Government of Saskatchewan

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SASKATCHEWAN FORMULARY BULLETIN

Update to the 62nd Edition of the Saskatchewan Formulary

New Exception Drug Status (EDS) Listings Effective July 1, 2015 according to the following criteria:

- **aripiprazole, 300mg, 400 mg, long acting injection (Abilify Maintena - OTS)**

For treatment of patients exhibiting a compliance problem with an oral antipsychotic and in whom the administration of a conventional injectable extended action antipsychotic is ineffective or poorly tolerated.

- **eplerenone, 25mg, 50mg tablet (Inspra-PFI)**

For treatment of patients with New York Heart Association (NYHA) class II chronic heart failure with left ventricular systolic dysfunction (with ejection fraction ≤ 35%), as an adjunct to standard therapy

Note: patients must be on optimal therapy with an angiotensin-converting–enzyme (ACE) inhibitor, an angiotensin-receptor blocker (ARB), or both and a beta-blocker (unless contraindicated) at the recommended dose or maximal tolerated dose.

- **indacaterol/glycopyrronium, inhalation powder capsule, 100mcg/50mcg (Ultibro Breezhaler-NVR)**

For treatment of airflow obstruction in patients with moderate to severe COPD, as defined by spirometry, who have had an inadequate response to a long-acting beta-2 agonist (LABA), OR a long-acting muscarinic antagonist (LAMA).

- **lurasidone hydrochloride, 40mg, 80mg, 120mg tablet (Latuda–SNV)**

For manifestations of schizophrenia.

- **riociguat, tablet, 0.5mg, 1.0mg, 1.5mg, 2.0mg, 2.5mg (Adempas – BAY)**

For treatment of patients 18 years of age or older with chronic thromboembolic pulmonary hypertension (CTEPH) with World Health Organization (WHO) Functional Class 2 or 3 pulmonary hypertension, with;

a) inoperable chronic thromboembolic pulmonary hypertension (CTEPH), World Health Organization (WHO) Group 4, OR
b) persistent or recurrent CTEPH after surgical treatment.
Note: must be prescribed by clinicians experienced in the diagnosis and treatment of CTEPH.

- **romiplostim, solution for injection, 250 mcg/0.5 mL, 500mcg/mL, (Nplate-AMG)**

For the treatment of refractory chronic idiopathic thrombocytopenic purpura ("ITP") with bleeding complications in patients who meet the following conditions:
a) have undergone a splenectomy[1]; and
b) have tried and are unresponsive to other treatment modalities[2].

Dosage: To a maximum of 10 mcg/kg once weekly.

Renewal of requests for romiplostim will be assessed on a case-by-case basis.

Note: After one year of continuous treatment, therapeutic options should be reassessed.

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. The requesting physician's rationale must be evaluated by an independent physician.

2. Patients must be refractory to two of the following first line treatment modalities:
- Corticosteroids
- IV anti-D
- Intravenous immune globulin (IVIG)

In addition, patients must be refractory to two of the following second-line treatment modalities:
- Azathioprine
- Cyclosporine
- Cyclophosphamide
- Mycophenolate
- Rituximab
- Danazol
- Dapsone

- **stiripental, capsules and powder for suspension, 250 mg and 500 mg (Diacomit – BCX)**

For use in combination with clobazam and valproate as adjunctive therapy of refractory generalized tonic-clonic seizures in patients with severe myoclonic epilepsy in infancy (Dravet syndrome), whose seizures are not adequately controlled with clobazam and valproate alone.

Note: The patient must be under the care of a neurologist or a pediatrician.

- **umeclidinium bromide/vilanterol trifenatate, powder for inhalation 62.5/25mcg (Anoro Ellipta-GSK)**

For treatment of airflow obstruction in patients with moderate to severe COPD, as defined by spirometry, who have had an inadequate response to a long-acting beta-2 agonist (LABA), OR a long-acting muscarinic antagonist (LAMA).

New Exception Drug Status (EDS) Listings Effective July 1, 2015 with online adjudication according to the following criteria:

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

Treatment of wAMD

For the treatment of neovascular (wet) age-related macular degeneration (AMD) if all of the following circumstances apply to the eye to be treated:

(i) The best corrected visual acuity (BCVA) is between 6/12 and 6/96

(ii) The lesion size is less than or equal to 12 disc areas in greatest linear dimension

(iii) There is evidence of recent (< 3 months) presumed disease progression (blood vessel growth, as indicated by fluorescein angiography, optical coherence tomography (OCT) or recent visual acuity changes); and

(iv) Injection will be by a qualified ophthalmologist with experience in intravitreal injections

Coverage will not be provided for patients:

(a) With permanent structural damage to the central fovea or no active disease (as defined in the Royal College of Ophthalmology guidelines); and

(b) Receiving concurrent verteporfin PDT treatment.

