TYSABRI EXCEPTION DRUG STATUS (EDS) APPLICATION

Check if:
☐ **New Application (Complete Sections 1 thru 4 in full)**
☐ **Annual Renewal (Complete Sections 1, 3 and 5 in full)**

Section 1 (Please print):

PATIENT INFORMATION:	NEUROLOGIST INFORMATION:
Name: ______________________	**Name:** ______________________
Date of Birth: ______________________	**Address:** ______________________
HSN: ______________________	______________________
Address: ______________________	**Postal Code:** ______________________
______________________	**Phone #:** ______________________
Postal Code: ______________________	**Fax #:** ______________________
Phone #: ______________________	**Date of Most Recent Consultation:** __________
Family Physician:	**Neurologist's Signature:** **Date:**
______________________	______________________ __________

Section 2:

EDS approval will be given to patients with Relapsing Remitting Multiple Sclerosis (RRMS) and meet <u>ALL</u> of the following criteria:

i. Has failed to respond to a full and adequate course of at least ONE disease modifying therapy listed on the SK Formulary as initial therapy [trial of at least 6 months **AND** experienced at least one relapse/attack while on treatment] ☐ YES ☐ NO

<u>**OR**</u>

Has documented intolerance or contraindication to at least **TWO** disease modifying therapies listed on the SK Formulary as initial therapy ☐ YES ☐ NO

Name of Drug	Duration of Treatment

ii. Has a current Extended Disability Status Scale (EDSS) score of 5.0 or less ☐ YES ☐ NO
Date of most recent EDSS score: (D / M / Y) _______________ EDSS Score_______

iii. Has the patient experienced **ONE** of the following relapses in the past year? ☐ YES ☐ NO

- 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 (provide summary of MRI findings) **OR**
- The occurrence of two or more relapses with partial recovery during the past year **OR**
- 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 (provide summary of MRI findings).

Please provide details of the relapse:____

____

____

Section 3:

Contraindications to Treatment (does the patient have any of the following?):

i. Any evidence of disease progression independent of relapses .... ☐ YES ☐ NO

ii. Immunocompromised due to immunosuppressant or anti-neoplastic therapy or due to immunodeficiency (HIV, leukemia, lymphoma, etc.) .... ☐ YES ☐ NO

iii. History of progressive multifocal leukoencephalopathy (PML) .... ☐ YES ☐ NO

iv. Concurrent malignancies .... ☐ YES ☐ NO

v. Pregnancy, anticipated pregnancy or breast-feeding within the next year .... ☐ YES ☐ NO

vi. Active infectious disease (such as tuberculosis) .... ☐ YES ☐ NO

Section 4:

Have the benefits/risks of this medication been discussed with your patient? ☐ YES ☐ NO

Has your patient agreed to proceed with treatment with this medication? ☐ YES ☐ NO

Section 5:

Renewal of Coverage: Renewal will be given to patients who meet ALL of the following criteria:

i. Patient has been stable or has experienced no more than one disabling attack/ relapse in the past year ☐ YES ☐ NO

ii. Has an EDSS score of 5.0 or less ☐ YES ☐ NO
Date of most recent EDSS score: (D / M / Y) ________________ EDSS Score_______

Please forward clinical history including:

a) documentation of attacks, date of onset, date of diagnosis
b) neurological findings (exam must have occurred within 90 days of the request, EDSS score
c) MRI reports/summary of findings or other significant information
d) complete medication profile

TO: Saskatchewan MS Drugs Program
Suite 7718 – 7th Floor
Saskatoon City Hospital
SASKATOON SK S7K 0M7

OR Fax: (306) 655-8404

For clinical program information: Phone (306) 655-8400 For reimbursement information: Phone 1-800-667-7578