May 1, 2021
Bulletin #199
ISSN 1923-0761

SASKATCHEWAN FORMULARY BULLETIN

Update to the 62nd Edition of the Saskatchewan Formulary

Full Formulary Listing:

- **fluticasone propionate, powder for inhalation, 55ug/dose, 113ug/dose, 232ug/dose (Aermony Respiclick-TVM)**

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

- **lanadelumab, solution for injection, 300mg/2mL (pre-filled syringe; vial) (Takhzyro-TAK)**

  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 lanadelumab 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 lanadelumab[2].
  - Will not be using lanadelumab in combination with other medications used for long-term prophylactic treatment of angioedema[3] (e.g., C1 esterase inhibitors); and
  - Will not use a dose of lanadelumab that is more than 300mg every two weeks.

  Initial approval duration: Three (3) months.

  Renewal criteria – approval duration six (6) months
  Renewal requests[4] may be considered:

  - After treatment with lanadelumab 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 lanadelumab compared to the rate of attacks observed before starting lanadelumab, 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 lanadelumab;

  AND

- Patients must continue to:
  - Be under the care of a specialist experienced in the diagnosis and management of angioedema;
  - Not use lanadelumab in combination with other long-term prophylactic angioedema treatments (e.g., C1 esterase inhibitors); and
  - Not use a dose larger than 300mg every two weeks even in cases of inadequate response or loss of response.

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 lanadelumab is not indicated).
2) To determine which patients would be eligible for reimbursement of lanadelumab, 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 lanadelumab.

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.

- **teduglutide, powder for injection, 5mg/vial (Revestive-TAK)**

  For the treatment of adult patients with short bowel syndrome (SBS) who are dependent on parenteral nutrition according to the following criteria:

  - Initiation Criteria:
    - Age 18 years or greater.
    - SBS as a result of major intestinal resection (e.g. due to injury, volvulus, vascular disease, cancer, Crohn's disease).
    - Resection has resulted in dependency on parenteral nutrition (PN) for at least 12 months.
    - PN is required at least three times weekly to meet caloric, fluid or electrolyte needs due to ongoing malabsorption.
    - PN frequency and volume have been stable for at least one month.

  Initial approval duration: Six (6) months

  - Renewal Criteria:
    - A positive response to treatment, defined as at least a 20% reduction in parenteral nutrition volume compared to the baseline volume, achieved within 52 weeks of teduglutide therapy.

  Renewal approval duration: Six (6) months

Notes:

- *Parenteral support volume and percentage of total consumption should be documented at each clinic visit.*
- *Parenteral Support (PS) will represent parenteral nutrition (PN) which encompasses parenteral delivery of lipids, protein, and/or carbohydrates to address caloric needs, and intravenous (IV) fluids (IVF) which addresses fluid and electrolyte needs of patients.*
- *Initiation and assessment for continued treatment with teduglutide should be done only by physicians currently working within a specialized multi-disciplinary intestinal rehabilitation program.*
- *Discontinuation of treatment should be based on the prescribing physician's assessment of the patient's response and tolerance to treatment with teduglutide.*

Pediatric Criteria:

For the treatment of pediatric patients one year of age and above with short bowel syndrome (SBS) who are dependent on parenteral support according to the following criteria:

- Initiation Criteria:
  - Children between one and 17 years old.
  - The cumulative lifetime duration of parenteral support therapy must be at least 12 months.
  - Parenteral support (PS) must provide more than 30% of caloric and/or fluid/electrolyte needs within at least the preceding three months.
  - PS requirements must be stable for at least the preceding three months, or there must have been no improvement in enteral feeding for at least the preceding three months.

Initial approval duration: Six (6) months

- Renewal Criteria:
  - A positive response to treatment, defined as at least a 20%reduction in weight adjusted parenteral support volume compared to the baseline volume.

Renewal approval duration: Six (6) months

Notes:

- *Parenteral support volume and percentage of total consumption should be documented at each clinic visit.*
- *Parenteral Support (PS) will represent parenteral nutrition (PN) which encompasses parenteral delivery of lipids, protein, and/or carbohydrates to address caloric needs, and intravenous (IV) fluids (IVF) which addresses fluid and electrolyte needs of the patients.*

- *Initiation and assessment for continued treatment with teduglutide should be done only by physicians currently working within a specialized multi-disciplinary intestinal rehabilitation program.*
- *Discontinuation of treatment should be based on the prescribing physician's assessment of the patient's response and tolerance to treatment with teduglutide.*

Recommended Additional Strength of an EDS Benefit According to Existing Criteria:

- **dalteparin sodium, injection, 16,500IU pre-filled syringe (0.66mL) (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.
  - (h) For extracorporeal anticoagulation in home hemodialysis patients.
  - (i) For prophylaxis following abdominal or pelvic surgery for up to 28 days.

- **COVID-19 UPDATE – SEE FORMULARY BULLETIN #197**

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