Government of Saskatchewan

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SASKATCHEWAN FORMULARY BULLETIN

Update to the 62nd Edition of the Saskatchewan Formulary

Full Formulary Benefit Listing:

- **glucagon, nasal powder, 3mg/dose (Baqsimi-LIL)**
- **halobetasol propionate/tazarotene, topical lotion, 0.01%/0.045% (Duobrii-BAU)**

Exception Drug Status benefit according to the following criteria:

- **brolucizumab, solution for intravitreal injection, 6mg/0.05mL (mg) (Beovu-NVR)**

Indication	Criteria
Neovascular (wet) Age-Related Macular Degeneration (nAMD)	*For the treatment of mild to moderate neovascular (wet) age-related macular degeneration (nAMD)[1]. Injection will be by a qualified ophthalmologist with experience in intravitreal injections.* *[1]Coverage will not be provided for patients with permanent structural damage to the central fovea or no active disease.* *The interval between doses should be no shorter than eight weeks (following the first three initiation doses that are given every four weeks).* *Treatment with brolucizumab should be continued only in people who maintain adequate response to therapy.* *Brolucizumab should be permanently discontinued if any one of the following occurs:* *(a) Reduction in best corrected visual acuity (BCVA) in the treated eye to less than 15 letters (absolute) on 2 consecutive visits in the treated eye, attributed to AMD in the absence of other pathology.* *(b) Reduction in BCVA of 30 letters or more compared to baseline and/or best recorded level since baseline, as this may indicate either poor treatment effect or adverse event or both.* *(c) There is evidence of deterioration of the lesion morphology despite treatment over three consecutive visits.*

- **indacaterol/glycopyrronium/mometasone furoate, inhalation powder capsule, 150ug/50ug/160ug (Enerzair Breezhaler-VAL)**
  For the treatment of asthma in patients uncontrolled on inhaled steroid therapy in conjunction with a long acting beta-2 agonist (LABA) who experienced one or more asthma exacerbations in the previous 12 months.
  It is important that these patients also have access to a short-acting beta-2 agonist for symptomatic relief.

- **indacaterol/mometasone furoate, inhalation powder capsule, 150ug/80ug, 150ug/160ug, 150ug/320ug (Atectura Breezhaler-VAL)**
  For the treatment of asthma in patients uncontrolled on inhaled steroid therapy.
  It is important that these patients also have access to a short-acting beta-2 agonist for symptomatic relief.

- **methylphenidate HCl, controlled release capsule, 25mg, 35mg, 45mg, 55mg, 70mg, 85mg, 100mg (Foquest-ELS)**
  For the treatment of Attention Deficit Hyperactivity Disorder (ADHD).

- **risdiplam, powder for oral solution, 0.75mg/mL (Evrysdi-HLR)**
  Coverage may be available for this product through the Drug Plan for the treatment of spinal muscular atrophy. Due to the unique nature of this condition and the cost of this treatment, Exception Drug Status (EDS) requests will require additional details to facilitate assessment of the application and accompanying clinical information. In addition, patients who are approved will be required to undergo ongoing assessment to monitor for improvement over time and must meet renewal criteria for continuation of treatment. Please contact the Drug Plan at 1-800-667-7581 for more information regarding coverage availability and the EDS application process for this product.

- **siponimod, tablet, 0.25mg, 2mg (Mayzent-NVR)**
  For the treatment of patients with secondary progressive multiple sclerosis (SPMS) with active disease[1] evidenced by relapses or imaging features characteristic of multiple sclerosis inflammatory activity, to delay the progression of physical disability.
  Patients must:
  - Have a history of relapsing-remitting multiple sclerosis (RRMS) and current active SPMS,
  - Have an Expanded Disability Status Scale (EDSS) score of 3.0 to 6.5,
  - Have documented EDSS progression during the two years prior to initiating siponimod treatment (≥ 1 point if EDSS < 6.0; ≥ 0.5 points if EDSS ≥ 6.0 at screening),
  - Not be using siponimod in combination with other disease-modifying treatments used to treat multiple sclerosis, and
  - Be under the care of a specialist with experience in the diagnosis and management of multiple sclerosis.

