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:

- **diazoxide, capsule, 100mg (Proglycem-MRK)**

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

- **etanercept, subcutaneous injection, pre-filled syringe/pre-filled pen, 50mg/mL (Brenzys-MRK)**
  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) 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 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 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.

- **fentanyl, 37ug/hr transdermal system (generic)**
  For treatment of patients:
  (a) Intolerant to, or unable to take, oral sustained-release strong opioids; or
  (b) As an alternative to subcutaneous narcotic infusion therapy.

  Pharmacists are not required to call the Drug Plan if a prescription has been filled for an oral sustained release or injectable opioid, such as hydromorphone, morphine, or oxycodone in the past 6 months.

- **pilocarpine HCl, tablet, 5mg (Salagen-PFI)**
  For the treatment of:
  (a) Symptoms of xerostomia (dry mouth) due to salivary gland hypofunction caused by radiotherapy for cancer of the head and neck; or
  (b) Symptoms of xerostomia (dry mouth) and xerophthalmia (dry eyes) in patients with Sjogren's syndrome.

- **rotigotine, transdermal system, 2mg/24hr, 4mg/24hr, 6mg/24hr, 8mg/24hr (Neupro-UCB)**
  For adjunctive therapy to levodopa for the treatment of patients with advanced stage Parkinson's disease (APD).

Recommended Revised Exception Drug Status criteria:

- **lansoprazole/clarithromycin/amoxicillin, tablet, 30mg/500mg/500mg (Hp-PAC-BGP)**
  For **14-day** eradication of H. pylori-related infections in individuals with peptic ulcer disesase. *Provision will be made for additional coverage in treatment failures.*

- **certolizumab pegol, solution for injection, 200mg/ml (Cimzia-UCB)**
  For treatment of 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 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 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.

- **esomeprazole, delayed-release tablet, 20mg, 40mg (Nexium-AST) and listed generics**
  (d) For **14-day** eradication of H. pylori-related infections in individuals with peptic ulcer disease. *Provision will be made for additional coverage in treatment failures.*

- **etanercept, powder for injection (vial), 25mg/vial; pre-filled syringe, 50mg/mL (Enbrel-AMG)**
  For treatment of:
  (a) **For patients with active rheumatoid arthritis who have failed or are intolerant to methotrexate and leflunomide and have had initial approval of Enbrel before October 1, 2017.**

  Effective October 1, 2017, 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 rheumatoid arthritis.

  (b) Active juvenile rheumatoid arthritis in pediatric patients who have failed one DMARD.
  (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 who have had initial approval of Enbrel before October 1, 2017, according to the following criteria.**

  Effective October 1, 2017, 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 ankylosing spondylitis.

  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 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.

(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.

<u>The following product is NOT RECOMMENDED for Formulary Listing:</u>

- **budesonide, 9mg delayed and extended release, tablet (Cortiment-FER)**

Saskatchewan Ministry of Health
Drug Plan and Extended Benefits Branch
2nd Floor, 3475 Albert Street
Regina, Saskatchewan S4S 6X6
(306) 787-3317
1-800-667-7581