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:

- **adapalene/benzoyl peroxide, topical gel, 0.3%/2.5% (TactuPump Forte-GAC)**
- **tranexamic acid, tablet, 500mg (Cyklokapron-PFI and generics)**

Recommended as a change from Exception Drug Status (EDS) benefit to full Formulary benefit:

- **fosfomycin tromethamine, oral powder, 3g/sachet (Monurol-PAL)**

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

- **acamprosate calcium, delayed release tablet, 333mg (Campral-MYL)**

  For alcohol use disorder in patients who have been abstinent from alcohol for at least four days and when the medication is being used as a component of an alcohol counselling program. Coverage will be reviewed every six months.

- **naltrexone, tablet, 50mg (Revia-TEV and generic)**

  For alcohol use disorder when used as a component of an alcohol counselling program. Coverage will be reviewed every six months.

- **filgrastim, sterile solution for injection, 300mcg/0.5mL, 480mcg/0.8mL (Grastofil-APX)**

  For patients requiring filgrastim for the treatment of:

  (a) Congenital, cyclic or idiopathic neutropenia in patients with absolute neutrophil counts of less than or equal to 500.
  (b) Non-cancer patients who have undergone bone marrow transplantation.
  (c) HIV patients with absolute neutrophil counts of less than 500.

  Effective July 1, 2017, all EDS requests for filgrastim will be assessed for coverage with Grastofil and the Drug Plan will only cover Grastofil brand for patients seeking EDS approval for filgrastim for the indications above. The Saskatchewan Drug Plan will cover Grastofil and Neupogen for patients who were granted EDS approval for Neupogen before July 1, 2017 until that EDS coverage expires.

- **riluzole, tablet, 50mg (Rilutek-AVT and generics)**

  For the treatment of amyotrophic lateral sclerosis (ALS) when initiated by a neurologist with expertise in the management of ALS, when the patient has:
  - Probable or definite diagnosis of ALS;
  - ALS symptoms for less than five years;
  - FVC > 60% predicted upon initiation of therapy; and
  - No tracheostomy for invasive ventilation.

  Coverage will be reviewed every six months.
  Coverage cannot be renewed once the patient has a tracheostomy for the purpose of invasive ventilation or mechanical ventilation.

- **deferasirox, film-coated tablet, 90mg, 180mg, 360mg (Jadenu-NVR)**

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

- **dapagliflozin and metformin HCl, tablet, 5mg/850mg, 5mg/1000mg (Xigduo-AZT)**

  For the convenience of patients who have been stabilized on metformin and dapagliflozin. 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 combination therapy of metformin and a sulfonylurea, and for whom insulin is not an option.

- **elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide, 150mg/150mg/200mg/10mg, combination tablets (Genvoya – GSI)**

  For the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults and pediatric patients 12 years of age and older (and weighing ≥ 35kg) with no known mutations associated with resistance to the individual components.

  This drug as with other antivirals in the treatment of HIV, should be used under the direction of an infectious disease specialist.

Recommended Additional Exception Drug Status criteria:

- **adalimumab, pre-filled syringe, 40mg/0.8mL (Humira-ABV); pre-filled pen, 40mg/0.8mL (Humira Pen-ABV)**

  For treatment of ulcerative colitis in patients unresponsive to high dose intravenous steroids.
  Note: Clinical response should be assessed after three months of 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.

- **vedolizumab, solution for infusion, 300mg/vial (Entyvio-TAK)**

  For the treatment of moderate to severely active Crohn's Disease (CD) patients who demonstrate continuing symptoms despite the use of optimal conventional therapies, such as glucocorticoids and immunosuppressive therapy, or are intolerant to glucocorticoids and immunosuppressive therapy.

  Note: Clinical response should be assessed after the three dose induction phase. 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 Revised Exception Drug Status criteria:

- **aflibercept, injection, 40mg (Eylea-BAY)**

  For the treatment of visual impairment due to clinically significant macular edema secondary to **branch retinal vein occlusion (BRVO)** or central retinal vein occlusion (CRVO) for patients meeting all of the following:

  (i) Diffuse RVO with macular thickness of 300 microns or greater on Optical Coherence Tomography (OCT) and a vision of 20/40 or less.
  (ii) The interval between two doses should not be shorter than one month.
  (iii) Patients should be monitored at regular intervals up to monthly for retinal thickness and visual acuity.
  (iv) Treatment should be discontinued if there is no improvement after 6 months of initial treatment; and
  (v) Injections will be by a qualified ophthalmologist with experience in administering intravitreal injections.

  Note:
  - Fluorescein Angiography (FA) should be considered prior to initiation of treatment to assess perfusion and characterize the leakage, and should also be considered if the patient is not responding to treatment as expected.