  Approval Duration: 12 months

  [1] A clear relapse in the last two years OR evidence of a new enhancing lesion OR a new T2 lesion on MRI in comparison to a prior MRI completed in the last 2 years. Please include all relevant imaging reports.

  Note: The manufacturer's patient support program will cover the cost of CYP2C9 genotyping prior to initiating siponimod treatment as this medication is contraindicated in patients with some cytochrome P450 enzyme 2C9 genotype (CYP2C9) variants while other variants require dosage adjustments.

  Renewal criteria

Annual renewals[1] will be considered for patients who do not exhibit evidence of disease progression[2] since the previous annual assessment.

[1] Available imaging reports to be submitted with both initial and renewal applications for coverage consideration. This includes baseline (i.e., prior to starting siponimod) as well as any regularly scheduled imaging reports.

[2]Disease progression is defined as an increase in the EDSS score of ≥ 1 point if the EDSS score was 3.0 to 5.0 at siponimod initiation, or an increase of ≥ 0.5 points if the EDSS score was 5.5 to 6.5 at siponimod initiation.

Renewal Duration: 12 months

Discontinuation criteria

In addition to the renewal criteria above, coverage will be discontinued if the patient has an EDSS score of 7.0 or higher at any time during siponimod treatment.

Additional Exception Drug Status (EDS) Criteria:

- **cefixime, tablet, 400mg (Suprax-ODN) (and listed generics); suspension, 20mg/mL (Suprax-ODN) (and listed generics)**
  (e) For prophylaxis of infection in immunocompromised patients. Should be prescribed in consultation with an infectious diseases specialist.

- **cyclosporine, capsule, 10mg, 25mg, 50mg 100mg; liquid, 100mg/mL (Neoral-NVR)**
  (f) For patients with dermatomyositis or polymyositis where azathioprine and methotrexate are inappropriate or not effective.
  (g) For treatment of chronic idiopathic urticaria in patients refractory or intolerant to antihistamines.
  (h) For the treatment of pyoderma gangrenosum.

  For the above indications prescriptions are subject to deductible (where applicable) and co-payment as for other drugs covered under the Drug Plan. **Pharmacies note: claims on behalf of these patients must use the following identifying numbers (not the DIN):**

10mg - 00950792	100mg - 00950815
25mg - 00950793	100mg/mL - 00950823
50mg – 00950807	

- **imiquimod, topical cream, 5% (Aldara-BAU) (and listed generics)**
  (d) For treatment of actinic keratosis in patients who are intolerant or have not responded to 5-fluorouracil.
  (e) For treatment of squamous cell carcinoma in situ (Bowen's disease) in patients who are intolerant or have not responded to 5-fluorouracil.
  (f) For the management of molluscum contagiosum in immunosuppressed patients where conventional treatment options 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.

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

- **rifampin, capsule, 150mg, 300mg (Rofact-BAU)**

  (b) For treatment of pruritis (itching) in patients with cholestatic liver disease who are unresponsive or intolerant to cholestyramine.

  (c) For treatment of non-tuberculosis infections when:
  - the organism is susceptible to rifampin, AND
    - o alternative agents are not appropriate, OR
    - o the patient does not respond or is intolerant to other recommended agents, OR
    - o rifampin treatment is being completed following initiation in hospital.

  Organism susceptibility should be determined.
  This medication should be prescribed in consultation with an infectious diseases specialist.
  Note: Contact TB Prevention and Control Saskatchewan if rifampin is being prescribed for treatment of tuberculosis.

- **tocilizumab, subcutaneous solution, 162mg/0.9mL syringe, autoinjector (Actermra-HLR)**

  (c) 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.
  - Actemra should not be used concomitantly with TNF alpha inhibitors.
  - This product should be used in consultation with a specialist in this area.

