Government of Saskatchewan

March 1, 2026
Bulletin #264
ISSN 1923-0761

SASKATCHEWAN FORMULARY BULLETIN
Update to the 62nd Edition of the Saskatchewan Formulary

Temporary Non-Interchangeable Exception Drug Status (EDS) Benefit Due to Shortages:

- **rifabutin, capsule, 150mg (US-Labelled Rifabutin) - effective February 3, 2026**

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

- **estradiol, transdermal therapeutic system, 25ug, 50ug, 75ug (Climara);**
- **estradiol, transdermal gel, 0.1% (0.25mg packet, 0.5mg packet, 1mg packet) (Divigel);**
- **estradiol, transdermal therapeutic system, 25ug, 37.5ug, 50ug, 75ug, 100ug (Estradot and listed generics);**
- **estradiol, transdermal gel (metered dose pump), 0.06% (Estrogel);**
- **estradiol/norethindrone acetate, transdermal therapeutic system (8), 50ug/140ug, 50ug/250ug (Estalis)**

Additional Criteria for an Existing Exception Drug Status (EDS) Benefit:

- **pimecrolimus, topical cream, 1% (Elidel)**
  (c) For the treatment of prurigo nodularis (PN) in patients where topical corticosteroids (TCS) are not advisable, or not effective.

- **tacrolimus, topical ointment, 0.03%, 0.1% (Protopic)**
  (c) For the treatment of prurigo nodularis (PN) in patients where topical corticosteroids (TCS) are not advisable, or not effective.

Additional Formulation of an Existing Exception Drug Status (EDS) Benefit According to the Following Criteria:

- **deferiprone, modified release tablet, 1000mg (Ferriprox MR)**
  For the 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).

- **leuprolide acetate, prefilled syringe, 45mg (mg) (Eligard)**
  For the treatment of central precocious puberty.

- **ondansetron HCl dihydrate, oral solution, 4mg/5mL (listed generics)**
  For treatment of severe nausea in patients refractory to dexamethasone, dimenhydrinate, metoclopramide or prochlorperazine, who cannot tolerate or use the ondansetron orally disintegrating tablets (ODTs).

- **ondansetron HCl dihydrate, solution for injection, 2mg/mL (mL) (listed generics)**
  For the treatment of:
  a) Severe nausea in patients uncontrolled on, or who cannot tolerate or use ondansetron oral liquid, AND orally disintegrating tablets (ODTs).
  b) Hyperemesis gravidarum in patients who are uncontrolled on, OR who cannot tolerate or use available ondansetron oral formulations.

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

- **rozanolixizumab, solution for subcutaneous infusion, 140mg/mL (mg) (2mL vial) (Rystiggo)**
  For the treatment of adult patients with generalized myasthenia gravis (gMG) who:
  - Have a positive serologic test for either anti-acetylcholine receptor (anti-AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibodies; AND,
  - Have a Myasthenia Gravis Activities of Daily Living (MG-ADL) score[1] at baseline of ≥3 (with at least 3 points coming from nonocular symptoms); AND,
  - Have Myasthenia Gravis Foundation of America (MGFA) class II to IV disease; AND,
  - Have symptoms persisting despite an adequate trial of conventional therapy[2] for gMG; AND,
  - Will not have rozanolixizumab initiated during a gMG exacerbation or crisis, or within 3 months of a thymectomy; AND,
  - Will not be using rozanolixizumab concomitantly with rituximab, a complement inhibitor, or another neonatal Fc receptor (FcRn) antagonist; AND,
  - Are under the care of a neurologist with expertise in the diagnosis and management of gMG.

  Initial Coverage Duration: 6 months

  Initial Renewal Criteria:
  Renewal of rozanolixizumab coverage will be considered in individuals who:
  - Have a documented improvement (decrease) in MG-ADL score[1] of 2 or more points; AND,
  - Will not be using rozanolixizumab concomitantly with rituximab, a complement inhibitor, or another FcRn antagonist; AND,
  - Remain under the care of a neurologist with expertise in the diagnosis and management of gMG.

  Subsequent Renewal Criteria:
  Ongoing coverage of rozanolixizumab will be considered in individuals who:
  - Have not had a worsening of (increase in) MG-ADL score[1] compared to the initial renewal score; AND,
  - Will not be using rozanolixizumab concomitantly with rituximab, a complement inhibitor, or another FcRn antagonist; AND,
  - Remain under the care of a neurologist with expertise in the diagnosis and management of gMG.

  [1]The MG-ADL score must be measured and provided by the physician at baseline and with each renewal request.
  [2]Conventional therapy should include an adequate trial of, or intolerance to, rituximab. If rituximab is not appropriate, an adequate trial of another preventative treatment (including, but not limited to, other monoclonal antibodies, acetylcholinesterase inhibitors (AChEIs), azathioprine, mycophenolate, etc.) should have been tried.

