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:

- **fluticasone furoate, powder for inhalation, 100mcg, 200mcg (Arnuity Ellipta-GSK)**

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

- **pantoprazole magnesium, enteric-coated tablet, 40mg (Tecta-TAK) (and listed generics)**

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

- **secukinumab, subcutaneous solution, 150mg/1.0mL (Cosentyx-NVR)**

  For treatment of adult patients with **severe debilitating** plaque psoriasis who meet all of the following criteria:
  i) failure to respond to, contraindications to, or intolerant of methotrexate and cyclosporine; AND
  ii) failure to respond to, intolerant to or unable to access phototherapy.
  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.
  This product should be used in consultation with a specialist in this area.
  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.

- **nintedanib, capsule, 100mg, 150mg (OFEV-BOE)**

  Initial approval criteria:

  Adult patients with a diagnosis of mild to moderate idiopathic pulmonary fibrosis (IPF):
  - Diagnosis confirmed by a respirologist and a high-resolution CT scan within the previous 24 months.
  - All other causes of restrictive lung disease (e.g. collagen vascular disorder or hypersensitivity pneumonitis) should be excluded.
  - Mild to moderate IPF is defined as forced vital capacity (FVC) greater than or equal to 50% of predicted.
  - Patient is under the care of a physician with experience in IPF.

  Prescribers may be asked to provide documentation to support confirmation of diagnosis.

Initial approval period: seven months (allow four weeks for repeat pulmonary function tests)

Initial renewal criteria (at 6 months):

Patients must NOT demonstrate progression of disease defined as an absolute decline in percent predicted FVC of ≥10% from initiation of therapy until renewal (initial six month treatment period). If a patient has experienced progression as defined above, then the results should be validated with a confirmatory pulmonary function test conducted four weeks later.

Approval period: six months

Second and subsequent renewals (at 12 months and thereafter):

Patients must NOT demonstrate progression of disease defined as an absolute decline in percent predicted FVC of ≥10% within any 12 month period. If a patient has experienced progression as defined above, then the results should be validated with a confirmatory pulmonary function test conducted four weeks later.

Approval period: 12 months

Exclusion Criteria:

Combination use of Ofev (nintedanib) and Esbriet (pirfenidone) will not be funded.

Notes:

Patients who have experienced intolerance or failure to Ofev (nintedanib) or Esbriet (pirfenidone) will be considered for the alternate agent provided that the patient continues to meet the above coverage criteria.

- **somatropin, prefilled pen, 5mg/1.5mL, 10mg/1.5mL, 15mg/1.5mL (Norditropin Nordiflex-NOO)**

  For treatment of children who have growth failure due to inadequate secretion of normal endogenous growth hormone.

Recommended Additional Exception Drug Status criteria (changes are indicated in bold):

- **fluticasone furoate/vilanterol, 100ug/25ug (Breo-Ellipta-GSK)**

(a) For treatment of COPD in patients where there has been concurrent or past use of a long-acting muscarinic receptor antagonist (LAMA) or a long-acting beta-2 agonist (LABA).

(b) **For the treatment of asthma in patients uncontrolled on inhaled steroid therapy. It is important that these patients also have access to a short-acting beta-2 agonist for symptomatic relief**.

Recommended Additional Formulations of Existing EDS medications according to the following criteria:

- **fluticasone furoate/vilanterol, 200ug/25ug (Breo-Ellipta-GSK)**

  For the treatment of asthma in patients uncontrolled on inhaled steroid therapy. It is important that these patients also have access to a short-acting beta-2 agonist for symptomatic relief.

Recommended Revised Exception Drug Status criteria (changes are indicated in bold):

- **pirfenidone, capsule, 267mg (Esbriet-HLR) – criteria change**

  Initial approval criteria:

  Adult patients with a diagnosis of mild to moderate idiopathic pulmonary fibrosis (IPF):
  - Diagnosis confirmed by a respirologist and a high-resolution CT scan within the previous 24 months.
  - **All other causes of restrictive lung disease (e.g. collagen vascular disorder or hypersensitivity pneumonitis) should be excluded.**
  - Mild to moderate IPF is defined as forced vital capacity (FVC) **greater than or equal to 50% of predicted**.
  - **Patient is under the care of a physician with experience in IPF.**

  Prescribers may be asked to provide documentation to support confirmation of diagnosis.

  Initial approval period: seven months (allow four weeks for repeat pulmonary function tests)

  Initial renewal criteria (at six months):

  Patients must NOT demonstrate progression of disease defined as an absolute decline in percent predicted FVC of ≥10% from initiation of therapy until renewal (initial six month treatment period). If a patient has experienced progression as defined above, then the results should be validated with a confirmatory pulmonary function test conducted four weeks later.

  Approval period: six months

  Second and subsequent renewals (at 12 months and thereafter):

  Patients must NOT demonstrate progression of disease defined as an absolute decline in percent predicted FVC of ≥10% within any 12 month period. If a patient has experienced progression as defined above, then the results should be validated with a confirmatory pulmonary function test conducted four weeks later.

  Approval period: 12 months

  Exclusion Criteria:

  Combination use of Esbriet (pirfenidone) and Ofev (nintedanib) will not be funded.

Notes:

Patients who have experienced intolerance or failure to Esbriet (pirfenidone) or Ofev (nintedanib) will be considered for the alternate agent provided the patient continues to meet the above coverage criteria.

The following product was NOT RECOMMENDED for Formulary Listing:

- **riociguat, tablet, 0.5mg, 1mg, 1.5mg 2mg, 2.5mg (Adempas-BAY) – for pulmonary arterial hypertension**

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