Government of Saskatchewan

October 1, 2020
Bulletin #192
ISSN 1923-0761

SASKATCHEWAN FORMULARY BULLETIN

Update to the 62nd Edition of the Saskatchewan Formulary

Recommended as Full Formulary Listing:

- **epinephrine, prefilled pen, 0.15mg/0.15mL, 0.3mg/0.3mL, 0.5mg/0.5mL (Emerade-BAU)**

Recommended as Exception Drug Status benefit according to the following criteria:

- **inotersen, solution for injection, 284mg/1.5mL (Tegsedi-AKC)**

  For the treatment of polyneuropathy in adult patients with a confirmed genetic diagnosis of hereditary transthyretin-mediated amyloidosis (hATTR), where patients are symptomatic with early-stage neuropathy as defined by ONE of the following:
  - Polyneuropathy disability [PND][1] stage I to ≤ IIIB, or
  - Familial amyloidotic polyneuropathy [FAP][2] stage I or II.

  Patients must be under the care of a specialist with experience in the diagnosis and management of hATTR.

  Exclusion Criteria (at therapy initiation):
  - Patients exhibiting severe heart failure symptoms (defined as New York Heart Association [NYHA] class III or IV); or
  - Patients who have previously undergone a liver transplant; or
  - Patients receiving other interfering ribonucleic acid drugs (such as Onpattro [patisiran]) or transthyretin stabilizers (such as Vyndaqel [tafamidis meglumine]); or
  - Patients who are permanently bedridden and dependent on assistance for basic activities of daily living, or who require end-of-life care.

  Initial approval duration: Nine (9) months

  Discontinuation Criteria:
  Treatment with Tegsedi (inotersen) should be reviewed nine months after the initial approval, and then at least every six months thereafter, to determine the continued clinical benefit for the patient.
  Treatment should be discontinued if the patient is:
  - Permanently bedridden and dependent on assistance for basic activities of daily living, or
  - Receiving end-of-life care[3].

After the initial nine (9) month approval, renewal requests not meeting the discontinuation criteria will be considered for a six (6) month approval duration.

Notes:
[1]PND is classified according to the following stages:

- Stage 0 – No symptoms
- Stage I – Sensory disturbances but preserved walking capability
- Stage II – Impaired walking capacity but ability to walk without a stick or crutches
- Stage IIIA – Walking with the help of one stick or crutch
- Stage IIIB – Walking with the help of two sticks or crutches
- Stage IV – Confined to a wheelchair or bedridden.

[2]FAP is classified according to the following stages:

- Stage 0 – No symptoms
- Stage I – Unimpaired ambulation; mostly mild sensor, motor, and autonomic neuropathy in the lower limbs
- Stage II – Assistance with ambulation required, mostly moderate impairment progression to the lower limbs, upper limbs, and trunk
- Stage III – Wheelchair bound or bedridden; severe sensory, motor, and autonomic involvement of all limbs.

[3]End-of-life care is defined as care in the late stages of a terminal illness, where life expectancy is measured in months, and treatment aimed at cure or prolongation of life is no longer deemed appropriate, but care is aimed at improving or maintaining the quality of remaining life (e.g., management of symptoms such as pain, nausea and stress).

- **semaglutide, solution, 1.34mg/mL (2mg/pen, 4mg/pen) (Ozempic-NOO)**
  For the treatment of type 2 diabetes in combination with metformin and a sulfonylurea, when diet and exercise plus dual therapy with metformin and a sulfonylurea do not achieve adequate glycemic control.

- **tacrolimus, extended release tablet, 0.75mg, 1mg, 4mg (Envarsus PA-PAL)**
  For prophylaxis of graft rejection following renal or liver transplant. This medication should be prescribed by a transplant physician.

Recommended Additional Strength of an Exception Drug Status benefit according to the following criteria:

- **adalimumab, pre-filled syringe, 20mg/0.2mL (Humira-ABV)**
  For pediatric patients requiring a 20mg dose of adalimumab for the treatment of the following indications. **Please note:** once patients escalate to a dose greater than 20mg of adalimumab, they will only be eligible for coverage of the 40mg/0.8mL strength.

(a) Juvenile idiopathic arthritis in patients who are intolerant to, or have inadequate response to one or more disease-modifying anti-rheumatic drugs.

This medication should be prescribed by a rheumatologist.

(b) Crohn's disease as follows:
Initially for a 6 month period: For the treatment of moderate to severely active Crohn's disease in patients refractory to or with contraindications to an adequate course of corticosteroids and other immunosuppressive therapy. Eligible patients should receive an induction dose of 160mg followed by 80mg two weeks later. Clinical response to adalimumab should be assessed after the induction dose.
Ongoing coverage: Adalimumab maintenance therapy should only be provided for responders, as noted above, and for a dose not exceeding 20mg every two weeks. Patients undergoing this treatment should be reviewed every 6 months.

- **tofacitinib, tablet, 10mg (Xeljanz-PFI)**
  For treatment of ulcerative colitis in patients unresponsive to high dose steroids. Note: Clinical response should be assessed after eight (8) weeks of therapy. Ongoing coverage will only be provided for those who respond to therapy. Patients undergoing this treatment should be reviewed every six months by a specialist in this area.

Additional Exception Drug Status criteria:

- **tofacitinib, tablet, 5mg (Xeljanz-PFI)**
  For treatment of ulcerative colitis in patients unresponsive to high dose steroids. Note: Clinical response should be assessed after eight (8) weeks of therapy. Ongoing coverage will only be provided for those who respond to therapy. Patients undergoing this treatment should be reviewed every six months by a specialist in this area.

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