Government of Saskatchewan

November 1, 2022
Bulletin #222
ISSN 1923-0761

SASKATCHEWAN FORMULARY BULLETIN

Update to the 62nd Edition of the Saskatchewan Formulary

Full Formulary Benefit:

- **tazarotene, lotion, 0.045% (Arazlo)**

Exception Drug Status (EDS) Benefit According to the Following Criteria:

- **budesonide /glycopyrronium/formoterol fumarate, metered dose inhaler, 182ug/8.2ug/5.8ug (Breztri Aerosphere)**
  For treatment of chronic obstructive pulmonary disease (COPD) in patients who are not controlled on optimal dual inhaled therapy (i.e., LAMA/LABA or LABA/ICS) or to replace existing triple therapy regimens currently achieved with more than one inhaler.

  Patients should not be started on triple inhaled therapy as initial therapy for COPD.

- **satralizumab, pre-filled syringe, 120 mg/mL (Enspryng)**
  For the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult and adolescent patients (aged 12 years or older) who meet ALL of the following:
  - The patient is anti–aquaporin 4 (AQP4) seropositive; and
  - The patient has had at least *one* relapse of NMOSD in the previous 12 months; and
  - The patient has experienced relapse or intolerance following an adequate trial of other accessible preventive treatments for NMOSD[1], and
  - The patient has an Expanded Disability Status Scale (EDSS) score of 6.5 points or less; and
  - Satralizumab is being prescribed by a neurologist with expertise in treating NMOSD.

  [1]Other accessible preventative treatments should include consideration of monoclonal antibodies including rituximab, and may include other immunosuppressants.

Initial approval duration: 12 months

Note: Satralizumab should not be initiated during a NMOSD relapse episode.

Renewal

- The patient must maintain an EDSS score of less than 8 points to be eligible for ongoing coverage of satralizumab. The EDSS score must be measured every 6 months after the initial approval period.

Renewal duration: 6 months

- **trientine HCl, capsule, 250 mg (Waymade-Trientine)**
  For the treatment of Wilson's disease patients who are intolerant to penicillamine.

Revised Exception Drug Status (EDS) Criteria:

- **imiquimod, topical cream, 5% (Aldara, and listed generics)**

  For treatment of:
  (a) Genital warts.
  (b) Biopsy-confirmed primary superficial basal cell carcinoma (sBCC) in patients meeting the following criteria:
  • Tumour diameter of ≤ 2 cm, AND
  • Tumour location on the trunk, neck or extremities (excluding hands and feet), AND
  • Surgery or irradiation therapy is not medically indicated (e.g. recurrent lesions in previously irradiated area, number of lesions too numerous to irradiate or remove surgically).

  Notes for the sBCC criteria:
  • Renewals for the same tumour will not be considered.
  • Requests approved for sBCC will be approved for six weeks.
  • Surgical management should be considered first-line for superficial basal cell carcinoma in most patients, especially for isolated lesions.

  c) For treatment of actinic keratosis in patients who are intolerant or have not responded to 5-fluorouracil.
  d) For treatment of squamous cell carcinoma in situ (Bowen's disease) in patients who are intolerant or have not responded to 5-fluorouracil.
  e) For the management of molluscum contagiosum in immunosuppressed patients where conventional treatment options[1] are ineffective, intolerable, or cannot be used due to:
    - o Widespread distribution, or large number of lesions; or
    - o Lesions located in difficult-to-treat areas, such as the genital area.

  [1]Examples of conventional treatment include surgical removal, cryosurgery (liquid nitrogen/freezing), laser therapy, podofilox, tretinoin, tazarotene.

- **Infliximab, injection (mg), 100mg/vial (Remicade)**

Effective November 1st, 2022, new patients (i.e., patients without previous EDS approval for Remicade) will be eligible only for a listed biosimilar formulation of infliximab.

See Appendix A for Criteria.

- **rituximab, injection solution, 10mg/mL (Rituxan**)

Effective November 1, 2022, patients without *current* EDS approval for Rituxan will only be eligible for one of the listed biosimilar formulations of rituximab.

See Appendix A for Criteria.

