GILENYA 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:** _____ **Fax:** _____
Postal Code: _____	**Date:** _____
Phone: _____	**Date of Most Recent Consultation:** _____
Family Physician: _____	**Neurologist's Signature:** (required)
Patient Signature: (required) _____	_____ **Date:** _____

Section 2:

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

i. Has failed to respond to an adequate course (ie: at least 6 months) of at least one disease modifying therapy listed on the SK Formulary as initial therapy **AND** experienced at least one relapse attack while on treatment ☐ YES ☐ NO

<u>OR</u>

Has documented intolerance (serious side effect 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 experienced one or more clinically disabling relapses in the previous year ☐ YES ☐ NO

iii. Has shown evidence of a significant increase in T2 lesion load (i.e. 3 or more new lesions) compared to a previous MRI OR at least one gadolinium-enhancing lesion on MRI (include summary of MRI findings or attach MRI report if available) ☐ YES ☐ NO

iv. Has a current Extended Disability Status Scale (EDSS) score of 5.5 or less ☐ YES ☐ NO
Date of most recent EDSS score: (D / M / Y) _____ EDSS Score_____

Section 3:

Contraindications to treatment:

i. Patient has had a heart attack or stroke in the last 6 months ☐ YES ☐ NO

ii. History of sick sinus syndrome, atrioventricular block, significant QT prolongation, bradycardia, ischemic heart disease, or congestive heart failure ☐ YES ☐ NO

iii. Patient is currently taking class Ia or class III anti-arrhythmic medications ☐ YES ☐ NO

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

v. Severe hepatic impairment ☐ YES ☐ NO

vi. Concurrent malignancies ☐ YES ☐ NO

vii. Pregnancy, anticipated pregnancy or breast-feeding ☐ YES ☐ NO

viii. Active infectious disease (such as tuberculosis, hepatitis) ☐ YES ☐ NO

ix. Patient is less than 18 years of age ☐ YES ☐ NO

Section 4:

Has a risk factor assessment been done? ☐ YES ☐ NO
(due to safety considerations with Gilenya, applications cannot be considered until the required investigations are completed. Please refer to the manufacturer's list of investigations as outlined on the Gilenya Treatment Checklist)

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

Have arrangements been made for the patient to be monitored following drug administration according to the Health Canada guidelines outlined in the product monograph? ☐ 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 5.5 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