Government of Saskatchewan

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SASKATCHEWAN FORMULARY BULLETIN

Update to the 62nd Edition of the Saskatchewan Formulary

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

- **macitentan, tablet, 10mg (Opsumit-JAN)**

  For the treatment of pulmonary arterial hypertension, on the recommendation of a specialist.

- **patisiran, solution for injection, 2mg/mL (Onpattro-ALN)**

  For the treatment of polyneuropathy in adult patients with a confirmed genetic diagnosis of hereditary transthyretin-mediated amyloidosis (hATTR), where patients are symptomatic with early-stage neuropathy as defined by ONE of the following:

  - Polyneuropathy disability [PND][1] stage I to ≤ IIIB, or
  - Familial amyloidotic polyneuropathy [FAP][2] stage I or II.

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

  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 Tegsedi (inotersen) or transthyretin stabilizers (such as Vyndaqel [tafamidis meglumine]); or
  - Patients who are permanently bedridden and dependent on assistance for basic activities of daily living, or who require end-of-life care.

  Initial approval duration: Nine (9) months.

  Discontinuation Criteria:

  Treatment with Onpattro (patisiran) 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.

  Treatment should be discontinued if the patient is:
  - Permanently bedridden and dependent on assistance for basic activities of daily living, or
  - Receiving end-of-life care[3].

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:

[1]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

[2]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.

[3]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).

Revised Exception Drug Status Criteria:

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

Effective March 1, 2021, all listed Enbrel indications have a biosimilar etanercept option. As such, new patients (i.e., patients without previous EDS approval for Enbrel) will be eligible only for a listed biosimilar formulation of etanercept.

For treatment of:

(a) For patients with active rheumatoid arthritis who have failed or are intolerant to methotrexate and leflunomide.

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

(b) Juvenile idiopathic arthritis in 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) Psoriatic arthritis in patients who have failed or are intolerant to methotrexate and one other DMARD.

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

(d) For patients with ankylosing spondylitis, 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 cm 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 OR 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 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.

(e) 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 16 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.

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

Effective March 1, 2021, new patients (i.e., patients **without** previous EDS approval for Enbrel) will only be eligible for one of the listed biosimilar formulations of etanercept.

- **etanercept, solution for injection, 25mg/0.5mL pre-filled syringe, 50mg/mL pre-filled syringe, 50mg/mL pre-filled autoinjector (Erelzi-SDZ)**
- **etanercept, subcutaneous injection, pre-filled syringe/pre-filled pen, 50mg/mL (Brenzys-MRK)**

Note: These products are not interchangeable. When requesting coverage, please state which specific etanercept product is being prescribed to avoid administrative and assessment delays.

For treatment of:

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

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

b) Juvenile idiopathic arthritis in 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) Psoriatic arthritis in patients who have failed or are intolerant to methotrexate and one other DMARD.

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

d) 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, the 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 OR 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 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.

e) For treatment of adult patients with severe debilitating plaque psoriasis who meet all of the following:
   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 16 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.

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

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