February 1, 2022
Bulletin #210
ISSN 1923-0761

SASKATCHEWAN FORMULARY BULLETIN

Update to the 62nd Edition of the Saskatchewan Formulary

Full Formulary Benefit Listing:

- **estrone, vaginal cream, 0.1% (Estragyn Vaginal Cream-SLP)**

Non Interchangeable Full Formulary Benefit Listing:

- **insulin aspart, injection solution, 100U/mL (5x3mL) (Trurapi-AVT) (Trurapi Solostar-AVT)**

Exception Drug Status (EDS) benefit according to the following criteria:

- **fremanezumab, pre-filled syringe; prefilled autoinjector, 225mg/1.5mL (Ajovy-TVM)**
  For patients who have a confirmed diagnosis of either:
  1) Episodic migraine: Migraine headaches on at least 4 days per month and less than 15 headache days per month for more than 3 months; OR
  2) Chronic migraine: Headaches for at least 15 days per month for more than 3 months of which at least 8 days per month are with migraine.

  Initiation criteria:
  - The patient must have experienced an inadequate response[1], intolerance or contraindication to at least two oral prophylactic migraine medications[2] of different classes, and;
  - The patient must be under the care of a physician who has appropriate experience in the management of migraine headaches, and;
  - The physician must provide the number of migraine days per month with the EDS application.

  Initial approval duration = Six (6) months

  Initial Renewal criteria:
  Reduction of at least 50% in the average number of migraine days per month compared to baseline.

  Renewal duration = Six (6) months

[1] Inadequate response to oral prophylactic therapies is defined as less than a 30% reduction in frequency of headache days to an adequate dose and duration of at least two prophylactic medications, which must be of a different class.
[2] Oral prophylactic medication alternatives include: beta blockers, tricyclic antidepressants, verapamil or flunarizine, sodium valproate or divalproex sodium, topiramate, gabapentin.

Subsequent Renewals:
Maintenance of 50% reduction in the average number of migraine days per month from baseline.

EDS approval will not be provided if used in combination with alternative anti-calcitonin gene-related peptide therapies.

Revised Exception Drug Status (EDS) Criteria:

- **canagliflozin, tablet, 100mg, 300mg (Invokana-JAN)**
  For treatment of patients with Type 2 diabetes who are not adequately controlled on, or are intolerant to, metformin AND a sulfonylurea.

- **dapagliflozin, tablet, 5mg, 10mg (Forxiga-AST)**
  a) For treatment of patients with Type 2 diabetes who are not adequately controlled on, or are intolerant to, metformin AND a sulfonylurea.
  b) For treatment of patients with New York Heart Association (NYHA) class II and III heart failure, as an adjunct to standard of care therapy, for the treatment of heart failure with reduced ejection fraction (HFrEF) [Left ventricular ejection fraction (LVEF ≤ 40%)]. Standard of care therapies include beta-blockers, angiotensin converting enzyme inhibitors (ACEIs) or angiotensin receptor blockers (ARBs), plus a mineralocorticoid receptor antagonist (if tolerated).

- **dapagliflozin/metformin HCl, tablet, 5mg/850mg, 5mg/ 1000mg (Xigduo-AST)**
  For treatment of patients with Type 2 diabetes who are not adequately controlled on, or are intolerant to, metformin AND a sulfonylurea.

- **empagliflozin, tablet, 10mg, 25mg (Jardiance-BOE)**
  a) For treatment of patients with Type 2 diabetes who are not adequately controlled on, or are intolerant to, metformin AND a sulfonylurea.
  b) To reduce the incidence of cardiovascular (CV) death in patients with Type 2 diabetes who meet the following criteria:
     - Inadequate glycemic control despite an adequate trial of metformin; AND
     - Established cardiovascular disease defined as one of the following:
       - History of myocardial infarction;
       - Multi-vessel coronary artery disease in two or more major coronary arteries (irrespective of revascularization status);
       - Single-vessel coronary artery disease with significant stenosis and either a positive non-invasive stress test or discharged from hospital with a documented diagnosis of unstable angina within 12 months prior to selection;
       - Last episode of unstable angina > 2 months prior with confirmed evidence of coronary multi-vessel or single-vessel disease;
       - History of ischemic or hemorrhagic stroke;
       - Occlusive peripheral artery disease.

