Government of Saskatchewan

November 1, 2014
Bulletin #150
ISSN 1923-0761

SASKATCHEWAN FORMULARY BULLETIN

Update to the 62nd Edition of the Saskatchewan Formulary

New Exception Drug Status (EDS) Listings Effective November 1, 2014 according to the following criteria:

- **teriflunomide, tablet, 14 mg (Aubagio-GZY)**

  Approval for coverage will be given to patients who are assessed and meet the following criteria:
  - have clinical definite relapsing and remitting multiple sclerosis;
  - have had at least two documented attacks of MS during the previous two years (an attack is defined as the appearance of new symptoms or worsening of old symptoms, lasting at least 24 hours in the absence of fever, preceded by stability for at least one month);
  - are fully ambulatory for 100 meters without aids (canes, walkers or wheelchairs)
  - Extended Disability Status Scale (EDSS) 5.5 or less;
  - are age 18 or older (Note: Applications for patients under 18 will be considered.)

  Physicians should also forward the following information:
  - documentation of attacks, date of onset, date of diagnosis;
  - neurological findings, Extended Disability Status Scale (EDSS);
  - MRI reports or other significant information;
  - list of current medications.

- **pirfenidone, capsule, 267mg (Esbriet-IMC)**

  Initial approval criteria:

  Adult patients who have a diagnosis of mild to moderate idiopathic pulmonary fibrosis (IPF)* confirmed by a respirologist and a high-resolution CT scan within the previous 24 months.

  Note:
  - **Mild-moderate IPF is defined as: a FVC between 50-80% predicted, and a Percent Carbon Monoxide Diffusing Capacity (%DLCO) between 30-90% predicted.*
  - *In order to access Esbriet, patients must enrol in the Inspiration Patient Assistance Program (product is only available through a network of specialty pharmacies)*

  Initial approval period: 7 months

  Initial renewal criteria:

  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 6 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 4 weeks later.

  Approval period: 6 months

Second renewal (12 months after initiation of therapy):

Patients must NOT demonstrate progression of disease defined as an absolute decline in percent predicted FVC of ≥10% since initiation of therapy (baseline). If a patient has experienced progression as defined above, then the results should be validated with a confirmatory pulmonary function test conducted 4 weeks later.

Approval period: 12 months

- **simeprevir, capsule, 150mg (Galexos-JAN)**

  For the treatment of chronic hepatitis C genotype 1 infection in adult patients with compensated liver disease, in combination with peginterferon alpha/ribavirin (pegINF/RBV) when all of the following criteria are met:
  - detectable levels of hepatitis C virus (HCV) RNA in the last six months
  - a fibrosis stage of F2, F3, or F4
  - one course of treatment only (12 weeks duration).

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

  Exclusion Criteria:
  - Patients with the NS3 Q80K polymorphism.
  - Patients who have received a prior treatment with boceprevir or telaprevir in combination with pegINF/RBV and did NOT receive an adequate response.
  - Simeprevir in combination with sofosbuvir.

- **lanthanum carbonate hydrate, chewable tablet, 250 mg, 500 mg, 750 mg, 1000mg (Fosrenol-SCI)**

  For treatment of:
  a) end-stage renal disease in patients intolerant to aluminum or calcium containing phosphate-binding agents.
  b) end-stage renal disease in patients where aluminum or calcium containing phosphate-binding agents are inappropriate.

- **aclidinium bromide, powder for inhalation, 400 mcg (Tudorza Genuair-ACL)**

  For treatment of:
  a) COPD in patients unresponsive to short-acting beta agonists or short-acting anticholinergic bronchodilators, OR
  b) Moderate to severe COPD (i.e. Medical Research Council (MRC) dyspnea scale score 3 to 5), in conjunction with spirometry demonstrating moderate to severe airflow obstruction (i.e. FEV1 < 60 % and low FEV1/FVC < 0.7), without a trial of short-acting agents.

