended for these patient populations.

- **eltrombopag olamine tablet, 25mg, 50mg (Revolade-GSK)**

  For the treatment of refractory chronic idiopathic thrombocytopenic purpura ("ITP") with bleeding complications in patients who meet the following conditions:

  a) have undergone a splenectomy[1]; and
  b) have tried and are unresponsive to other treatment modalities[2].

  Dosage: 50 mg once daily to a maximum of 75 mg once daily.
  Renewal of requests for Revolade will be assessed on a case-by-case basis.

  Note: After 1 year of continuous treatment, therapeutic options should be reassessed.

  1. Where surgery is contraindicated, the requesting physician must provide a rationale for why a splenectomy cannot be considered, and where possible, include both a preoperative/surgical evaluation of the patient's risks and a consideration of risks of laparoscopic and open surgical interventions if these are available. The requesting physician's rationale must be evaluated by an independent physician.

  2. Patients must be refractory to two of the following first line treatment modalities:
  • Corticosteroids
  • IV anti-D
  • Intravenous immune globulin (IVIG)

  In addition, patients must be refractory to two of the following second-line treatment modalities:
  • Azathioprine
  • Cyclosporine
  • Cyclophosphamide
  • Mycophenolate
  • Rituximab
  • Danazol
  • Dapsone

- **elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil fumarate tablet, 150mg/150mg/200mg/300mg (Stribild – GSI)**

  As a complete regimen for antiretroviral treatment-naïve HIV-1 infected patients in whom efavirenz is not indicated.

***Revised Exception Drug Status Criteria:***

- **prasugrel tablet, 10mg (Effient – LIL)**

  In combination with ASA for patients with:

  a) ST-elevated myocardial infarction (STEMI) undergoing primary percutaneous coronary intervention (PCI) who have not received antiplatelet therapy prior to arrival in the catheterization lab. Treatment must be initiated in hospital.

  **OR**

  b) Acute coronary syndrome who failed on optimal clopidogrel and ASA therapy as defined by definite stent thrombosis[a], or recurrent STEMI, or non-ST elevation myocardial infarction (NSTEMI) or unstable angina (UA) after prior revascularization via PCI.

  Approval: Up to 12 months

  **Notes:**

  a) Definite stent thrombosis, according to the Academic Research Consortium, is a total occlusion originating in or within 5 mm of the stent or is a visible thrombus within the stent or is within 5 mm 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 evidence of acute thrombosis.

b) As per the product monograph, prasugrel is contraindicated in patients with a known history of transient ischemic attack or stroke; those with active pathological bleeding such as peptic ulcer or intracranial hemorrhage; and those with severe hepatic impairment (Child-Pugh Class C).

c) As per the product monograph, prasugrel is not recommended in patients > than 75 years of age because of the increase risk of fatal and intracranial bleeding; or those with body weight < 60 kg because of increased risk of major bleeding due to an increase in exposure to the active metabolite of prasugrel.

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