Government of Saskatchewan

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SASKATCHEWAN FORMULARY BULLETIN

Update to the 62nd Edition of the Saskatchewan Formulary

Change from an Exception Drug Status (EDS) Benefit to a Full Formulary Benefit:

- buprenorphine/naloxone, sublingual tablet, 2mg/0.5mg, 8mg/2mg (Suboxone-ICL) (and listed generics)
- tiotropium bromide monohydrate, inhalation solution, 2.5ug (Spiriva Respimat-BOE); powder capsule, 18ug/dose (Spiriva-BOE)

Exception Drug Status benefit according to the following criteria:

- **enoxaparin**

  Effective August 1, 2021, new patients (i.e., patients without current EDS approval for Lovenox) will only be eligible for one of the listed biosimilar formulations of enoxaparin:

  - **enoxaparin, solution for injection (pre-filled syringe), 30mg/0.3mL, 40mg/0.4mL, 60mg/0.6mL, 80mg/0.8mL, 100mg/mL (Inclunox-SDZ); 120mg/0.8mL, 150mg/1mL (Inclunox HP-SDZ)**
  - **enoxaparin, solution for injection (pre-filled syringe), 20mg/0.2mL, 30mg/0.3mL, 40mg/0.4mL, 60mg/0.6mL, 80mg/0.8mL, 100mg/mL (Noromby-JNO); 120mg/0.8mL, 150mg/mL (Noromby HP-JNO)**
  - **enoxaparin sodium, solution for injection (pre-filled syringe), 30mg/0.3mL, 40mg/0.4mL, 60mg/0.6mL, 80mg/0.8mL, 100mg/mL (Redesca-VAL); solution for injection (multiple dose vial), 300mg/3mL; solution for injection (pre-filled syringe), 120mg/0.8mL, 150mg/mL (Redesca HP-VAL)**

  Note: These products are not interchangeable. When requesting coverage, please state which specific enoxaparin product is being prescribed to avoid administrative and assessment processing delays.
  (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 to 10 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) For treatment of pediatric patients where anticoagulant therapy is required and warfarin therapy cannot be administered.
(h) Prophylaxis in patients undergoing total hip replacement or following hip fracture surgery for up to 35 days following the procedure.
(i) For prophylaxis following abdominal or pelvic surgery for up to 28 days.

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- **prasugrel, tablet, 10mg (Jamp Prasugrel-JPC)**

  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 therapy with ASA and either clopidogrel or ticagrelor, as defined by definite stent thrombosis, 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.

Additional Exception Drug Status criteria (changes are indicated in bold):

- **methadone HCl, tablet, 1mg, 5mg, 10mg, 25mg; oral suspension, 1mg/mL, 10mg/mL (Metadol-PAL)**

  a) Coverage for Drug Plan registered palliative care patients. An Exception Drug Status request is not required for these patients.
  b) For management of moderate to severe chronic pain in non-palliative patients, under the care of a chronic pain specialist (or where it is prescribed in consultation with a chronic pain specialist), when the patient has at least one of the following:

  - **Moderate to severe renal impairment; or**
  - **Has failed or is intolerant to other opioid therapies.**

Revised Exception Drug Status criteria:

- **enoxaparin, prefilled syringe, 30mg/0.3mL, 40mg/0.4mLmL, 60mg/0.6mL, 80mg/0.8mL, 100mg/mL (Lovenox-AVT); injection solution, 120mg/0.8mL, 150mg/mL (Lovenox HP-AVT)**

  Note: Effective August 1, 2021, new patients (i.e., patients without current approval for Lovenox) will only be eligible for a listed biosimilar formulation of enoxaparin.

  (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 to 10 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) For treatment of pediatric patients where anticoagulant therapy is required and warfarin therapy cannot be administered.
  (h) Prophylaxis in patients undergoing total hip replacement or following hip fracture surgery for up to 35 days following the procedure.
  (i) For prophylaxis following abdominal or pelvic surgery for up to 28 days.

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Additional Formulation of an Existing Exception Drug Status benefit with the same criteria:

- **adalimumab, prefilled syringe, 40mg/0.8mL (Idacio-FCL)**

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