- **empagliflozin/metformin HCl, tablet, 5mg/500mg, 5mg/850mg, 5mg/1000mg, 12.5mg/500mg, 12.5mg/850mg, 12.5mg/1000mg (Synjardy-BOE)**
  a) For treatment of patients with Type 2 diabetes who are not adequately controlled on, or are intolerant to, metformin AND a sulfonylurea.
  b) To reduce the incidence of cardiovascular (CV) death in patients with Type 2 diabetes who meet the following criteria:
     - Inadequate glycemic control despite an adequate trial of metformin; AND
     - Established cardiovascular disease defined as one of the following:
       - History of myocardial infarction;
       - Multi-vessel coronary artery disease in two or more major coronary arteries (irrespective of revascularization status);
       - Single-vessel coronary artery disease with significant stenosis and either a positive non-invasive stress test or discharged from hospital with a documented diagnosis of unstable angina within 12 months prior to selection;
       - Last episode of unstable angina > 2 months prior with confirmed evidence of coronary multi-vessel or single-vessel disease;
       - History of ischemic or hemorrhagic stroke;
       - Occlusive peripheral artery disease.

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

  For treatment of chronic heart failure in patients who have previously tried spironolactone. Patients should be on optimal therapy with an angiotensin converting enzyme inhibitor (ACEI), or an angiotensin receptor blocker (ARB) or an angiotensin receptor-neprilysin inhibitor (ARNI), as well as a beta blocker.

- **insulin aspart, injection solution, 100U/mL (5x3mL) (10mL) (NovoRapid-NOO)**

  Note: Effective February 1, 2022, new patients (i.e., patients without previous approval for NovoRapid) will only be eligible for a listed biosimilar formulation of insulin aspart.

  Exceptions will be considered for patients who require a vial format for administration via an insulin pump.

  a) For treatment of Type 1 diabetes.
  b) For treatment of difficult to control Type 2 diabetes in patients who have not responded to alternative insulin agents listed in the Formulary.

- **linagliptin, tablet, 5mg (Trajenta-BOE)**
  For treatment of patients with Type 2 diabetes who are not adequately controlled on, or are intolerant to, metformin AND a sulfonylurea.

- **linagliptin/metformin, tablet, 2.5mg/500mg, 2.5mg/850mg, 2.5mg/1000mg (Jentadueto-BOE)**
  For treatment of patients with Type 2 diabetes who are not adequately controlled on, or are intolerant to, metformin AND a sulfonylurea.

- **saxagliptin, tablet, 2.5mg, 5mg (Onglyza-AST)**
  For treatment of patients with Type 2 diabetes who are not adequately controlled on, or are intolerant to, metformin AND a sulfonylurea.
- **saxagliptin/metformin HCl, tablet, 2.5mg/500mg, 2.5mg/850mg, 2.5mg/1000mg**

(Komboglyze-AST)
For treatment of patients with Type 2 diabetes who are not adequately controlled on, or are intolerant to, metformin AND a sulfonylurea.

- **sitagliptin phosphate, tablet, 25mg, 50mg (Januvia-MRK)**
  For the treatment of patients with Type 2 diabetes with reduced renal function who are not adequately controlled on, or are intolerant to, metformin AND a sulfonylurea.

- **sitagliptin phosphate, tablet, 100mg (Januvia-MRK)**
  For treatment of patients with Type 2 diabetes who are not adequately controlled on, or are intolerant to, metformin AND a sulfonylurea.

- **sitagliptin and metformin hydrochloride, tablet, 50mg/500mg, 50mg/850mg, 50mg/1000mg (Janumet-MRK); modified release tablet, 50mg/500mg, 50mg/1000mg, 100mg/1000mg (Janumet XR-MRK)**
  For treatment of patients with Type 2 diabetes who are not adequately controlled on, or are intolerant to, metformin AND a sulfonylurea.

The following products were NOT RECOMMENDED for Formulary Listing:

- **buprenorphine/naloxone, soluble film, 2mg/0.5mg, 8mg/2mg, 12mg/3mg (Suboxone-ICL)**
- **esketamine HCl, nasal spray, 28mg/2 actuations (Spravato-JAN)**
- **omeprazole magnesium, delayed release tablet, 20mg (LOSEC MUPS-CHP)**
- **onabotulinumtoxinA, injection, 50IU/vial, 100IU/vial, 200IU/vial (Botox-ALL)-for migraines**
- **tretinoin, gel microspheres, 0.04%, 0.1% (Retin-A Micro-BAU)**

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