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:

- **benztropine mesylate, tablet, 1mg (PDP-Benztropine-PED)**
- **methotrexate, pre-filled syringe, 7.5mg/0.75mL, 10mg/mL, 15mg/1.5mL (Metoject-MDX); pre-filled syringe, 7.5mg/0.15mL, 10mg/0.2mL, 12.5mg/0.25mL, 15mg/0.3mL, 17.5mg/0.35mL, 20mg/0.4mL, 22.5mg/0.45mL, 25mg/0.5mL (Metoject Subcutaneous-MDX)**
- **potassium chloride, capsule, 8mmol (Jamp-Potassium Chloride ER-JPC)**

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

- **etanercept, pre-filled syringe, 25mg/0.5mL, 50mg/mL; pre-filled autoinjector, 50mg/mL (Erelzi-SDZ)**

  For treatment of:

  a) Active rheumatoid arthritis in patients who have failed or are intolerant to methotrexate and leflunomide.

  b) Active juvenile rheumatoid arthritis in pediatric patients who have failed one DMARD.

  Note: Exceptions can be considered in cases where methotrexate or leflunomide are contraindicated. Treatment should be combined with an immunosuppressant.

  c) Ankylosing spondylitis (AS) according to the following criteria:

  Initial Application (for a 12-week medication trial):

  - For patients who have already been treated conventionally with two or more non-steroidal anti-inflammatory drugs (NSAIDs) taken sequentially at maximum tolerated or recommended doses for four weeks without symptom control;

    AND

  - Satisfy New York diagnostic criteria: a score ≥ 4 on the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) AND a score of ≥ 4 on the 0-10cm spinal pain visual analogue scale (VAS) on two occasions at least 12 weeks apart without any change of treatment.

Second Application (following the initial 12-week approval, requests will be considered for a one-year approval timeframe):

- Adequate response to treatment assessed at 12 weeks defined as at least 50% reduction in pre-treatment baseline BASDAI score by ≥ 2 units AND a reduction of ≥ 2cm in the spinal pain VAS.

Subsequent Annual Renewal Applications (beyond the first 15 months, requests are to be submitted annually for consideration of ongoing approval on a yearly basis):

- 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.

Notes:

- Requests for coverage for this indication must be made by a rheumatologist.
- Applications for this indication must be submitted on the designated EDS Application – Ankylosing Spondylitis Drugs form found on the Formulary website.
- Coverage may be provided for one switch for patients transitioning to another anti-TNF biologic agent following an adequate trial of the first agent if the patient fails to respond, if there is a loss of response, or is intolerant, to the first agent. Approval will be subject to the published Exception Drug Status criteria for the requested biologic agent.
- Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.

For all of the above indications this product should be used in consultation with a specialist in this area.

- **ixekizumab, subcutaneous injection, 80mg/mL (Taltz-LIL)**

For treatment of adult patients with severe debilitating plaque psoriasis who meet all of the following criteria:

- failure to respond to, contraindication to, or intolerant of methotrexate and cyclosporine; AND
- 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.

- **glycerol phenylbutyrate, oral liquid, 1.1g/mL (Ravicti-HOR)**

  For the chronic management of urea cycle disorders (UCDs).
  Medication should be prescribed in consultation with a specialist in this area.

- **paliperidone palmitate, prolonged release pre-filled syringe, 175mg/0.875mL, 263mg/1.315mL, 350mg/1.75mL, 525mg/2.625mL (Invega Trinza-JAN)**

  For the treatment of patients exhibiting a compliance problem with an oral antipsychotic and in whom the administration of a conventional injectable extended action antipsychotic is ineffective or poorly tolerated.

- **selexipag, tablet, 200mcg, 400mcg, 600mcg, 800mcg, 1000mcg, 1200mcg, 1400mcg, 1600mcg (Uptravi-ACT)**

  For the long-term treatment of idiopathic pulmonary arterial hypertension (PAH), heritable PAH, PAH associated with connective tissue disorders, and PAH associated with congenital heart disease, in adult patients with World Health Organization (WHO) functional class (FC) II to III who have failed to control symptoms or are intolerant to a PDE5 inhibitor (such as sildenafil citrate or tadalafil) AND one other drug (such as bosentan) with or without a calcium channel blocker. This medication should be prescribed under the direction of a specialist in the area of PAH.

