May 1, 2025
Bulletin #254
ISSN 1923-0761

SASKATCHEWAN FORMULARY BULLETIN

Full Formulary Benefit:

- **drospirenone, tablet, 4mg (Slynd)**

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

- **berotralstat HCl, capsule, 150mg (Orladeyo)**
  For the routine prevention of attacks of hereditary angioedema (HAE) in patients 12 years of age or older with HAE type I or II[1] diagnosed by a specialist physician experienced in the diagnosis and management of HAE, who:
  - Have experienced at least three HAE attacks within any four week period before initiating berotralstat therapy that required the use of an acute injectable treatment.
    - Applications must include the baseline number of attacks requiring acute injectable treatment in the three months prior to initiation of berotralstat[2].
  - Will not be using berotralstat in combination with other medications used for long-term prophylactic treatment of angioedema[3] (e.g., C1 esterase inhibitors or lanadelumab); A**ND**
  - Will not use a dose of berotralstat that is more than 150mg once daily.

  Initial approval duration: 3 months

  Renewal criteria
  Renewal requests[4] may be considered:
  - After treatment with berotralstat for three months if there has been a 50% or more reduction[2] in the number of HAE attacks where acute injectable treatment was received in the first three months of treatment with berotralstat compared to the rate of attacks observed before starting berotralstat; **OR**
  - For patients with continued response[2] defined as maintenance of 50% or more reduction from baseline with no increase in the number of HAE attacks for which acute injectable treatment was received compared with the number of attacks observed prior to starting treatment with berotralstat;

  AND
  Patients must continue to:
  - Be under the care of a specialist experienced in the diagnosis and management of angioedema; **AND**
  - Not use berotralstat in combination with other long-term prophylactic angioedema treatments (e.g., C1 esterase inhibitors or lanadelumab); **AND**
  - Not use a dose of berotralstat that is more than 150mg once daily even in cases of inadequate response or loss of response.

  Renewal duration: 6 months

  Notes:
  [1] A definitive diagnosis of HAE type I and II requires testing C1 esterase level and activity, as well as C1q levels (to rule out acquired angioedema for which berotralstat is not indicated).
  [2] To determine which patients would be eligible for reimbursement of berotralstat, the current attack rate may be used for patients who are not receiving long-term prophylactic treatment, and a historical attack rate may be used for those who are already receiving long-term prophylactic treatment and intend to transition to berotralstat.

[3] Patients on long-term prophylactic treatment will continue to require access to on-demand treatments that are used in the management of acute attacks.
[4] Coverage will be discontinued for patients who no longer meet the renewal criteria.

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

- **cenobamate, tablet, 12.5mg, 25mg, 50mg, 100mg, 150mg, 200mg; tablet 28-day starter (kit), 12.5mg & 25mg, 50mg & 100mg, 150mg & 200mg; formats revised (Xcopri)**
  For the adjunctive treatment of refractory partial-onset seizures (POS) seizures in patients who meet all of the following criteria:
  a) Are currently receiving two or more antiepileptic drugs; **AND**
  b) less costly antiepileptic drugs are ineffective or inappropriate; **AND**
  c) the medication is being used under the direction of a neurologist.

  Note: Patients should have tried and failed at least two less costly antiepileptic drugs.

- **vericiguat, tablet, 2.5mg, 5mg, 10mg (Verquvo) (possible OEA)**
  For the treatment of symptomatic chronic heart failure (HF) if all of the following are met:
  - Heart failure decompensation event requiring hospitalization within the previous 6 months and/or IV diuretic therapy within the previous 3 months; **AND**
  - Left ventricular ejection fraction below 45%; **AND**
  - Prescribed in combination with standard of care heart failure therapy[1].

  Notes:
  [1] Standard of care therapy includes ALL of the following;
  - angiotensin converting enzyme (ACE) inhibitor, angiotensin receptor blocker (ARB), **OR** angiotensin receptor/neprilysin inhibitor (ARNI); **AND**
  - beta blocker; **AND**
  - mineralocorticoid receptor antagonist (MRA); **AND**
  - sodium glucose cotransporter-2 (SGLT2) inhibitor.

  Consideration may be given to requests where these options are not tolerated or not appropriate

Revised Exception Drug Status (EDS) Criteria:

- **insulin glargine/lixsenatide, solution for injection, 100IU/33mcg/mL (Soliqua) (possible OEA)**
  For treatment of patients with type 2 diabetes in combination with a basal insulin (less than 60U/day) in patients who have been uncontrolled on, or are intolerant to, a sulfonylurea and metformin.

The following products have been REMOVED from the Formulary at the request of the manufacturer:

- **indomethacin, suppository, 50mg, 100mg (Odan-Indomethacin)**

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