Government of Saskatchewan

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SASKATCHEWAN FORMULARY BULLETIN

Update to the 62nd Edition of the Saskatchewan Formulary

Recommended as a full Formulary benefit:

- **calcipotriol/betamethasone dipropionate, topical aerosol foam, 50mcg/0.5mg/g (Enstilar-LEO)**
- **insulin glargine, injection solution, 100U/mL (Basaglar-LIL) (Basaglar Kwikpen-LIL) (Basaglar Kwikpen 80U-LIL)**
- **insulin lispro, injection solution, 200U/mL (Humalog Kwiken-LIL)**
- **morphine, immediate release capsule, 5mg, 10mg, 20mg, 30mg (M-Ediat-ETH)**

Recommended as a change from Exception Drug Status (EDS) benefit to full Formulary benefit:

- **emtricitabine/tenofovir disoproxil fumarate, tablet, 200mg/300mg (Truvada-GSI and listed generics)**

Recommended Additional Exception Drug Status criteria:

- **adalimumab, pre-filled syringe, 40mg/0.8mL (Humira-ABV); pre-filled pen, 40mg/0.8mL (Humira Pen-ABV)**
  For the treatment of adult patients with active moderate to severe hidradenitis suppurativa (HS) who have not responded to conventional therapy (including systemic antibiotics) and who have met the following:
  - A total abcess and nodule count of 3 or greater
  - Lesions in at least two distinct anatomic areas, one of which must be Hurley Stage II or III
  - An inadequate response to a 90 day trial of oral antibiotics
  - Prescribed by a specialist with expertise in the management of patients with HS

Note: Treatment with adalimumab should be discontinued if there is no improvement after 12 weeks of treatment.

- **rituximab, injection solution, 10mg/mL (Rituxan-HLR)**

  For the treatment of refractory chronic immune thrombocytopenia (ITP) with bleeding complications in patients who:
  a) Have undergone a splenectomy[1]; and
  b) Have tried and are unresponsive to other treatment modalities[2].

  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.
  2) Patients must be refractory to corticosteroids.
     In addition, patients must be refractory to one of the following second-line treatment modalities:
     - Azathioprine,
     - Cyclophosphamide
     - Mycophenolate mofetil
     - Danazol
     - Dapsone

<u>Recommended Additional Version of EDS medication according to the existing criteria:</u>

- **certolizumab pegol, solution for injection, 200U/mL autoinjector (Cimzia-UCB)**

<u>Recommended Revised Exception Drug Status criteria:</u>

- **adalimumab, pre-filled syringe, 40mg/0.8mL (Humira-ABV); pre-filled pen, 40mg/0.8mL (Humira Pen-ABV); golimumab, 50mg/0.5mL, 100mg/1.0mL, pre-filled syringe; autoinjector (Simponi-JAN) ; infliximab, injection (mg),100mg/vial (Remicade-JAN); infliximab, powder for solution, 100mg/vial (Inflectra-HOS); vedolizumab, solution for infusion, 300mg/vial (Entyvio-TAK)**

For treatment of ulcerative colitis in patients unresponsive to high dose steroids.
Note: Clinical response should be assessed after three months 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.

- **denosumab, pre-filled syringe, 60mg/mL (Prolia-AMG)**

  a) To increase bone mass in men or postmenopausal women with osteoporosis who are at a high risk for fracture or who have failed or are intolerant to other available osteoporosis therapy, where the following clinical criteria are met:
     - High fracture risk defined as either:
       - Moderate 10-year fracture risk (10% to 20%) as defined by either the Canadian Association of Radiologists and Osteoporosis Canada (CAROC) tool or the World

Health Organization's Fracture Risk Assessment (FRAX) tool with a prior fragility fracture;
OR
- High 10-year fracture risk (≥ 20%) as defined by either the Canadian Association of Radiologists and Osteoporosis Canada (CAROC) tool or the World Health Organization's Fracture Risk Assessment (FRAX) tool

AND
- Contraindication to oral bisphosphonates.

Notes:
- Bisphosphonate failure will be defined as a fragility fracture and/or evidence of a decline in bone mineral density below pre-treatment baseline levels, despite adherence for one year.
- Contraindication to oral bisphosphonates will be considered. Contraindications include renal impairment, hypersensitivity, and abnormalities of the esophagus (e.g., esophageal stricture or achalasia).

b) For treatment of osteoporosis in patients with a moderate – high 10-year fracture risk (10% or more) and one of the following:
- Men on androgen deprivation therapy for prostate cancer; or
- Women on aromatase inhibitor therapy for breast cancer.

- **methylphenidate HCl, extended release capsule, 10mg, 15mg, 20mg, 30mg, 40mg, 50mg, 60mg, 80mg (Biphentin-PFR)**

For the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients:
(a) Where the use of an another (short or long-acting) formulation has not properly controlled the symptoms of the disease; or
(b) Who cannot swallow tablets/capsules whole and require a long-acting ADHD medication.

Recommended change to the Compound Policy regarding Mouthwash Preparations for Cancer Patients:

Effective January 1, 2018 the following four mouthwash compounds may be submitted to the Drug Plan for adjudication if used in cancer patients for the treatment and prevention of mucositis:
- Alcohol and glycerin free formulation of benzydamine 0.15% mouthwash,
- Alcohol and glycerin free formulation of dexamethasone 0.5mg/5mL mouthwash,
- Alcohol and glycerin free formulation of morphine 0.2% mouthwash, or
- Alcohol and glycerin free formulation of doxepin 0.5% mouthwash.

Please note:
- The above benefit compounds each contain only a single active drug ingredient. Compounded mouthwashes containing any combination of active drug ingredients are not a Drug Plan benefit.
- Once it has been confirmed that one of the above formulations has been prescribed for a cancer patient for the treatment or prevention of mucositis, the pharmacy may submit the prescription to the Drug Plan using the regular compound DIN (i.e., 00990019).
- Pharmacies may see pre-printed prescription forms for these mouthwash compounds from Saskatchewan Cancer Agency physicians.

- Some of the above mouthwash formulations may require specialized compounding materials and procedures, which may require preparation by a compounding pharmacy.
- The Drug Plan and Extended Benefits Branch will be conducting regular audits to ensure that claims are billed appropriately. Any inappropriately billed claims will be reversed.

The following product is NOT RECOMMENDED for Formulary Listing:

- perindopril arginine/amlodipine besylate, tablet, 3.5mg/2.5mg, 7mg/5mg, 14mg/10mg (Viacoram-SEV)

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