

APPENDIX D

SASKATCHEWAN MS DRUGS PROGRAM

PROCEDURE FOR OBTAINING COVERAGE OF MS DRUGS UNDER THE DRUG PLAN

- Requests are initiated by a physician. The patient and physician complete the application form and the physician forwards all relevant information to the Saskatchewan MS Drugs Program. For a copy of the application forms please refer to the website at: <http://formulary.drugplan.health.gov.sk.ca/>
- The MS Drug Advisory Panel reviews the application form and relevant documentation and provides advice regarding the request based on the criteria for coverage. **Note: The MS Drug Advisory Panel advises if a patient's application meets the Exception Drug Status (EDS) criteria.**
- The Drug Plan communicates the decision and notifies:
 - The patient if the request meets the EDS criteria.
 - The patient and physician if the request does not meet the EDS criteria
- Please note, annual renewal applications are required for ongoing advisory review by the MS Drug Advisory Panel.
- Renewal application forms are mailed by the Drug Plan to the prescribing physician one month before expiration of coverage.
- **Questions regarding criteria eligibility should be directed to:**

Saskatchewan MS Drugs Program	Telephone: (306) 655-8400
Saskatoon City Hospital – Room 8229	Toll-Free: 1-866-655-7966
701 Queen Street	FAX: (306) 655-8404
Saskatoon, S7K 0M7	
- Upon approval of coverage, patients are encouraged to apply for assistance with the cost of these medications under the Drug Plan Special Support Program. For more detailed information regarding this program, see Special Coverages in Formulary Appendices, Indices & Other under: <http://formulary.drugplan.health.gov.sk.ca/> .

1. CRITERIA FOR COVERAGE OF:

- *dimethyl fumerate (Tecfidera-BGN)*
- *glatiramer acetate (Copaxone-TVM)*
- *glatiramer acetate (Glatect-PED)*
- *interferon beta-1b (Betaseron-BAY) (Extavia-NVR)*
- *interferon beta-1a (Rebif-SRO), and*
- *interferon beta-1a (Avonex-BGN)*
- *ocrelizumab (Ocrevus-HLR)*
- *peginterferon beta-1a (Plegridy-BGN)*
- *teriflunomide (Aubagio-GZY)*

Approval for coverage will be given to patients who are assessed and meet the following criteria:

- have clinical definite relapsing - remitting multiple sclerosis, as defined by the 2017 McDonald diagnostic criteria; and
- have had a clinical relapse¹ and/or new MRI activity² in the last two years; and
- are fully ambulatory for 100 meters without aids (canes, walkers, or wheelchairs) – Expanded Disability Status Scale (EDSS) of 5.5 or less; and
- are age 18 or older (Note: Applications for patients under 18 will be considered.)

¹ 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.

² MRI activity is defined as any new multiple sclerosis lesion/s, expanding lesion/s, and/or enhancing lesion/s.

Physicians should also forward the following information:

- documentation of attacks, date of onset, date of diagnosis;
- neurological findings, Expanded Disability Status Scale (EDSS);
- MRI reports or other significant information; and
- list of current medications.

Note: Effective July 1, 2018, glatiramer acetate naive patients will be eligible for EDS coverage of only the Glatect formulation of glatiramer acetate. Patients with existing EDS approval of Copaxone will remain eligible for coverage of Copaxone at this time, subject to the EDS criteria.

2. CRITERIA FOR COVERAGE OF:

- ***natalizumab (Tysabri-BGN)***

Initial Request:

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

The patient's physician is a neurologist experienced in the management of relapsing-remitting multiple sclerosis (RRMS); AND

The patient:

- Has a current Expanded Disability Status Scale (EDSS) less than or equal to 5.0; AND
- Has failed to respond to a full and adequate course* (i.e. at least six months) of at least ONE disease modifying therapy listed on the SK Formulary as initial therapy OR has contraindications/intolerance to at least TWO disease modifying therapies listed on the SK Formulary as initial therapy; AND
- Has had ONE of the following types of relapses in the past year:
 - o The occurrence of one relapse with partial recovery during the past year AND has at least ONE gadolinium-enhancing lesion on brain MRI, OR significant increase in T2 lesion load compared to a previous MRI; OR
 - o The occurrence of two or more relapses with partial recovery during the past year; OR
 - o The occurrence of two or more relapses with complete recovery during

the past year AND has at least ONE gadolinium-enhancing lesion on brain MRI, OR significant increase in T2 lesion load compared to a previous MRI.

Approval period: 1 year

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 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.

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.
- MRI reports do NOT need to be submitted with the initial request.

Renewal:

- Date and details of the most recent neurological examination and EDSS scores must be provided (exam must have occurred within the last 90 days); AND
- Patients must be stable or have experienced no more than 1 disabling attack/relapse in the past year; AND
- Recent EDSS score is less than or equal to 5.0.

Approval period: 1 year

3. CRITERIA FOR COVERAGE OF:

- ***fingolimod hydrochloride (Gilenya-NVR) (and listed generic)***

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.

4. CRITERIA FOR COVERAGE OF:

- **alemtuzumab (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); **AND**
- At least one relapse while on at least six months of a disease modifying therapy within the last 10 years; **AND**
- At least two attacks (first episode or relapse) in the previous two years, with at least one attack in the previous year; **AND**
- An inadequate response to a treatment course at least six months in length (i.e., at least one attack) to at least **TWO different** disease modifying therapies listed on the Saskatchewan Formulary, **except for when any other DMT is contraindicated or otherwise unsuitable; AND**
- An Expanded Disability Status Scale (EDSS) score of five or less; **AND**
- 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.

5. CRITERIA FOR COVERAGE OF:

- **ocrelizumab (Ocrevus-HLR)**

For treatment of RRMS

Approval for coverage will be given to patients who are assessed and meet the following criteria:

- have clinical definite relapsing - remitting multiple sclerosis, as defined by the 2017 McDonald diagnostic criteria; and
- have had a clinical relapse¹ and/or new MRI activity² in the last two years; and
- are fully ambulatory for 100 meters without aids (canes, walkers, or wheelchairs) – Expanded Disability Status Scale (EDSS) of 5.5 or less; and
- are age 18 or older (Note: Applications for patients under 18 will be considered.)

¹ 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.

² MRI activity is defined as any new multiple sclerosis lesion/s, expanding lesion/s, and/or enhancing lesion/s.

Physicians should also forward the following information:

- documentation of attacks, date of onset, date of diagnosis;
- neurological findings, Expanded Disability Status Scale (EDSS);
- MRI reports or other significant information; and
- list of current medications.

For treatment of PPMS

For the management of adult patients with early primary progressive multiple sclerosis (PPMS) as defined by disease duration and level of disability, in conjunction with imaging features characteristic of inflammatory activity if the following criteria are met:

- Has a confirmed diagnosis of PPMS (based on McDonald criteria);
- Expanded Disability Status Scale (EDSS) score between 3.0 and 6.5;
- Score of at least 2.0 on the Functional Systems scale for the pyramidal system due to lower extremity findings;
- Disease duration of less than:
 - 15 years for those with an EDSS greater than 5.0; OR
 - 10 years for those with an EDSS of 5.0 or less.
- The patient is under the care of a neurologist with experience in the diagnosis and management of multiple sclerosis.

Discontinuation criteria:

- Treatment should be discontinued for patients with an EDSS score of equal to or greater than 7.0.

6. CRITERIA FOR COVERAGE OF:

- ***cladribine (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.