  (d) 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.

  This product should be used in consultation with a specialist in this area.

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

  (c) For the treatment of patients with symptomatic congenital CMV under the advice of an infectious disease specialist.

  (d) For the treatment of CMV in immunocompromised patients under the advice of an infectious disease specialist.

<u>Additional Exception Drug Status (EDS) listing:</u>

- **mycophenolate mofetil, capsule, 250mg; tablet, 500mg (CellCept-HLR) (and listed generics); powder for oral suspension, 200mg/mL (CellCept-HLR)**

  (a) For treatment of autoimmune conditions.

For the above indication prescriptions are subject to deductible (where applicable) and co-payment as for other drugs covered under the Drug Plan. **Pharmacies note: claims on behalf of these patients must use the following identifying numbers (not the DIN):**

250mg Capsule: 00951169- Sandoz Mycophenolate 00951167- Teva-Mycophenolate 00951163- Apo-Mycophenolate 00951174- Mycophenolate Mofetil (Accord) 00951175- Jamp-Mycophenolate 00951359- Mycophenolate (Sanis) 00950887 Cellcept 200mg/mL powder for oral suspension: 00950937 Cellcept	500mg tablet: 00951172- Mycophenolate Mofetil (Accord) 00951164- Apo-Mycophenolate 00951170- Sandoz Mycophenolate 00951168- Teva-Mycophenolate 00951176- Jamp-Mycophenolate 00951360- Mycophenolate (Sanis) 00950888 Cellcept

Revised Exception Drug Status Criteria:

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

Indication	Criteria
Neovascular (wet) Age-Related Macular Degeneration (nAMD)	*For the treatment of neovascular (wet) age-related macular degeneration (nAMD)[1]. Injection will be by a qualified ophthalmologist with experience in intravitreal injections.* *[1] Coverage will not be provided for patients with permanent structural damage to the central fovea or no active disease.* *The interval between the doses should be no shorter than one month for aflibercept.* *Treatment with aflibercept should be continued only in people who maintain adequate response to therapy.* *Aflibercept should be permanently discontinued if any one of the following occurs:* *(a) Reduction in best corrected visual acuity (BCVA) in the treated eye to less than 15 letters (absolute) on 2 consecutive visits in the treated eye, attributed to AMD in the absence of other pathology.* *(b) Reduction in BCVA of 30 letters or more compared to baseline and/or best recorded level since baseline, as this may indicate either poor treatment effect or adverse event or both.* *(c) There is evidence of deterioration of the lesion morphology despite treatment over three consecutive visits.*
Diabetic Macular Edema (DME)	For the treatment of visual impairment due to Diabetic Macular Edema (DME) for patients meeting all of the following: (a) Diffuse DME involving the central fovea with central fovea thickness of 300 microns or greater on optical coherence tomography (OCT) and vision less than 20/32.

	(b) Patients with focal macular edema for which laser photocoagulation is indicated should be treated with laser, except in situations where focal laser therapy treatment cannot be safely performed due to the proximity of microaneurysms to the fovea. (c) A haemoglobin A1c of less than 11%. (d) Treatment should be discontinued if there is no improvement of retinal thickness on OCT or if there is no improvement in visual acuity after five consecutive treatments. (e) The interval between two doses should not be shorter than one month. (f) Patients responding to treatment should be monitored at regular intervals up to monthly for visual acuity AND retinal thickness. (g) Injection will be by a qualified ophthalmologist with experience in 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.
Retinal Vein Occlusion (RVO)	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: (a) Diffuse RVO with macular thickness of 300 microns or greater on Optical Coherence Tomography (OCT) and a vision of 20/40 or less. (b) The interval between two doses should not be shorter than one month. (c) Patients should be monitored at regular intervals up to monthly for retinal thickness and visual acuity. (d) Treatment should be discontinued if there is no improvement after 6 months of initial treatment; and (e) Injection 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.