- **rituximab, injection solution, 10mg/mL (Riximyo)**
- **rituximab, injection solution, 10mg/mL (Ruxience)**
- **rituximab, injection solution, 10mg/mL (Truxima)**

Effective November 1, 2022, patients without *current* EDS approval for Rituxan will only be eligible for one of the listed biosimilar formulations of rituximab.

Note: These products are not interchangeable. When requesting coverage, please state which specific rituximab product is being prescribed to avoid administrative and assessment processing delays.

Rheumatoid Arthritis	For treatment of severe rheumatoid arthritis when used in combination with methotrexate in adult patients who have failed to respond to an adequate trial of an anti-TNF agent, when prescribed in consultation with a specialist. *Rituximab should not be used in combination with biologics for rheumatoid arthritis, or other target specific DMARDS (tsDMARDS) (such as janus kinase (JAK) inhibitors, or phosphodiesterase 4 (PDE4) inhibitors, etc.).*
Anti-Neutrophil Cytoplasmic Autoantibody (ANCA) Associated Vasculitis	For treatment of patients with severely active anti-neutrophil cytoplasmic antibody (ANCA) associated vasculitis (AAV), when prescribed in consultation with a specialist.
Antibody-mediated rejection	For treatment of antibody-mediated rejection in kidney, lung, heart or liver transplant patients.
Chronic Immune Thrombocytopenia	For the treatment of refractory chronic immune thrombocytopenia (ITP) with bleeding complications in patients who: a) Have undergone a splenectomy[1]; and b) Have tried and are unresponsive to other treatment modalities[2]. 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. 2) Patients must be refractory to corticosteroids. In addition, patients must be refractory to *one* of the following second-line treatment modalities: • Azathioprine • Cyclophosphamide • Mycophenolate mofetil • Danazol • Dapsone
Neuromyelitis Optica Spectrum Disorder	For the management of neuromyelitis optica spectrum disorder, when prescribed in consultation with a specialist.
Myasthenia Gravis	For the treatment of patients with myasthenia gravis refractory to pyridostigmine and immunosuppressants, when prescribed in consultation with a specialist.
Prevention of Transplant Rejection	For prevention of antibody mediated rejection in individuals undergoing renal transplantation from an ABO-incompatible living donor, when prescribed in consultation with a specialist.
Primary Membranous Nephropathy	For patients 18 years and older at moderate to high risk of developing progressive kidney injury or complications of nephrotic syndrome, who meet one of the following criteria: • Proteinuria >5 g/day despite a minimum of 6 months of conservative therapy with an angiotensin-converting enzyme (ACE) inhibitor or angiotensin II receptor blocker (ARB). o An observation period of less than 6 months can be considered when proteinuria is > 8 g/day or high anti-PLA2R titres > than 50

	or eGFR less than 60ml/min/1.73m^2. • Proteinuria >3.5 g/day with life- or organ-threatening complications of nephrotic syndrome (i.e., venous thrombosis, infection, or rapid decline in kidney function not otherwise explained). • Biopsy-proven or serology (anti-PLA2R)-proven recurrence in a patient who has received a kidney transplant and has proteinuria > 3.5 g/day. Notes: • Initial approval will allow for two doses to be administered on day 0 and day 15. **Renewal criteria:** Additional courses of rituximab may be approved 6 months after completion of initial treatment course for patients who: • After an initial course of therapy, proteinuria is reduced from baseline by at least 25%, but do not achieve complete remission[1]; or • Relapse[2]. Coverage will not be renewed for patients who demonstrate non-response.[3] [1] Complete Remission: proteinuria < 0.3 g/day or protein-creatinine ratio < 30 mg/mmol. [2] Relapse: Recurrence of proteinuria (as per the initiation criteria) accompanied by a decrease in serum albumin to less than 30g/L in patients who have achieved a complete or partial remission following prior rituximab treatment. [3]Non-response: Lower than 25% reduction in proteinuria by 6 months after initial course.
Dermatomyositis/Polymyositis	For patients with dermatomyositis or polymyositis where azathioprine and methotrexate are inappropriate or not effective, when prescribed in consultation with a specialist.
Refractory interstitial lung disease	For treatment of refractory interstitial lung disease associated with a connective tissue disease (or autoimmune disease), when prescribed in consultation with a specialist.
Systemic lupus erythematosus (SLE)	For patients with systemic lupus erythematosus (SLE) flares who have not responded to, or are unable to take, cyclophosphamide and mycophenolate, when prescribed by a specialist.
Thrombotic thrombocytopenic purpura (TTP)	For treatment of acute acquired thrombotic thrombocytopenic purpura (TTP) in patients who are refractory to or unable to tolerate plasma exchange as well as corticosteroids. For prevention of relapse of acquired thrombotic thrombocytopenic purpura in patients with a history of relapse and ADAMTS13 level <10%.
Multiple Sclerosis	For the treatment of multiple sclerosis (MS) in patients who meet the following criteria: • Confirmation of the diagnosis of Multiple Sclerosis from a

