Government of Saskatchewan

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SASKATCHEWAN FORMULARY BULLETIN

Update to the 62nd Edition of the Saskatchewan Formulary

Recommended as a Full Formulary benefit:

- **lipase/amylase/protease, granules, 5,000U/5,100U/320U (Creon Minimicrospheres Micro-BGP)**

Recommended as Exception Drug Status benefit according to the following criteria:

- **deferiprone, tablets, 1000 mg, solution, 100 mg/mL (Ferriprox-APP)**

  For treatment of chronic iron overload in patients with transfusion dependent anemias.

  Note: Should not be used in combination with deferasirox, tablet for oral suspension, 125mg, 250mg, 500mg (Exjade-NVR).

- **omalizumab, sterile powder for reconstitution, 150 mg vial (Xolair – NVR)**

  For the treatment of adults and adolescents (12 years of age or older) with moderate to severe chronic idiopathic urticaria (CIU) who remain symptomatic (presence of hives and/or associated itching) despite optimal management with H1 antihistamines.

  Notes:
  - Document the baseline urticaria activity score over seven days (UAS7) on the initial request.
  - Prescribed by a specialist (allergist, immunologist, dermatologist, etc.) or other authorized prescriber with knowledge of CIU treatment.
  - Initial approval will be granted for a period of 24 weeks at a maximum dose of 300mg every 4 weeks.
  - Treatment cessation could be considered for patients who experience complete symptom control for at least 12 consecutive weeks at the end of a 24 week treatment period.

  Extension requests:
  - Continued coverage may be authorized if the patient has achieved:
    - complete symptom control for less than 12 consecutive weeks; or
    - partial response to treatment, defined as at least a ≥ 9.5 point reduction in baseline urticaria activity score over 7 days (UAS7)

Re-initiation requests:

- In patients where treatment is discontinued due to temporary symptom control, treatment re-initiation may be considered should CIU symptoms reappear.

- **dapagliflozin, tablet, 5mg, 10mg (Forxiga-AST)**

  For treatment of patients with Type 2 diabetes who have concurrent prescriptions for metformin and a sulfonylurea.

  This product should not be used in combination with dipeptidyl peptidase-4 inhibitors.

  Please note: This product should be used in patients with diabetes who are not adequately controlled on or are intolerant to metformin and/or a sulfonylurea, and for whom insulin is not an option.

Recommended expansion of a non-interchangable Exception Drug Status listing to include the following:

- **infliximab, powder for solution, 100mg/vial (Inflectra-HOS) – in addition to the existing criteria for rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis and plaque psoriasis**

  Crohn's Disease:
  (a) *Moderate to severe Crohn's Disease*:
  • For treatment of patients who demonstrate continuing symptoms despite the use of optimal conventional therapies, such as 5-ASA agents, glucocorticoids and immunosuppressive therapy.
  • For treatment of patients who are intolerant to conventional therapy, including 5-ASA agents, glucocorticoids and immunosuppressive therapy.
  (b) Fistulizing Crohn's Disease:
  • For treatment of patients with symptomatic enterocutaneous or perineal fistulae, enterovaginal fistulae or enterovesical fistulae (i.e. any type of fistulizing Crohn's Disease).

  Clinical response should be assessed after the induction dose. Ongoing coverage will only be provided for those who respond to treatment.
  Patients undergoing this treatment should be reviewed every six months by a specialist in this area.

  Ulcerative colitis:
  • For treatment of ulcerative colitis in patients unresponsive to high dose intravenous steroids.

  Clinical response should be assessed after the three-dose induction phase before proceeding to maintenance therapy. Ongoing coverage will only be provided for those who respond to therapy.

Patients undergoing this treatment should be reviewed every six months by a specialist in this area.

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

- **rituximab, injection solution, 10mg/mL (Rituxan-HLR) – in addition to the rheumatoid arthritis and granulomatosis/polyangiitis criteria**

  For treatment of antibody-mediated rejection in kidney, lung, heart or liver transplant patients.

- **clopidogrel bisulfate, tablet, 75mg (Plavix-BMY, and listed generics)**
  (a) For treatment of patients who have experienced a transient ischemic attack, stroke, or a myocardial infarction while on acetylsalicylic acid.
  (b) For treatment of patients who have experienced a transient ischemic attack, stroke, or who have had a myocardial infarction and have a clearly demonstrated allergy to acetylsalicylic acid (manifested by asthma or nasal polyps).
  (c) For treatment of patients who have experienced a transient ischemic attack, stroke, or a myocardial infarction and are intolerant to acetylsalicylic acid (manifested by gastrointestinal hemorrhage).
  (d) When prescribed following intracoronary stent placement. *Coverage will be provided for a period of 1 year. In patients intolerant or allergic to ASA coverage may be renewed.*
  (e) For reduction of atherothrombotic events in patients with acute coronary syndrome (i.e. unstable angina or non-Q-wave myocardial infarction without ST segment elevation) concurrently with acetylsalicylic acid. Coverage will also be considered for patients intolerant or allergic to acetylsalicylic acid.
  Coverage will be provided for a period of 1 year.
  In patients intolerant or allergic to ASA coverage may be renewed.

(f)

EDS criteria for this indication has been revised. Please refer to Appendix A.

(g) For treatment of peripheral arterial disease in patients intolerant/allergic to ASA.

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

- **deferasirox, tablet for oral suspension, 125mg, 250mg, 500mg (Exjade-NVR)**

  For treatment of chronic iron overload in patients with transfusion dependent anemias who have a contraindication to the injectable deferoxamine.

  Note: Should not be used in combination with deferiprone, tablets, 1000 mg, solution, 100 mg/mL (Ferriprox-APP).

- **buprenorphine/naloxone, sublingual tablet, 2mg/0.5mg, 8mg/2mg (Suboxone-RBI, and listed generics)**

  For treatment of opioid addiction when prescribed by a designated Suboxone (buprenorphine/naloxone) prescriber as determined by the Saskatchewan College of Physicians and Surgeons.

Recommended for inclusion on the Hospital Benefit Drug List:

- **sugammadex sodium, solution for injection 100mg/mL (Bridion-MRK)**

  Restricted Coverage: For use as a second line agent for the reversal of neuromuscular blockade induced by rocuronium or vecuronium in adults undergoing surgery by open and/or laparoscopic abdominal procedures.

- **ceftolozane sulfate/tazobactam sodium, powder for injection, 1g/0.5g (1.5g/vial) (Zerbaxa – MRK)**

  Restricted Coverage: For treatment of severe infections on the recommendation of an infectious disease specialist.

The following product was NOT RECOMMENDED for Formulary Listing:

- **ivermectin, 1% w/w cream (Rosevir-GAC)**

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