- **ranibizumab, injection solution, 10mg/mL (mcg) (Lucentis-NVR)**

Indication	Criteria
Neovascular (wet) Age-Related Macular Degeneration (nAMD)	*For the treatment of neovascular (wet) age-related macular degeneration (nAMD)[1]. Injection will be by a qualified ophthalmologist with experience in intravitreal injections.* *[1]Coverage will not be provided for patients with permanent structural damage to the central fovea or no active disease.*

	The interval between the doses should be no shorter than one month. Treatment with ranibizumab should be continued only in people who maintain adequate response to therapy. *Ranibizumab should be permanently discontinued if any one of the following occurs:* *(a) Reduction in best corrected visual acuity (BCVA) in the treated eye to less than 15 letters (absolute) on 2 consecutive visits in the treated eye, attributed to AMD in the absence of other pathology.* *(b) Reduction in BCVA of 30 letters or more compared to baseline and/or best recorded level since baseline, as this may indicate either poor treatment effect or adverse event or both.* *(c) There is evidence of deterioration of the lesion morphology despite treatment over three consecutive visits.*
Diabetic Macular Edema (DME)	For the treatment of visual impairment due to Diabetic Macular Edema (DME) for patients meeting all of the following: (a) Diffuse DME involving the central fovea with central fovea thickness of 300 microns or greater on optical coherence tomography (OCT) and vision less than 20/32. (b) Patients with focal macular edema for which laser photocoagulation is indicated should be treated with laser, except in situations where focal laser therapy treatment can not be safely performed due to the proximity of microaneurysms to the fovea. (c) A haemoglobin A1c of less than 11%. (d) Treatment to be given monthly for three consecutive treatments. Treatment should be discontinued if there is no improvement of retinal thickness on OCT or if there is no improvement in visual acuity after three consecutive treatments. (e) Patients responding to treatment should be monitored at regular intervals up to monthly for visual acuity AND retinal thickness. (f) Treatment should be resumed with monthly injections when monitoring indicates a loss in visual acuity and increase in retinal thickness and continued until stable visual acuity and improvement in retinal thickness is reached again for three consecutive monthly assessments. (g) Treatment should be discontinued if there is no improvement of retinal thickness or visual acuity after three consecutive treatments. (h) Injection will be by a qualified ophthalmologist with experience in 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.
Retinal Vein Occlusion (RVO)	For the treatment of visual impairment due to clinically significant macular edema secondary to non-ischemic branch retinal vein occlusion (BRVO) or central retinal vein occlusion (CRVO) for patients meeting all of the following:

	(a) Diffuse RVO with macular thickness of 300 microns or greater on Optical Coherence Tomography (OCT) and a vision of 20/40 or less. (b) Treatment is to be given monthly until edema is resolved or there is no further improvement with three consecutive treatments. (c) Patients should be monitored at regular intervals up to monthly for retinal thickness and visual acuity. (d) Treatment should be resumed if there is a recurrence of macular edema with macular thickness greater than 300 microns or loss of visual acuity, and continued until stable visual acuity and improvement in retinal thickness is reached again for three consecutive assessments. (e) Treatment should be discontinued if there is no improvement after 6 months of initial treatment. (f) Injection will be by a qualified ophthalmologist with experience in administering intravitreal injections.
Choroidal Neovascularization	For treatment of visual impairment due to choroidal neovascularization secondary to pathologic myopia. Must be administered by a qualified ophthalmologist with experience in 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. • Grid Laser photocoagulation can also be considered for BRVO at the discretion of the treating ophthalmologist.

- **tacrolimus, topical ointment, 0.3%, 0.1% (Protopic-LEO) (possible OEA)**
  (a) For treatment of atopic dermatitis in patients unresponsive or intolerant to topical steroids tried within the last 3 months.
  (b) For the treatment of pyoderma gangrenosum.

Saskatchewan Ministry of Health
Drug Plan and Extended Benefits Branch
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