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SASKATCHEWAN FORMULARY BULLETIN

Update to the 62nd Edition of the Saskatchewan Formulary

Recommended as Full Formulary Listing:

- **5-aminosalicyclic Acid (mesalamine), foam enema, 1.0g/actuation; suppository, 1g (Mezera-AVR)**

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

- **buprenorphine, extended-release subcutaneous injection, 100mg/0.5mL, 300mg/1.5mL (Sublocade-ICL)**

  For the management of moderate to severe opioid use disorder in adult patients who have been induced and clinically stabilized on an equivalent of 8mg to 24mg per day of transmucosal buprenorphine for a minimum of seven days.

  Patients should be under the care of a prescriber with expertise in the management of opioid use disorder who has received any required training specified in the product monograph.

  Notes:
  - Buprenorphine extended-release injection should be used as part of a complete treatment plan that includes counselling and psychosocial support.
  - Buprenorphine extended-release injection must be injected subcutaneously in the abdominal region by a health care provider trained in the administration of this product as per the product monograph.

- **cladribine, tablet, 10mg (Mavenclad-SRO)**

  For treatment of Relapsing-Remitting Multiple Sclerosis (RRMS) according to the following criteria:

  The patient is under the care of a specialist with experience in the diagnosis and management of relapsing-remitting multiple sclerosis (RRMS); AND
  The patient :
  - Has a current Expanded Disability Status Scale (EDSS) less than or equal to 5.5; AND
  - Has failed to respond to a full and adequate course* (i.e., at least 6 months) of at least ONE disease modifying therapy listed on the Saskatchewan Formulary as initial therapy OR has contraindications/intolerance** to at least TWO disease modifying therapies listed on the Saskatchewan Formulary as initial therapy; AND

- Has had at least one relapse*** within the previous 12 months.

Notes:
*Failure to respond to a full and adequate course: defined as a trial of at least 6 months of treatment with a disease modifying therapy listed on the Saskatchewan Formulary as initial therapy AND experienced at least one disabling relapse (attack) while receiving an alternative disease modifying therapy listed on the Saskatchewan Formulary OR evidence of new disease activity on MRI in the last year compared to a prior MRI.

**Intolerance is defined as documented serious adverse effects or contraindications that are incompatible with further use of that class of drug.

***A clinical relapse 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.

Requirements for Initial Requests:
- The patient's physician provides documentation setting out the details of the patient's most recent neurological examination within ninety (90) days of the submitted request. This must include a description of any recent attacks, the dates, and the neurological findings.
- Please submit MRI reports if available with the application.
- Prescribers are aware, and will ensure, that patients are monitored appropriately.

Approval period: 18 months to allow completion of one two-year treatment course, according to the product monograph.

Note: Retreatment beyond two treatment courses may be considered.

- **edaravone, intravenous solution, 30mg/100mL (Radicava-MTC)**

Initiation Criteria
For the treatment of amyotrophic lateral sclerosis (ALS) when initiated by a neurologist with expertise in the management of ALS, when the patient has:
- A probable or definite diagnosis of ALS; and
- Scores of at least two points on each item of the ALS Functional Rating Scale – Revised (ALSFRS-R);
- Forced vital capacity ≥ 80% of predicted;
- Had ALS symptoms for two years or less; and
- Not currently required permanent non-invasive or invasive ventilation.

Coverage will be reviewed every six months.

Coverage cannot be renewed once the patient meets either of the following:

- Becomes non-ambulatory (ALSFRS-R score ≤ 1 for item 8) AND is unable to cut food and feed themselves without assistance, irrespective of whether a gastrostomy is in place (ALSFRS-R score < 1 for item 5a or 5b); or
- Requires permanent non-invasive or invasive ventilation.

Note: Please submit the patient's updated ALSFRS-R scores (items 5a/5b and 8) AND current ventilation status every 6 months to request renewal of coverage.

- **letermovir, tablet 240mg, 480mg (Prevymis-MRK)**

  For the prophylaxis therapy of cytomegalovirus (CMV) infection in patients meeting the following criteria:

  - Patient is an adult CMV-seropositive recipient [R+] of an allogeneic hematopoietic stem cell transplant (HSCT); and
  - Patient has undetectable CMV viremia at baseline; and
  - Prevymis is being prescribed by a clinician with expertise in the management of HSCT (such as a medical oncologist, hematologist, or infectious disease specialist); and
  - Patient has at least ONE of the following characteristics:
    - Received stem cells sourced from umbilical cord blood; or
    - Is a haploidentical recipient, or
    - Is a recipient of T-cell depleted grafts, or
    - Was treated with antithymocyte globulin (ATG) for conditioning, or
    - Requires high-dose steroids (defined as the use of $\geq$ 1mg/kg/day of prednisone or equivalent dose of another corticosteroid) or other immunosuppression for acute graft versus host disease (GVHD), or
    - Was treated with ATG for steroid-refractory acute GVHD treatment, or
    - Has documented history of CMV disease prior to transplantation.