- **zilucoplan (zilucoplan sodium), prefilled syringe, 16.6mg/0.416mL, 23mg/0.574mL, 32.4mg/0.81mL (100mcg) (Zilbrysq)**
  Initiation Criteria
  For the treatment of adult patients with generalized myasthenia gravis (gMG) who:

- Have a positive serologic test for anti-acetylcholine receptor (anti-AChR) antibodies; AND,
- Have a Myasthenia Gravis Activities of Daily Living (MG-ADL) score[1] at baseline of ≥6; AND,
- Have Myasthenia Gravis Foundation of America (MGFA) class II to IV disease; AND,
- Have symptoms persisting despite an adequate trial of conventional therapy[2] for gMG; AND,
- Will not have zilucoplan initiated during a gMG exacerbation or crisis, or within 12 months of a thymectomy; AND,
- Will not be using zilucoplan concomitantly with rituximab, a neonatal Fc receptor (FcRn) antagonist, or a complement inhibitor; AND,
- Are under the care of a neurologist with expertise in the diagnosis and management of gMG.

Initial Coverage Duration: 6 months

Initial Renewal Criteria
Renewal of zilucoplan coverage will be considered in individuals who:

- Have a documented improvement (decrease) in MG-ADL score[1] of 2 or more points; AND,
- Will not be using zilucoplan concomitantly with rituximab, a neonatal Fc receptor (FcRn) antagonist, or a complement inhibitor; AND,
- Remain under the care of a neurologist with expertise in the diagnosis and management of gMG.

Subsequent Renewal Criteria:
Ongoing coverage of zilucoplan will be considered in individuals who:

- Have not had a worsening of (increase in) MG-ADL score[1] compared to the initial renewal score; AND,
- Will not be using zilucoplan concomitantly with rituximab, a neonatal Fc receptor (FcRn) antagonist, or a complement inhibitor; AND,
- Remain under the care of a neurologist with expertise in the diagnosis and management of gMG.

[1]The MG-ADL score must be measured and provided by the physician at baseline and with each renewal request.
[2]Conventional therapy should include an adequate trial of, or intolerance to, rituximab. If rituximab is not appropriate, an adequate trial of another preventative treatment (including, but not limited to, other monoclonal antibodies, acetylcholinesterase inhibitors (AChEIs), azathioprine, mycophenolate, etc.) should have been tried.

Additional Biosimilar Formulation of an Existing Exception Drug Status (EDS) Benefit with Same Criteria:

- **tocilizumab, autoinjector, 162mg/0.9mL; prefilled syringe, 162mg/0.9mL; solution for IV infusion, 20mg/mL (4mL vial, 10mL vial, 20mL vial) (Avtozma)**

Indication	Criteria
Giant Cell Arteritis (GCA) (auto-injector and pre-filled syringe ONLY)	For the treatment of Giant Cell Arteritis (GCA) in adult patients who are receiving prednisone at initiation of therapy, or with relapse. **Notes:** • Patients should be under the care of a prescriber with experience in the diagnosis and management of GCA. • Discontinuation of tocilizumab should be considered at 12 weeks if there is no response to therapy.
Polyarticular Juvenile Idiopathic Arthritis (pJIA) (auto-injector, pre-filled syringe, and solution for IV infusion)	For the treatment of polyarticular juvenile idiopathic arthritis in patients 2 years of age and older, who are intolerant to, or have inadequate response to one or more disease-modifying anti-rheumatic drugs (DMARDs). This product should be used in consultation with a specialist in this area.
Rheumatoid Arthritis (auto-injector, pre-filled syringe, and solution for IV infusion)	For the treatment of moderate to severe active rheumatoid arthritis, alone or in combination with methotrexate (MTX) or other disease-modifying antirheumatic drugs (DMARDs), in patients who have failed to respond to an adequate trial of DMARDs. Patients should be assessed after 16 weeks of treatment and therapy continued only if there is a clinical response to treatment. Tocilizumab should not be used concomitantly with tumor necrosis factor (TNF) alpha inhibitors. This product should be used in consultation with a specialist in this area.
Systemic Juvenile Idiopathic Arthritis (sJIA) (auto-injector, pre-filled syringe, and solution for IV infusion)	For the treatment of active systemic juvenile idiopathic arthritis (sJIA) in patients two years of age and older who have responded inadequately to nonsteroidal anti-inflammatory drugs (NSAIDs) and systemic corticosteroids (with or without methotrexate), due to intolerance or lack of efficacy. Tocilizumab should not be used concomitantly with tumor necrosis factor (TNF) alpha inhibitors. This product should be used in consultation with a specialist in this area

Revised Exception Drug Status (EDS) Criteria:

- **ondansetron, orally disintegrating tablet/film, 4mg, 8mg (Ondissolve and listed generics)**
  For the treatment of:
  a) Severe nausea in patients refractory to dexamethasone, dimenhydrinate, metoclopramide OR prochlorperazine.
  b) Hyperemesis gravidarum.

- **satralizumab, pre-filled syringe, 120mg/mL (mg) (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. Satralizumab will not be eligible for coverage in combination with rituximab, inebilizumab, eculizumab, or ravulizumab.

  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 12 months after the initial approval period.

  Renewal duration: 12 months

The Following Product was NOT RECOMMENDED for Formulary listing:

- **trofinetide, oral solution, 200mg/mL (Daybue) -** for Rett Syndrome

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