Recommended as Exception Drug Status benefit on a case-by-case basis

- **bupivacaine intrathecal pain pump compound**

  Requests for compound mixtures containing bupivacaine for intrathecal pain pump will be reviewed on a case-by-case basis when prescribed by a specialist, for the treatment of severe pain in patients who have exhausted all alternative treatment options.

Revised Exception Drug Status Criteria (see bold italicized portion):

- **alendronate sodium, tablet, 10mg (Apo-Alendronate-APX) (Teva-Alendronate-TEV) (Mylan-Alendronate-MYL) (Sandoz Alendronate-SDZ) (Alendronate Sodium Tablets-AHI) (Ran-Alendronate-RAN) (Auro-Alendronate-API) (Mint-Alendronate-MNT); tablet, 70mg (Fosamax-MSD) (CO Alendronate-COB) (pms-Alendronate-PMS) (Apo-Alendronate-APX) (Teva-Alendronate-TEV) (ratio-Alendronate-RPH) (Mylan-Alendronate-MYL) (pms-Alendronate-FC-PMS) (Alendronate-SAN) (Alendronate Sodium-AHI) (Alendronate Sodium Tablets-AHI) (Ran-Alendronate-RAN) (Jamp-Alendronate-JPC) (Auro-Alendronate-API) (Mint-Alendronate-MNT)**
  a) For treatment of osteoporosis ***in patients*** with a 20% or greater 10-year fracture risk;
  Note: The fracture risk can be determined by the World Health Organization's fracture risk assessment tool, FRAX, or the most recent (2010) version of the Canadian Association of Radiologist and Osteoporosis Canada (CAROC) table.
  The links to the tools are available at:
  http://www.shef.ac.uk/FRAX/tool.jsp?country=19
  http://www.osteoporosis.ca/multimedia/pdf/CAROC.pdf
  The Drug Plan will not require FRAX or CAROC documentation to be included with EDS applications for oral bisphosphonates.
  b) For treatment of osteoporosis in patients with:
    - ***Pre-existing and/or recent fragility fractures; or***
    - ***Glucocorticoid treatment for a duration of 3 months or longer; or***
    - ***Men on androgen deprivation therapy for prostate cancer; or***
    - ***Women on aromatase inhibitor therapy for breast cancer.***
  c) For treatment of osteogenesis imperfecta.

- **risedronate sodium, tablet, 5mg, 150mg (Actonel-WCI) (Teva-Risedronate-TEV) (Apo-Risedronate-APX) (Mylan-Risedronate-MYL) (pms-Risedronate-PMS); tablet, 35mg (Actonel-ASP) (Apo-Risedronate-APX) (pms-Risedronate-PMS) (ratio-Risedronate-RPH) (Sandoz Risedronate-SDZ) (Mylan-Risedronate-MYL) (Risedronate-SAN) (Jamp-Risedronate-JPC) (Auro-Risedronate-API) (Risedronate-35-SIV) (Teva-Risedronate-TEV); delayed release tablet, 35mg (Actonel DR-ASP)**
  a) For treatment of osteoporosis ***in patients*** with a 20% or greater 10-year fracture risk;
  Note: The fracture risk can be determined by the World Health Organization's fracture risk assessment tool, FRAX, or the most recent (2010) version of the Canadian Association of Radiologist and Osteoporosis Canada (CAROC) table.
  The links to the tools are available at:
  http://www.shef.ac.uk/FRAX/tool.jsp?country=19
  http://www.osteoporosis.ca/multimedia/pdf/CAROC.pdf
  The Drug Plan will not require FRAX or CAROC documentation to be included with EDS applications for oral bisphosphonates.
  b) For treatment of osteoporosis in patients with:
    - ***Pre-existing and/or recent fragility fractures; or***
    - ***Glucocorticoid treatment for a duration of 3 months or longer; or***
    - ***Men on androgen deprivation therapy for prostate cancer; or***
    - ***Women on aromatase inhibitor therapy for breast cancer.***
  c) For treatment of osteogenesis imperfecta.

