

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 renders a decision based on the criteria for coverage. **Note: A patient's eligibility for coverage is determined by the MS Drug Advisory Panel.** The Drug Plan is notified of the decision and communicates the results to the patient and the physician. Please note, annual renewal applications are required for consideration of ongoing Exception Drug Status (EDS) approval 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 eligibility should be directed to:**
Saskatchewan MS Drugs Program Telephone: (306) 655-8400
Suite 7718-7th Floor FAX: (306) 655-8404
Saskatoon City Hospital
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:

- *interferon beta-1b (Betaseron-BAY) (Extavia-NVR),*
- *glatiramer acetate (Copaxone-TVM),*
- *interferon beta-1a (Rebif-SRO), and*
- *interferon beta-1a (Avonex-BGN)*

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.)

Contraindications to Treatment

- concurrent illness likely to alter compliance or substantially reduce life expectancy;
- pregnancy, anticipated pregnancy or breast feeding within the next year;
- active, severe depression.

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.

2. CRITERIA FOR COVERAGE OF:

- **natalizumab (Tysabri-BGN)**

For monotherapy treatment in patients with a diagnosis of multiple sclerosis who also meet **ALL** of the following criteria:

- a) Failure to respond to full and adequate courses of treatment with at least two disease-modifying therapies or have contraindications to, or be intolerant of these therapies, **AND**
- b) Significant increase in T2 lesion load compared to a previous MRI or at least one gadolinium-enhancing lesion, **AND**
- c) Two or more disabling relapses in the previous year.

Contraindications to Treatment

- any evidence of disease progression independent of relapses;
- immune compromise due to immunosuppressant or anti-neoplastic therapy or due to immunodeficiency (HIV, leukemia, lymphoma, etc.);
- history of progressive multifocal leukoencephalopathy (PML);
- concurrent malignancy;
- pregnancy, anticipated pregnancy or breast-feeding within the next year;
- active infectious disease (such as tuberculosis).

Neurologists should also forward the following information:

- name of previous disease-modifying therapies and duration of treatment;
- details of intolerance or failure with previous disease-modifying therapies;
- documentation of attacks including date of onset, duration of relapse, etc.;
- neurological findings, including Extended Disability Status Scale (EDSS) scores;
- MRI reports or other significant information;
- list of current medications.

Note: Applications for Tysabri must be initiated by a neurologist.

MS DRUG APPROVAL PROCESS

Fax #: (306) 655-8404