  The maximum Prevymis oral dosage approved will not exceed 480mg administered orally per day.

  The approved duration of treatment will not exceed 100 days, per patient, per HSCT procedure. Requesting health professionals are asked to indicate the date of treatment initiation in hospital on the request.

- **triamcinolone hexacetonide, injection suspension, 20mg/mL (Triamcinolone Hexacetonide-MDX)**

  For the management of pediatric chronic inflammatory arthropathies.

Revised Exception Drug Status criteria:

- **onabotulinumtoxin A, injection, 100IU/vial (Botox-ALL)**

(c) For the treatment of patients with upper or lower limb spasticity associated with cerebral palsy or stroke.

Expanded Exception Drug Status criteria:

- **ivacaftor, tablet, 150mg (Kalydeco-VER)**

For the treatment of cystic fibrosis (CF) in patients age six (6) years and older who have one of the following mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene: G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N, or S549R; and in patients aged 18 and older with an R117H mutation in the CFTR gene.

Note: Initial requests should provide baseline sweat chloride and FEV1 scores along with the corresponding testing dates.

Renewal Criteria:
The sweat chloride test will be repeated at the next routine review appointment after starting ivacaftor to determine whether sweat chloride levels are reducing and to check compliance with the drug regimen. The sweat chloride level will then be re-checked 6 months after starting treatment to determine whether the full reduction (as detailed below) has been achieved. Thereafter sweat chloride levels will be checked annually.

When the baseline sweat chloride level is over 60mmol/litre, the patient will be considered to have responded to treatment if either:
a) The patient's sweat chloride test falls below 60mmol/litre; OR
b) The patient's sweat chloride test falls by at least 30%

In cases where the baseline sweat chloride test is already below 60mmol/litre, the patient will be considered to have responded to treatment if either:
c) The patient's sweat chloride test falls by at least 30%; OR
d) The patient demonstrates a sustained absolute improvement in FEV1 of at least 5%. In this instance FEV1 will be compared with the baseline pretreatment level one month and three months after starting treatment.

If the expected reduction in sweat chloride does not occur, the patient's CF clinician will first explore any challenges in following the recommended dosing schedule for ivacaftor. The patient's sweat chloride will then be retested around one week later and funding discontinued

if the patient does not meet the above criteria.

Note: Coverage may be approved for up to 150mg every 12 hours according to the following time frame:

- Initial approval: Six (6) months
- First Renewal: Six (6) months
- Subsequent renewals (second and later): One year

Patients will be limited to receiving a one month supply per prescription.

Recommended New Formulation of an Existing Exception Drug Status benefit according to existing criteria:

- **lisdexamfetamine dimesylate, chewable tablet, 10mg, 20mg, 30mg, 40mg, 50mg, 60mg (Vyvanse-SCI)**

- **mepolizumab, prefilled autoinjector; prefilled syringe, 100mg/mL (Nucala-GSK)**

Recommended New Delivery Device for an Existing Exception Drug Status benefit:

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

For the treatment of:

a) 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.
This medication should be prescribed by a rheumatologist.

b) Giant Cell Arteritis (GCA) in adult patients who are receiving prednisone at initiation of therapy, or with relapse.

Notes:

- Patients should be under the care of a prescriber with experience in the diagnosis and management of GCA.
- Discontinuation of tocilizumab should be considered at 12 weeks if there is no response to therapy.

Recommended for inclusion on the Hospital Benefit Drug List:

- **isavuconazole, powder for solution, 200mg/vial (Cresemba-AVR)**
- **letermovir, intravenous solution, 20mg/mL (Prevymis-MRK)**

The following products were NOT RECOMMENDED for Formulary Listing:

- **fluocinolone acetonide, intravitreal implant, 0.19mg (Iluvien-KTI)**
- **ertugliflozin, tablet, 5mg, 10mg (Steglatro-MRK)**
- **ertugliflozin/metformin HCl, tablet, 2.5mg/500mg, 2.5mg/1000mg, 7.5mg/500mg, 7.5mg/1000mg (Segluromet-MRK)**

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