- **tocilizumab, solution for IV infusion, 20mg/mL (4mL vial, 10mL vial, 20mL vial) (Actemra-HLR)**

a) For treatment of moderate to severe active rheumatoid arthritis, alone or in combination with methotrexate (MTX) or other disease-modifying antirheumatic drugs (DMARDs), in patients who have failed to respond to an adequate trial of DMARDs.
Patients should be assessed after 16 weeks of treatment and therapy continued only if there is a clinical response to treatment.
Actemra should not be used concomitantly with TNF alpha inhibitors.
This product should be used in consultation with a specialist in this area.

b) For the treatment of active systemic juvenile idiopathic arthritis (sJIA) in patients two years of age and older who have responded inadequately to nonsteroidal anti-inflammatory drugs (NSAIDs) and systemic corticosteroids (with or without methotrexate), due to intolerance or lack of efficacy.
Actemra should not be used concomitantly with TNF alpha inhibitors.
This product should be used in consultation with a specialist in this area.

c) For treatment of polyarticular juvenile idiopathic arthritis in patients 2 years of age and older, who are intolerant to, or have inadequate response to one or more disease-modifying anti-rheumatic drugs. This medication should be prescribed by a rheumatologist.

- **adalimumab, pre-filled syringe, 40mg/0.8mL (Humira-ABB); pre-filled pen, 40mg/0.8mL (Humira Pen-ABV)**

For treatment of:
(a) active rheumatoid arthritis in patients who have failed methotrexate and leflunomide.
(b) active rheumatoid arthritis in patients intolerant to methotrexate and leflunomide.
(c) psoriatic arthritis in patients who have failed methotrexate and one other DMARD.
(d) psoriatic arthritis in patients who are intolerant to methotrexate and one other DMARD.
Note: Treatment should be combined with an immunosuppressant. This product should be used in consultation with a specialist in this area. Exceptions can be considered in cases where methotrexate or leflunomide are contraindicated.
(e) For treatment of ankylosing spondylitis (A.S.) according to the following criteria:
1) For patients who have already been treated conventionally with two or more NSAIDs taken sequentially at maximum tolerated or recommended doses for four weeks without symptom control. AND
2) 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 VAS on two occasions at least 12 weeks apart without any change of treatment. AND
3) 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 > 2 cm in the spinal pain VAS.

NOTE:
Coverage will not be provided when a patient switches to another anti-TNF agent if the patient fails to respond or if there is loss of response to the first agent. Requests for coverage for this indication must be made by a rheumatologist.
A second application would also be required after 12 weeks to assess and would need to show an improvement to the patient's condition on either of these medications. Please refer to the Formulary website for the application form.
Subsequent annual renewal requests (beyond 15 months) will be considered for patients whose BASDAI scores do not worsen (i.e. remains within two points of the second assessment).

(f) Crohn's disease as follows:
Initially for a 6 month period: For the treatment of moderate to severely active Crohn's disease in patients refractory to or with contraindications to an adequate course of 5-aminosalicylic acid and corticosteroids and other immunosuppressive therapy. Eligible patients should receive an induction dose of 160mg followed by 80mg two weeks later. Clinical response to adalimumab should be assessed after the induction dose.

Ongoing coverage: Adalimumab maintenance therapy should only be provided for responders, as noted above, and for a dose not exceeding 40mg every two weeks. Patients undergoing this treatment should be reviewed every 6 months by a specialist.

(g) For treatment of adult patients with severe debilitating plaque psoriasis who meet all of the following criteria:
failure to respond to, contraindications 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 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.

(h) ***For treatment of polyarticular juvenile idiopathic arthritis in pediatric patients who are intolerant to, or have inadequate response to one or more disease-modifying anti-rheumatic drugs. This medication should be prescribed by a rheumatologist.***

Drugs Reviewed and Not Approved for Listing in the Saskatchewan Formulary:

- **rotigotine, transdermal patch, 2 mg/24h, 4 mg/24h, 6 mg/24h, 8 mg/24h (Neupro-UCB)** for idiopathic Parkinson's disease

- **dipyridamole, tablet, 50mg, 75mg (Apotex)**

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