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 July 1, 2016 according to the following criteria:

- **alemtuzumab, concentrate for solution for IV infusion, 12mg/1.2mL (Lemtrada-GZY)**

  *For the management of adult patients with relapsing-remitting multiple sclerosis (RRMS), if **ALL** of the following clinical criteria are met:*
  - Active disease defined by clinical and imaging features (i.e., one new lesion);
  - At least one relapse while on at least six months of a disease modifying therapy within the last 10 years;
  - At least two attacks (first episode or relapse) in the previous two years, with at least one attack in the previous year;
  - An inadequate response to a treatment course at least six months in length (i.e., at least one attack) to at least ONE disease modifying therapy listed on the Saskatchewan Formulary;
  - An Expanded Disability Status Scale (EDSS) score of five or less;
  - The medication is being prescribed by a neurologist with experience in the treatment of multiple sclerosis.

  Approval period: Two years (i.e., 8 vials).

  Note:
  - Retreatment beyond two courses (eight vials) may be considered.

  Requirements for 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.

Recommended Revised Exception Drug Status Criteria:

- **fingolimod hydrochloride, capsule, 0.5mg (Gilenya-NVR)**

  Initial Request:
  For the treatment of patients with Relapsing Remitting Multiple Sclerosis (RRMS) who meet all of the following criteria:

- Have failed to respond to **an** adequate course* (i.e. at least six months) of at least ONE disease modifying therapy (DMT) listed on the SK Formulary listed as initial therapy, OR has contraindications/intolerance** to at least TWO disease modifying therapies listed on the SK Formulary as initial therapy; AND
- One or more clinically disabling relapses in the previous year
- Significant increase in T2 lesion load compared with that from a previous MRI scan (i.e. 3 or more new lesions) or at least one gadolinium-enhancing lesion
- Requested and followed by a neurologist experienced in the management of RRMS
- Recent Expanded Disability Status Scale (EDSS) score***

Dosage: 0.5 mg once daily

Approval period: 1 year

Exclusion Criteria:

- Patients on combination therapy of ***Gilenya with other disease modifying therapies.***
- Patients with EDSS > 5.5
- Patients who have had a heart attack or stroke in the last six months of funding request, history of sick sinus syndrome, atrioventricular block, significant QT prolongation, bradycardia, ischemic heart disease or congestive heart failure
- Patients taking class IA or III anti-arrhythmic drugs, immunocompromised due to immunosuppressant or cancer or AIDS, severe hepatic impairment, concurrent malignancies, pregnancy/anticipated pregnancy/breast feeding or active infectious disease such as TB or hepatitis.
- Patients < 18 years of age
- Skin reactions at the site of injection do NOT qualify as a contraindication to injectable disease modifying therapy

Renewal:

- Date and details of the most recent neurological examination and EDSS scores must be provided (exam must have occurred within that last 90 days).
- Patients must be stable or have experienced no more than 1 disabling attack/relapse in the past year; AND
- Recent Expanded Disability Status Scale (EDSS) score ***

Dosage: 0.5 mg once daily

Renewal period: 1 year

Renewal requests where patients have experienced more than 1 disabling attack in the past year are to be externally reviewed.

Notes:

*Failure to respond to **an** adequate course: defined as a trial of at least six months of treatment with a disease modifying therapy listed on the SK Formulary as initial therapy AND experienced at least one disabling relapse (attack) while receiving an alternative disease modifying therapy listed on the SK Formulary.
(**The MRI report is not necessary for approval but if available, please submit report with the application**.)

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

***Recent Expanded Disability Status Scale (EDSS) score less than or equal to 5.5 (i.e. patients must be able to ambulate at least 100 meters without assistance).

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.

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

- **tolvaptan, tablet, 15mg, 30mg, 45mg, 60mg, 90mg (Jinarc-OTS)**

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