Government of Saskatchewan

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# SASKATCHEWAN FORMULARY BULLETIN
## Update to the 62nd Edition of the Saskatchewan Formulary

***Non Interchangeable Full formulary Benefit:***

- **needles, pen needles, 32G 4mm, 32G 5mm, 31G 6mm (Nanofine Plus)**

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

- **mecasermin, solution for injection, 10 mg/mL (4mL vial) (mg) (Increlex)**
  **Initiation Criteria**
  For the treatment of growth failure in children and adolescents age 2 to 18 years with confirmed severe primary insulin-like growth factor-1 deficiency (SPIGFD) in whom:
  - Epiphyseal closure has not yet occurred; **AND**
  - The confirmed diagnosis of SPIGFD has been made according to at least ONE of the following:
    - The patient has a known genetic mutation recognized as a cause of SPIGFD; and/or
    - The patient has clinical and biochemical features of SPIGFD. **AND**
  - Mecasermin treatment is being initiated by a pediatric endocrinologist; **AND**
  - Mecasermin is not being prescribed concomitantly with recombinant growth hormone treatment.

  Approval duration: 1 year

  Coverage renewal may be requested for patients who do not meet the discontinuation criteria below.

  **Discontinuation Criteria**
  Patients will not be eligible for coverage initiation or renewal if any of the following are met:
  - The patient has reached their 18th birthday; or
  - The patient's height velocity is less than 1 cm per 6 months or less than 2 cm per year; or
  - The patient's bone age is more than 16 years in boys or 14 years in girls.

- **triheptanoin, oral liquid, 100% w/w (mL) (Dojolvi)**
  **Initiation Criteria**
  For the treatment of patients with an acute life-threatening long-chain fatty acid oxidation disorder (LC-FAOD) in whom:
  - Alternative therapy to conventional even-chain medium-chain triglyceride (MCT) supplementation is required; **and**
  - Triheptanoin treatment will be prescribed and monitored by a clinician experienced in the management of LC-FAOD (i.e. metabolic or genetic specialist physician); **and**
  - One of the following are met:
    - The patient has a confirmed diagnosis of LC-FAOD and is experiencing acute life-threatening events*; or

- The patient lacks a confirmed diagnosis of LC-FAOD but is presenting with acute life-threatening events* consistent with LC-FAOD.

*Acute life-threatening events associated with LC-FAOD may include:

- A catastrophic presentation with acute or recurrent rhabdomyolysis with severe pain, compartment syndrome, acute renal failure requiring hospitalization and life-saving interventions including dialysis, treatment of hyperkalemia, and surgical treatment of compartment syndrome.
- Severe hypoglycemia, recurrent or acute, with or without seizures.
- Cardiomyopathy with or without arrhythmia.

A description of the patient's baseline acute life-threatening events, response to conventional even-chain MCT supplementation, and individualized treatment goals for triheptanoin treatment must be submitted with the initial coverage request.

Approval duration: 12 months

**Renewal Requests**
Patients who exhibit continued benefit with triheptanoin will be considered for renewal. Requesters must include a description of the patient's current response to triheptanoin therapy and clearly outline how this response meets the clinical treatment goals established at initiation.

Renewal duration: up to 12 months

***Additional Exception Drug Status (EDS) Criteria:***

- **levofloxacin, tablet, 250mg (listed generics); 500mg (listed generics)**
  For treatment of:
  (a) Pneumonia in patients with underlying lung disease (excluding asthma).
  (b) Pneumonia in nursing home patients.
  (c) Infections in patients allergic to two or more alternative antibiotics.
  (d) Infections known to be resistant to alternative antibiotics. Resistance must be determined by culture and sensitivity testing (C&S). Where C&S cannot be obtained coverage will be approved when a patient has failed at least 2 other classes of antibiotics, and:
  (e) For completion of antibiotic treatment initiated in hospital when alternatives are not appropriate.
  (f) For treatment of pelvic inflammatory disease.
  ***(g) Infection (and prophylaxis) in patients with prolonged neutropenia.***

- **tadalafil, tablet, 20mg (Adcirca, and listed generics) (possible OEA)**
  For the treatment of:
  a) Pulmonary arterial hypertension on the recommendation of a specialist.
  ***b) Raynaud's phenomenon in patients with severe digital ischemia refractory to lifestyle management, calcium channel blockers and nitrate agents (unless contraindicated or not tolerated).***

  Note: The maximum dose that will be provided as a benefit is 40mg once daily.

