Government of Saskatchewan

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SASKATCHEWAN FORMULARY BULLETIN

Update to the 62nd Edition of the Saskatchewan Formulary

New Exception Drug Status (EDS) Listings Effective May 1, 2016 according to the following criteria:

- **aclidinium bromide/formoterol fumarate dihydrate, 400µg/12mcg, inhalation powder (Duaklir Genuair-AST)**

  For treatment of airflow obstruction in patients with moderate to severe COPD, as defined by spirometry, who have had an inadequate response to a long-acting beta-2 agonist (LABA), OR a long-acting muscarinic antagonist (LAMA).

- **rifaximin, tablet, 550mg (Zaxine-LUP)**

  For recurrence of overt hepatic encephalopathy (HE), for patients who are unable to achieve adequate control of HE with maximal tolerated doses of lactulose alone.

  Note: To be used in combination with maximal tolerated dose of lactulose.

- **tiotropium/olodaterol, solution for inhalation, 2.5ug/2.5ug (Inspiolto Respimat-BOE)**

  For treatment of airflow obstruction in patients with moderate to severe COPD, as defined by spirometry, who have had an inadequate response to a long-acting beta-2 agonist (LABA), OR a long-acting muscarinic antagonist (LAMA).

- **tofacitinib, tablet, 5mg (Xeljanz-PFI)**

  For the treatment of active rheumatoid arthritis in patients who have failed or are intolerant to methotrexate and leflunomide.

  Maximum daily dose is 10 mg per day.

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

- **ulipristal acetate, tablet, 5mg (Fibristal-ASP)**

  For the treatment of moderate to severe signs and symptoms of uterine fibroids in adult women of reproductive age who are eligible for surgery. Approval duration will not exceed three months (i.e. 13 weeks), per patient, per lifetime.
  Patients should be under the care of an obstetrician/gynecologist or a physician experienced in the management of gynecological conditions such as uterine fibroids.

New Exception Drug Status (EDS) Listings Effective May 1, 2016 with possible online EDS adjudication according to the following criteria:

- **darunavir/cobicistat, tablet, 800mg/150mg (Prezcobix-JAN)**

  For treatment of human immunodeficiency virus (HIV) infection in treatment-naïve and treatment-experienced patients without darunavir (DRV) resistance-associated mutations (RAMS). *This drug, as with other antivirals in the treatment of HIV, should be used under the direction of an infectious disease specialist.*

- **empagliflozin, tablet, 10mg, 25mg (Jardiance-BOE)**

  For treatment of patients with Type 2 diabetes who have concurrent prescriptions for metformin and a sulfonylurea.

  This product should not be used in combination with dipeptidyl peptidase-4 inhibitors.

  Please note: This product should be used in patients with diabetes who are not adequately controlled on or are intolerant to metformin and/or a sulfonylurea, and for whom insulin is not an option.

- **umeclidinium bromide, 62.5µg dry powder for oral inhalation (Incruse Ellipta-GSK)**

  (a) For treatment of COPD in patients unresponsive to short-acting beta agonists or short-acting anticholinergic bronchodilators, or
  (b) For treatment of 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.

New Exception Drug Status Criteria (in addition to existing criteria):

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

  Ankylosing spondylitis (A.S.):
  - 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**
    3) A score of ≥ 4cm on the 0-10cm spinal pain VAS on two occasions at least 12 weeks apart without any change of treatment; **AND**
    4) 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.

    Coverage will not be provided when a patient switches to another anti-TNF agent if the patient fails to respond or if there is a loss of response to the first agent. Requests for coverage for this indication must be made by the 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.
    http://formulary.drugplan.health.gov.sk.ca/AppForms.aspx

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).

Psoriatic arthritis:

- Psoriatic arthritis in patients who have failed or are intolerant to methotrexate and one other DMARD.

  Treatment should be combined with an immunosuppressant. 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.

New Non-Interchangeable Exception Drug Status (EDS) Listings Effective May 1, 2016 according to the following criteria:

- **infliximab, powder for solution, 100mg/vial (Inflectra-HOS)**

  Rheumatoid arthritis:
  - For treatment of active rheumatoid arthritis in patients who have failed treatment with methotrexate and leflunomide;
    OR
  - For treatment of active rheumatoid arthritis in patients intolerant to methotrexate and leflunomide.

    Treatment should be combined with an immunosuppressant. 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.

  Plaque psoriasis:
  - For treatment of adult patients with severe debilitating plaque psoriasis who meet all of the following criteria:
    1) failure to respond to, contraindications to, or intolerant of methotrexate and cyclosporine; **AND**
    2) 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.

  Psoriatic arthritis:
  - Psoriatic arthritis in patients who have failed or are intolerant to methotrexate and one other DMARD.

    Treatment should be combined with an immunosuppressant. 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.

  Ankylosing spondylitis (A.S.):
  - 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**
3) A score of ≥ 4cm on the 0-10cm spinal pain VAS on two occasions at least 12 weeks apart without any change of treatment; **AND**
4) 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.

Coverage will not be provided when a patient switches to another anti-TNF agent if the patient fails to respond or if there is a loss of response to the first agent. Requests for coverage for this indication must be made by the 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.
http://formulary.drugplan.health.gov.sk.ca/AppForms.aspx

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).

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

Additional Formulation of an Exception Drug Status benefit effective May 1, 2016 according to the following criteria:

- **tocilizumab, subcutaneous solution, 162mg/0.9mL (Actemra-HLR)**

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.

Additional Formulation with Existing Exception Drug Status Criteria May 1, 2016:

- **lisdexamfetamine dimisylate, capsule, 10mg (Vyvanse-SCI)**

For treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients:
(a) Where the use of methylphenidate (short or long-acting formulations) or the use of dexamphetamine has not properly controlled the symptoms of the disease; OR
(b) Who cannot swallow tablets/capsules whole and require a dissolvable form of a long-acting ADHD medication.

Additional Formulation with Existing Exception Drug Status Criteria effective May 1, 2016 with possible online EDS adjudication:

- **tiotropium bromide, inhalation solution, 2.5ug (Spiriva Respimat-BOE)**

(a) For treatment of COPD in patients unresponsive to short-acting beta agonists or short-acting anticholinergic bronchodilators, or
(b) For treatment of 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 Revised Exception Drug Status Criteria:

- **leflunomide, tablet, 10mg, 20mg (Arava-AVT) (and listed generics)**

  - For treatment of:

(a) Active rheumatoid arthritis in patients who have failed methotrexate and at least one other DMARD (e.g. sulfasalazine, azathioprine or hydroxychloroquine).
(b) Active rheumatoid arthritis in patients intolerant to methotrexate and at least one other DMARD (e.g. sulfasalazine, azathioprine or hydroxychloroquine).
(c) ***For psoriatic arthritis patients who fail, or are intolerant, to methotrexate and one other DMARD.***
(d) ***For pediatric arthritis patients who fail, or are intolerant, to one DMARD.***
(e) ***For transplant patients with BK virus nephropathy.***
Note: Leflunomide is contraindicated in patients with pre-existing impairment of liver function.

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

- **macitentan, 10mg, film coated tablet (Opsumit-ACT)**

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