

## SASKATCHEWAN FORMULARY BULLETIN

### **Full Formulary Benefit:**

- cabotegravir, tablet, 30mg (Apretude)
- cabotegravir, injection suspension, 200mg/mL (3mL vial) (mg) (Apretude)
- clindamycin phosphate/adapalene/benzoyl peroxide, topical gel, 1.2%/0.15%/3.1% (Cabtreo)

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

- eplontersen, pre-filled autoinjector, 45mg/0.8mL (100mcg) (Wainua)  
For the treatment of adult patients with a confirmed genetic diagnosis of hereditary transthyretin-mediated amyloidosis with polyneuropathy (hATTR-PN), where patients are symptomatic with early-stage neuropathy as defined by ONE of the following:
  - Polyneuropathy disability [PND]<sup>1</sup> stage I to ≤ IIIB, or
  - Familial amyloidotic polyneuropathy [FAP]<sup>2</sup> stage I or II.

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

#### 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 patisiran or vutrisiran) or transthyretin stabilizers (such as tafamidis); or
- Patients who are permanently bedridden and dependent on assistance for basic activities of daily living, or who require end-of-life care<sup>3</sup>.

Initial approval duration: Nine (9) months

#### Discontinuation Criteria:

Treatment with eplontersen 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.

Coverage will be discontinued if the patient is:

- Permanently bedridden and dependent on assistance for basic activities of daily living, or
- Receiving end-of-life care<sup>3</sup>.

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:

<sup>1</sup>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.

<sup>2</sup>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.

<sup>3</sup>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).

- **etrasimod, tablet, 2mg (Velsipity)**

For the treatment of ulcerative colitis in patients unresponsive to high dose steroids. Initial clinical response should be assessed after 12 weeks of therapy.

Ongoing coverage will only be provided for those who respond to therapy.

Note: This product should be used in consultation with a specialist in this area.

This product will not be reimbursed for combination use with other escalated ulcerative colitis treatments (such as biologics and janus kinase inhibitors).

**Additional DIN for an Existing Exception Drug Status (EDS) Benefit:**

Novartis Cosentyx, pre-filled syringe and pre-filled pen, 150mg/1.0mL (DIN 02438070) was previously used for both versions. Now, each version will have a unique DIN.

- **Original DIN 02438070 for pre-filled pen, and**
- **New DIN 02547724 for pre-filled syringe**

**Additional Criteria to an Existing Exception Drug Status (EDS) Benefit: for Hidradenitis Suppurativa (HS)**

- **secukinumab, pre-filled syringe, 75mg/0.5mL, 150mg/1mL; pre-filled pen, 150mg/1mL (Cosentyx)**

Indication	Criteria
<b>Ankylosing Spondylitis</b>	<p><b>Initial:</b> For patients with ankylosing spondylitis (AS), with a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) <math>\geq 4</math>, who have had an inadequate response to two or more non-steroidal anti-inflammatory drugs (NSAIDs) taken sequentially at maximum tolerated or recommended doses for four weeks without symptom control. This treatment should be prescribed by a rheumatologist or clinician with experience treating adult patients with active AS.</p> <p>Approval Duration: 16 weeks</p> <p><b>First Renewal:</b> Coverage can be renewed in patients who have responded to therapy, defined as at least 50% reduction in pre-treatment baseline BASDAI score or by <math>\geq 2</math> units. Approval Duration: One Year</p>