- **adalimumab, pre-filled syringe, 40mg/0.8mL (Humira-ABV), pre-filled pen, 40mg/0.8mL (Humira Pen-ABV)**
  etanercept, powder for injection (vial), 25mg/vial; pre-filled syringe, 50mg/mL (Enbrel-AMG)
  golimumab, 50mg/mL, pre-filled syringe; autoinjector (Simponi-JAN)
  infliximab, powder for solution, 100mg/vial (Inflectra-HOS)
  infliximab, injection (mg), 100mg/vial (Remicade-JAN)

  This revision is to update the Notes section of the ankylosing spondylitis (AS) criteria to allow for one switch to another anti-TNF biologic agent.

  For treatment of ankylosing spondylitis (AS) according to the following criteria:

  Initial Application (for a 12-week medication trial):

- For patients who have already been treated conventionally with two or more non-steroidal anti-inflammatory drugs (NSAIDs) taken sequentially at maximum tolerated or recommended doses for four weeks without symptom control; **AND**
- Satisfy New York diagnostic criteria: a score ≥ 4 on the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) AND a score of ≥ 4 cm on the 0-10cm spinal pain visual analogue scale (VAS) on two occasions at least 12 weeks apart without any change of treatment.

Second Application (following the initial 12-week approval, requests will be considered for a one-year approval timeframe):

- Adequate response to treatment assessed at 12 weeks defined as at least 50% reduction in pre-treatment baseline BASDAI score by ≥ 2 units AND a reduction of ≥ 2cm in the spinal pain VAS.

Subsequent Annual Renewal Applications (beyond the first 15 months, requests are to be submitted annually for consideration of ongoing approval on a yearly basis):

- The BASDAI score does not worsen (i.e. remains within two units of the second assessment) AND remains at least two units less than the initial application's BASDAI score.

Notes:

- Requests for coverage for this indication must be made by a rheumatologist.
- Applications for this indication must be submitted on the designated *EDS Application – Ankylosing Spondylitis Drugs* form found on the Formulary website.
- Coverage may be provided for one switch for patients transitioning to another anti-TNF biologic agent following an adequate trial of the first agent if the patient fails to respond, if there is a loss of response, or is intolerant, to the first agent. Approval will be subject to the published Exception Drug Status criteria for the requested biologic agent.
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

- **adalimumab, pre-filled syringe, 40mg/0.8mL (Humira-ABV); pre-filled pen, 40mg/0.8mL (Humira Pen-ABV)**

The revision is to remove the requirement to have tries 5-ASA from the Crohn's disease criteria.

Crohn's disease as follows:
Initially for a 6 month period: For the treatment of moderate to severely active Crohn's disease in patients refractory to or with contraindications to an adequate course of corticosteroids and other immunosuppressive therapy. Eligible patients should receive an induction dose of 160mg followed by 80mg two weeks later. Clinical response to adalimumab should be assessed after the induction dose.
Ongoing coverage: Adalimumab maintenance therapy should only be provided for responders, as noted above, and for a dose not exceeding 40mg every two weeks. Patients undergoing this treatment should be reviewed every 6 months by a specialist.

- **infliximab, injection (mg), 100mg/vial (Remicade-JAN)**

  The revision is to remove the requirement to have tries 5-ASA from the Crohn's disease criteria.

  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 glucocorticoids and immunosuppressive therapy.
  • For treatment of patients who are intolerant to conventional therapy, including 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.

- **infliximab, powder for solution, 100mg/vial (Inflectra-HOS)**

  The revision is to remove the requirement to have tries 5-ASA from the Crohn's disease criteria.

  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 glucocorticoids and immunosuppressive therapy.
  • For treatment of patients who are intolerant to conventional therapy, including 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.

- **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) or deferasirox, film-coated tablet, 90mg, 180mg, 360mg (Jadenu-NVR).

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

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

  Note: Should not be used in combination with deferiprone, tablets, 1000 mg, solution, 100 mg/mL (Ferriprox-APP) or deferasirox, film-coated tablet, 90mg, 180mg, 360mg (Jadenu-NVR).

- **filgrastim, injection solution, 300mcg/mL (Neupogen-AMG)**

  For treatment of the following conditions on a case by case basis where there is a suitable documented reason that filgrastim, sterile solution for injection, 480mcg/0.8mL (Grastofil-APX) is not appropriate:
  (a) Congenital, cyclic, or idiopathic neutropenia in patients with absolute neutrophil count of less than or equal to 500.
  (b) Non-cancer patients who have undergone bone marrow transplantation.
  (c) AIDS patients with absolute neutrophil counts of less than 500.

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- **valganciclovir, tablet, 450mg (Valcyte-HLR, generics), powder for oral solution, 50mg/mL (Valcyte-HLR)**

  (b) For treatment and prophylaxis of CMV infection in transplant patients. Coverage will be approved for a **twelve month period for lung or heart/lung transplant patients**, or for a six month period **for other** transplant patients.

- **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.

  This drug as with other antivirals in the treatment of HIV, should be used under the direction of an infectious disease specialist.

The following product is NOT RECOMMENDED for Formulary Listing:

- fentanyl citrate, buccal/sublingual effervescent tablet, 100mcg, 200mcg, 400mcg, 600mcg, 800mcg (Fentora-TEV)

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