***Revised and Additional Exception Drug Status (EDS) Criteria:***

- **dupilumab, solution for injection, 200mg/1.14mL pre-filled syringe, 200mg/1.14mL pre-filled pen, 300mg/2mL pre-filled syringe, 300mg/2mL pre-filled pen (Dupixent)**

| Indication | Criteria |
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| Atopic Dermatitis | For the treatment of refractory moderate to severe[1] atopic dermatitis in patients 12 years and older who:<br>• Have had an adequate trial, or who were intolerant, or are ineligible for EACH of the following therapies:<br>o Maximally tolerated medical topical therapies for atopic dermatitis combined with phototherapy[2] (where available), and<br>o Maximally tolerated medical topical therapies for atopic dermatitis combined with at least one of the four systemic immunomodulators (methotrexate[2], cyclosporine[2], mycophenolate mofetil[2], or azathioprine[2]).<br><br>Requests must include documentation of the Eczema Area and Severity Index (EASI) score.<br><br>Initial approval: Six (6) months.<br><br>**Renewal Criteria**<br>Renewal requests will be considered for patients where there has been a 75% or greater improvement from baseline in the EASI score (EASI-75) after initiation and where this response is subsequently maintained thereafter every six months.<br><br>Renewal requests must include a recent EASI score.<br><br>Renewal approval: Six (6) months.<br><br>Both initial and renewal coverage requests for this indication must be made by, or in consultation with a specialist in this area.<br><br>Dupilumab should not be used in combination with phototherapy, any immunomodulatory agents (including biologics) or other janus kinase (JAK) inhibitor treatment for moderate to severe atopic dermatitis.<br><br>[1]Moderate to severe atopic dermatitis is defined as an EASI score of 16 points or higher.<br>[2]Adequate trials are defined as:<br>o Phototherapy – three times a week for 12 weeks.<br>o Methotrexate – 10 to 20mg per week for 12 weeks.<br>o Cyclosporine – 2.5 to 5mg/kg/day for 12 weeks.<br>o Mycophenolate mofetil – 1g twice daily for 12 weeks.<br>o Azathioprine – 1.5 to 2.5mg/kg/day for 12 weeks. |

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| Asthma for patients 12 and over | *For add-on maintenance treatment of patients age 12 years and older with a type 2/severe eosinophilic phenotype asthma[1], who are inadequately controlled with high-dose inhaled corticosteroids (ICS)[2] and one or more additional asthma controller(s) (e.g., a long-acting beta agonist [LABA]), and*<br>• *Blood eosinophil count of ≥ 300 cells/ µL (*0.3 x $10^9$) AND has experienced two or more clinically significant asthma exacerbations[3] in the in the past 12 months,<br>*OR*<br>• *Blood eosinophil count of ≥ 150cells/µL (*0.15 x $10^9$) *AND is receiving maintenance treatment with oral corticosteroids[4].*<br>*In addition:*<br>o *Dupilumab should not be used in combination with other biologics used to treat asthma.*<br>o *A baseline[5] assessment of asthma symptom control using a validated asthma control questionnaire[6] must be completed prior to initiation of dupilumab treatment and submitted with the application.*<br>o *Baseline[5] and follow up reporting of asthma exacerbations and oral corticosteroid dose are required with the initial and renewal applications.*<br>o *Patients should be managed by a specialist in the treatment of asthma.*<br>*[1]Patients must have a documented diagnosis of severe asthma with a type 2/eosinophilic phenotype.*<br>*[2]High dose inhaled corticosteroids is defined as greater or equal to 500mcg of fluticasone propionate or equivalent daily.*<br>*[3] Clinically significant asthma exacerbations are defined as worsening of asthma resulting in administration of systemic corticosteroids for at least three days, or hospitalization.*<br>*[4]Maintenance oral corticosteroid treatment is defined as receiving greater than the equivalent of prednisone 5mg per day.*<br>*[5]Baseline refers to results achieved prior to initiation of the requested therapy*<br>*[6]A validated asthma control questionnaire includes the Asthma Control Questionnaire (ACQ) or the Asthma Control Test (ACT). The same questionnaire must be used at each assessment for reimbursement renewal as was used at the start of treatment. Scores demonstrating a benefit of treatment for renewal of reimbursement are a decrease of 0.5 points or more on the ACQ or an increase of three or more points in the ACT.*<br><br>*Discontinuation Criteria*<br>*Patients should be reassessed every 12 months to determine efficacy with coverage being discontinued if:*<br>• *First Renewal (based on first 12 months of therapy)*<br>*o The asthma control questionnaire score has not improved from baseline[5,6],*<br>*OR*<br>*o The number of clinically significant exacerbations has increased[3],*<br>*OR*<br>*o The oral corticosteroid maintenance dose has not decreased.* |