  Note: Combination therapy with prostacyclin (such as epoprostenol) or prostacyclin analog therapies (such as treprostinil) will NOT be covered.

- **sodium phenylbutyrate, granules, 483mg/g (Pheburane-MDK)**

  For the chronic management of urea cycle disorders (UCDs).
  Medication should be prescribed in consultation with a specialist in this area.

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

- **leuprolide acetate, injection, 3.75mg/mL, 7.5mg/mL; depot injection, 11.25mg (3-month SR) (Lupron Depot-ABV)**

  For treatment of:

  a) Endometriosis. *(Coverage may be repeated after a six month lapse, for another 6 month course).*

  b) Menorrhagia in preparation for endometrial ablation, and:

  c) For pre-treatment of uterine fibroids prior to surgical removal.

*Coverage **for the above indications** will be provided for a maximum of 6 months.*

d) Central precocious puberty.

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

a) 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.

b) For the treatment of psoriatic arthritis in patients who have had an inadequate response to, or are intolerant to, methotrexate and one other DMARD.

Note: Exceptions can be considered in cases where methotrexate or leflunomide are contraindicated.

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

c) For the treatment of ankylosing spondylitis (AS) according to the following criteria:

Initial Application (for a 16-week medication trial):

- **For patients who have already been treated conventionally with two or more non-steroidal anti-inflammatory drugs (NSAIDs) taken sequentially at maximum tolerated or recommended doses for four weeks without symptom control;**

AND

- **Satisfy New York diagnostic criteria: a score ≥ 4 on the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) <u>AND</u> a score of ≥ 4 on the 0-10cm spinal pain visual analogue scale (VAS) on two occasions at least 12 weeks apart without any change of treatment.**

Second Application (following the initial 16-week approval, the requests will be considered for a one-year approval timeframe):

- **Adequate response to treatment assessed at 16 weeks defined as at least 50% reduction in pre-treatment baseline BASDAI score by ≥ 2 units <u>AND</u> a reduction of ≥ 2cm in the spinal pain VAS.**

Subsequent Annual Renewal Applications (beyond the first 16 months, requests are to be submitted annually for consideration of ongoing approval on a yearly basis):

- **The BASDAI score does not worsen (i.e. remains within two units of the second assessment) <u>AND</u> remains at least two units less than the initial application's BASDAI score.**

Notes:

- **Requests for coverage for this indication must be made by a rheumatologist.**
- **Applications for this indication must be submitted on the designated EDS Application – Ankylosing Spondylitis Drugs form found on the Formulary website.**
- **Coverage may be provided for one switch for patients transitioning to another biologic agent following an adequate trial of the first agent if the patient fails to respond, if there is a loss of response, or is intolerant, to the first agent. Approval will be subject to the published Exception Drug Status criteria for the requested biologic agent.**
- **Patients will not be permitted to switch back to a previously trialed biologic agent if they were deemed unresponsive to therapy.**
- **Patients are limited to receiving one biologic agent at a time regardless of the condition for which it is being prescribed.**

<u>Recommended Additional Formulations of Existing EDS medications according to the following criteria:</u>

- **pirfenidone, tablet, 267mg, 801mg (Esbriet-HLR)**

Initial approval criteria:

Adult patient 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.

- **lamivudine, oral solution, 5mg/mL (Heptovir-GSK)**

For management of hepatitis B.

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

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

- **etanercept, powder for injection (vial), 25mg/vial; pre-filled syringe, 50mg/mL (Enbrel-AMG)**

  For treatment of:
  b) Active juvenile rheumatoid arthritis in pediatric patients who have failed one DMARD.

  Effective April 1, 2018, new patients (i.e., patients without previous EDS approval for Enbrel) will be eligible only for a listed biosimilar formulation of etanercept for the treatment of juvenile rheumatoid arthritis.

The following products were NOT RECOMMENDED for Formulary Listing:

- apremilast, tablet, 30mg; titration pack, 10mg, 20mg, 30mg (Otezla-CLG) - plaque psoriasis and psoriatic arthritis
- canagliflozin/metformin HCl, tablet, 50mg/500mg, 50mg/850mg, 50mg/1000mg, 150mg/500mg, 150mg/850mg, 150mg/1000mg (Invokamet-JAN)
- sarilumab, solution for subcutaneous injection, 150mg/1.14mL, 200mg/1.14mL (Kevzara-AVT)

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