	neurologist with expertise in MS. • In the last two years had either one new gadolinium enhancing lesion, OR two or more new T2 lesions OR a definite clinical relapse (involving new or worsening objective neurological signs compared to the person's baseline). • EDSS less than or equal to 6.5. Consideration of switches for patients who have met the criteria for alternative MS therapies may be considered in some circumstances.

COPD medication Revised Exception Drug Status (EDS) Criteria:

- **aclidinium bromide, powder for inhalation, 400ug (Tudorza Genuair) (possible OEA)**
  For treatment of COPD.

- **aclidinium bromide/formoterol fumarate dihydrate, powder for inhalation, 400ug/12ug (Duaklir Genuair)**
  For treatment of COPD in patients with an inadequate response to a long acting beta-2 agonist (LABA) or a long acting muscarinic antagonist (LAMA).

- **formoterol fumarate, powder for inhalation (package), 6ug/dose, 12ug/dose (Oxeze Turbuhaler) (possible OEA)**
  For treatment of:
  (a) Asthma uncontrolled on concurrent inhaled steroid therapy. It is important that these patients also have access to a short-acting beta-2 agonist for symptomatic relief.
  (b) For treatment of COPD

- **formoterol fumarate, powder for inhalation (capsule), 12ug (Foradil) (possible OEA);**
  For treatment of:
  (a) Asthma uncontrolled on concurrent inhaled steroid therapy. It is important that these patients also have access to a short-acting beta-2 agonist for symptomatic relief.
  (b) For treatment of COPD.

- **indacaterol maleate, inhalation powder capsule, 75ug (Onbrez Breezhaler) (possible OEA)**
  For treatment of COPD.

- **salmeterol xinafoate, powder for inhalation (package), 50ug/dose (Serevent Diskus) (possible OEA)**
  For treatment of:
  (a) Asthma uncontrolled on concurrent inhaled steroid therapy. It is important that these patients also have access to a short-acting beta-2 agonist for symptomatic relief.
  (b) For treatment of COPD.

- **tiotropium bromide monohydrate/olodaterol HCl, inhalation solution, 2.5ug/2.5ug (Inspiolto Respimat)**
  For treatment of COPD in patients with an inadequate response to a long acting beta-2 agonist (LABA) or a long acting muscarinic antagonist (LAMA).

- **umeclidinium bromide, powder for inhalation, 62.5ug (Incruse Ellipta) (possible OEA)**
  For treatment of COPD.

- **umeclidinium bromide/vilanterol trifenatate, powder for inhalation, 62.5ug/25ug (Anoro Ellipta)**
  For treatment of COPD in patients with an inadequate response to a long acting beta-2 agonist (LABA) or a long acting muscarinic antagonist (LAMA).

The following product has been REMOVED from the Formulary:

- **rituximab, injection solution, 10mg/mL (Riabni)**

The following products were NOT RECOMMENDED for Formulary Listing:

- **certolizumab pegol, solution, autoinjector; pre-filled syringe, 200mg/mL (Cimzia) for moderate to severe plaque psoriasis.**
- **cyclosporine, capsules, 25mg, 50mg, 100mg (Cyclosporine Capsules)**
- **budesonide, orally disintegrating tablet, 1mg, 5mg (Jorveza)**

Saskatchewan Ministry of Health
Drug Plan and Extended Benefits Branch
2nd Floor, 3475 Albert St
REGINA SK S4S 6X6
306-787-3317
1-800-667-7581