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| | • *Subsequent Renewals (after 2 years of therapy)*<br>*o The asthma control questionnaire score achieved at the first renewal has not been maintained subsequently,*<br>*OR*<br>*o The number of clinically significant exacerbations has increased within the previous 12 months,*<br>*OR*<br>*o The oral corticosteroid maintenance dose reduction achieved at the first renewal has not been maintained subsequently.* |
| Asthma for patients 6-11 years of age | For add-on maintenance treatment of patients age 6 to 11 years of age with a type 2/severe eosinophilic phenotype asthma[1], who are inadequately controlled with medium to high-dose inhaled corticosteroids (ICS)[2] and one or more additional asthma controller(s) (e.g., a long-acting beta agonist [LABA]), and:<br>• Blood eosinophil count of ≥ 150 cells/µL (0.15 × 109 /L) within the past 12 months<br>AND<br>• Has uncontrolled asthma with at least one clinically significant asthma exacerbation[3] in the past 12 months.<br><br>In addition:<br>o Dupilumab should not be used in combination with other biologics used to treat asthma.<br>o A baseline[4] assessment of asthma symptom control using a validated asthma control questionnaire[5] must be completed prior to initiation of dupilumab treatment and submitted with the application.<br>o Baseline[4] and follow up reporting of asthma exacerbations and oral corticosteroid dose are required with the initial and renewal applications.<br>o Patients should be managed by a specialist in the treatment of asthma.<br><br>[1]Patients must have a documented diagnosis of severe asthma with a type 2/eosinophilic phenotype.<br>[2]High dose inhaled corticosteroids is defined as greater or equal to 400mcg of fluticasone propionate or equivalent daily. Medium dose inhaled corticosteroid is defined as greater than 100 mcg-400 mcg of fluticasone propionate or equivalent daily.<br>[3]Clinically significant asthma exacerbations are defined as worsening of asthma resulting in hospitalization, an emergency care visit, or treatment with systemic corticosteroids.<br>[4]Baseline refers to results achieved prior to initiation of the requested therapy.<br>[5]A validated asthma control questionnaire includes the Asthma Control Questionnaire (ACQ) or the Asthma Control Test (ACT). The same questionnaire must be used at each assessment for reimbursement renewal as was used at the start of treatment. Scores demonstrating a benefit of |

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| | treatment for renewal of reimbursement are a decrease of 0.5 points or more on the ACQ or an increase of three or more points in the ACT.<br><br>**Discontinuation Criteria**<br>Patients should be reassessed every 12 months to determine efficacy with coverage being discontinued if:<br>• First Renewal (based on first 12 months of therapy)<br>o The asthma control questionnaire score has not improved from baseline[4,5],<br>OR<br>o The number of clinically significant exacerbations has increased.<br>• Subsequent Renewals (after 2 years of therapy)<br>o The asthma control questionnaire score achieved at the first renewal has not been maintained subsequently,<br>OR<br>o The number of clinically significant exacerbations has increased within the previous 12 months. |

***<u>The following products were NOT RECOMMENDED for Formulary Listing:</u>***

- **eculizumab, solution for intravenous infusion, 10mg/mL (Soliris)** for generalized myasthenia gravis (gMG)
- **eculizumab, solution for intravenous infusion, 10mg/mL (Soliris)** for neuromyelitis optica spectrum disorder (NMOSD)
- **cariprazine, capsule, 1.5mg, 3mg, 4.5mg, 6mg (Vraylar)** for schizophrenia
- **pitolistant hydrochloride, tablet, 5mg, 20mg (Wakix)** for excessive daytime sleepiness or cataplexy in adults with narcolepsy

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