	<p><b>Subsequent renewal:</b> Coverage can continue to be renewed in patients where the BASDAI score does not worsen (i.e. remains within two units of the second assessment) and remains at least two units less than the initial application’s BASDAI score. Approval Duration: One Year</p> <p>Note: Escalated therapies for AS, (such as biologic disease modifying anti-rheumatic drugs (bDMARDs) and janus kinase inhibitors) will not be reimbursed in combination.</p>
<p><b>Hidradenitis Suppurativa</b></p>	<p><b><i>For the treatment of 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:</i></b></p> <ul style="list-style-type: none"> <li>• <b><i>A total abscess and nodule count of 3 or greater;</i></b></li> <li>• <b><i>Lesions in at least two distinct anatomic areas, one of which must be Hurley Stage II or III;</i></b></li> <li>• <b><i>An inadequate response to a 90 day trial of oral antibiotics;</i></b></li> <li>• <b><i>Prescribed by a specialist with expertise in the management of patients with HS.</i></b></li> </ul> <p><b><i>Note: Treatment with secukinumab should be discontinued if there is no improvement after 24 weeks of treatment.</i></b></p> <p><b><i>Initial Approval Duration: 12 months</i></b></p> <p><b><i>Renewal Criteria:</i></b> <b><i>Renewal of secukinumab may be considered for individuals who experience an HiSCR50 response at 12 months.</i></b></p>
<p><b>Psoriatic Arthritis</b></p>	<p>For the treatment of psoriatic arthritis in patients who have failed, or are intolerant to, methotrexate and one other non-biologic, disease-modifying anti-rheumatic drug (DMARD). Note: This product should be used in consultation with a specialist in this area.</p>
<p><b>Plaque Psoriasis</b></p>	<p>For the treatment of adult patients with severe debilitating plaque psoriasis who have failed, or are intolerant to methotrexate OR cyclosporine AND have failed, are intolerant to, or unable to access phototherapy.</p> <p>Coverage will be approved initially for the induction phase of up to 12 weeks. Coverage can be renewed in patients who have responded to therapy.</p> <p>Note: This product should be used in consultation with a specialist in this area.</p> <p>Coverage may be approved as follows: initial dosing of 300mg doses at weeks 0, 1, 2 and 3, followed by monthly maintenance dosing of 300mg doses starting at week 4.</p>

**Revised Exception Drug Status Criteria:**

- **insulin glargine/lixisenatide, solution for injection, 100IU/33mcg/mL (Soliqua) (possible OEA)**  
For the treatment of type 2 diabetes in patients who have been unable to achieve adequate glycemic control on, or are intolerant, to metformin and a basal insulin (less than 60 units per day).

**UPDATE Advanced Glucose Monitoring Product and Criteria:**

- Dexcom G7 Sensor
- Dexcom G6 Sensor
- Dexcom G6 Transmitter
- FreeStyle Libre 2 Sensor Kit
- FreeStyle Libre 3 Plus Sensor Kit **(NEW)**
- Medtronic Guardian Sensor (3) CGM Sensor
- Medtronic Guardian Link (3) Transmitter Kit (for MiniMed 670G pump)
- Medtronic Guardian Link (3) Transmitter Kit (for MiniMed 770G pump)
- Medtronic Guardian Connect Transmitter Starter Kit
- Medtronic Guardian Link 4 Transmitter (for MiniMed 780G pump)
- Medtronic Guardian Sensor 4

Age Group	Criteria
<b>Pediatric (Under 18 years of age)</b>	<p><i>For pediatric patients under the age of 18, who have diabetes treated with insulin, or have hyperinsulinism/hypoglycemic disorders of childhood that require frequent blood glucose monitoring.</i></p> <p><b>Note:</b></p> <ol style="list-style-type: none"> <li><b>1. Diabetes care teams should be familiar with the various products, their Health Canada approved age indications, and relevant features when assisting patients/caregivers with product selection.</b></li> <li><b>2. Requests for patients with diabetes may be approved through the online Exception Drug Status adjudication (OEA) process based on age and prior insulin history.</b></li> <li><b>3. Requests for patients with hyperinsulinism/hypoglycemic disorders of childhood requiring frequent blood glucose monitoring may require a manual application. Applications should include the diagnosis and the requesting pediatric specialist involved in the care of the patient.</b></li> </ol>
<b>Young Adult (ages 18 to 25)</b>	<p>For young adults, ages 18 to 25, with diabetes and being treated with insulin.</p> <p>Note: Requests may be approved through the online Exception Drug Status adjudication (OEA) process based on age and prior insulin history.</p>
<b>Seniors (ages 65 and over)</b>	<p>For seniors, ages 65 and up, with diabetes and being treated with insulin.</p> <p>Note: Requests may be approved through the online Exception Drug Status adjudication (OEA) process based on age and prior insulin history.</p>

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