The interval between the doses should be no shorter than one month.

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 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 either 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 optimum treatment over three consecutive visits.

Treatment of DME

For the treatment of visual impairment due to Diabetic Macular Edema (DME) for patients meeting all of the following:

(i.) 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.

(ii.) 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.

(iii.) A haemoglobin A1c of less than 11%.

(iv.) 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.

(v.) The interval between two doses should not be shorter than one month.

(vi.) Patients responding to treatment should be monitored at regular intervals up to monthly for visual acuity AND retinal thickness.

(vii.) 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.

Treatment of CRVO

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

(i.) Diffuse CRVO 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.) 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.

- **dolutegravir, tablet, 50 mg (Tivicay–VII)**

For management of HIV disease in patients 12 years of age and older. This drug, as with other antivirals in the treatment of HIV, should be used under the direction of an infectious disease specialist.
Note: Tivicay is not recommended for patients weighing less than 40 kgs.

When prescribed by, or on the advice of an Infectious Disease specialist familiar with HIV treatment, for post-exposure prophylaxis (PEP).

Alternate regimen for patients in whom compliance may be an issue. This regimen may improve adherence and has reduced potential for drug interactions.

- **mirabegron extended release tablet, 25 mg, 50 mg (Myrbetriq-APC)**

For treatment of overactive bladder (OAB) for patients intolerant to, or with an inadequate response to oxybutynin.

Note: Should not be used in combination with other pharmacologic treatments for OAB.

Additional Formulations of a Current Exception Drug Status (EDS) Listing effective July 1, 2015 according to the following criteria:

- **dalteparin sodium, syringe, 3,500 IU (0.28mL (Fragmin-PFI)**

(a) For treatment of venous thromboembolism for up to 10 days.
(b) For prophylaxis following total knee arthroplasty for up to 35 days.
(c) For major orthopedic trauma for up to10 days (treatment duration may be reassessed).
(d) For long-term outpatient prophylaxis in patients who are pregnant.
(e) For long-term outpatient prophylaxis in patients who have a contraindication to, are intolerant to, or have failed, warfarin therapy.
(f) For long-term outpatient prophylaxis in patients who have lupus anticoagulant syndrome.
(g) Prophylaxis in patients undergoing total hip replacement or following hip fracture surgery for up to 35 days following the procedure.

Revised Exception Drug Status Criteria; (Prescribers No Longer Required to Submit a Medication List; See Bold Italicized Portion):

- **donepezil HCl, tablet, 5mg, 10mg (Aricept-PFI, and generics)**

(a) A diagnosis of probable Alzheimer's disease as per ***DSM-V*** criteria.
All other criteria remains unchanged.

- **rivastigmine, capsule, 1.5mg, 3mg, 4.5mg, 6mg (Exelon-NVR, and generics); oral solution, 2mg/mL ((Exelon-NVR)**

(a) A diagnosis of probable Alzheimer's disease as per ***DSM-V*** criteria.
All other criteria remains unchanged.

- **galantamine hydrobromide, extended release capsule, 8mg, 16mg, 24mg (Reminyl ER-JAN, and generics)**

(a) A diagnosis of probable Alzheimer's disease as per ***DSM-V*** criteria.
All other criteria remains unchanged.

New Exception Drug Status Criteria (in addition to existing criteria):

- **norfloxacin, tablet, 400mg (Apo-Norflox-APX) (Novo-Norfloxacin-NOP) (pms-Norfloxacin-PMS)**

(e) For secondary prophylaxis in patients who have had an episode of spontaneous bacterial peritonitis and are intolerant or unresponsive to sulfamethoxazole/trimethoprim
(f) For primary prophylaxis for patients with cirrhosis considered high risk for spontaneous bacterial peritonitis who are intolerant to sulfamethoxazole/trimethoprim.

Note: High risk is defined as cirrhosis with ascities with an ascitic protein concentration less than 15g/L

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

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.

Drugs Reviewed and Not Approved for Listing in the Saskatchewan Formulary:

- **eltrombopag, tablet, 25mg, 50mg (Revolade-GSK) for thrombocytopenia associated with chronic hepatitis C infection**

- **pasireotide diaspartate, 0.3 mg/mL, 0.6 mg/mL and 0.9 mg/mL solution for injection (Signifor-NVR) for Cushing's disease**

- **lomitapide, capsules, 5 mg, 10 mg, 20 mg (Juxtapid -APL) for homozygous familial hypercholesterolemia**

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