GILENYA® (fingolimod) Start Form and Prescriptions **Fax** 1-877-428-5889 **Phone** 1-800-GILENYA (1-800-445-3692)

Please complete all fields indicated to prevent any delays in filling the prescription. Please include copies of both sides of all insurance plan cards.
Attn: New York Prescribers Please submit prescription on original NY state prescription forms.

1. Patient and Insurance Information

Cannot process form without this completed

First Name _____ Last Name _____

Sex: ☐ M ☐ F Date of Birth (MM/DD/YYYY) _____

Home Phone _____ Cell Phone _____

Address (For patients in Puerto Rico, please provide physical address) _____

City _____ State _____ ZIP _____

E-mail Address (To make more communications convenient and paperless) _____

OK to leave a GILENYA message on: ☐ Cell ☐ Home Phone

Primary Language: ☐ English ☐ Spanish ☐ Other _____

Name of Caregiver/Alternate Contact _____

Insurance Name(s) _____

Beneficiary/Cardholder Name(s) _____

Insurance ID Number(s) _____ Group Number(s) _____

Insurance Phone Number(s) _____

Prescription Insurance Name _____

Prescription Insurance ID Number _____ Phone _____

Cannot process form without this completed

X _____ / / _____

Patient/Legal Guardian Signature **Date of Signature (MM/DD/YYYY)**

I have read and agree to the attached Patient Authorization (page 2).

☐ I have read and agree to the Terms and Conditions for participation in the GILENYA Co-Pay Assistance Program on page 2.

☐ I have read and agree to receive text messages and calls as explained in the Telephone Consumer Protection Act (TCPA) consent on page 2. (optional)

☐ I have read and agree to the Novartis Patient Assistance Foundation (NPAF) and Fair Credit Reporting Act Authorization on page 2. (optional)

2. Prescriber Information

FOR OFFICE USE ONLY

Cannot process form without this completed

First Name _____ Last Name _____

Address / Site Name _____

City _____ State _____ ZIP _____

Phone _____ Fax _____

State Medical License # _____ NPI # _____

Office Contact Name _____ Office Contact Phone _____

E-mail Address _____

3. Assistance Requested From GILENYA Assessment Network (GAN)*

☐ GILENYA@Home† and/or GILENYA@Medical Facility‡

Blood Tests: ☐ CBC ☐ LFTs and Bilirubin ☐ VZV Antibody Serology

☐ ECG Through the GAN ☐ ECG Through CardioNet in Prescriber Office ☐ ME Screening§

☐ First-Dose Observation (FDO) ☐ Patient Is Cleared for FDO Scheduling

☐ Co-Pay Support Only

* A benefit investigation to determine co-pay support will be completed even if assistance for treatment initiation is not requested.

† Free to eligible commercially insured and uninsured patients. Health care professionals overseeing FDO via GAN will evaluate pre-existing conditions or concomitant medications that may preclude the patients from completing their FDO in a Novartis-sponsored facility.

‡ Medicare is accepted at most GAN medical facilities. There is a cash-pay option for residents of RI. This offer is not valid for medical assessments for which payment may be made in whole or in part under federal or state health programs, including but not limited to Medicare or Medicaid, and for RI residents. This program is subject to termination or modification at any time.

§ Macular Edema screening is available in select areas.

4. Starter Product Rx

Starter product is optional and available at no cost to the patient. It is dispensed directly from the GILENYA *Go Program*®.

☐ Dispense 2 boxes (7 capsules per box) of GILENYA 0.5 mg, 1 capsule taken by mouth once a day and, if needed, additional supplies for a maximum of a 56-day supply.

Alternate Instructions: _____

Starter product shipping address:

☐ Prescriber's Address ☐ Prescriber's FDO Site on File

☐ GILENYA@Home or GILENYA@Medical Facility ☐ Other Address (Provide Below)

New/Other Site Details _____

Address _____ City _____ State _____ ZIP _____ Phone _____

5. Ongoing Rx

Dispense (check one):

☐ 1-month supply followed by 11 refills. Take 0.5 mg by mouth once a day.

☐ 3-month supply followed by 3 refills. Take 0.5 mg by mouth once a day.

Primary diagnosis: ICD-10: G35 or Other: _____

Preferred specialty pharmacy: _____

Alternate instructions: _____

Additional notes:

I certify that the above therapy is medically necessary and that this information is accurate to the best of my knowledge. I certify that I am the physician who has prescribed GILENYA to the previously identified patient and that I provided the patient with a description of the GILENYA *Go Program*. For the purposes of transmitting these prescriptions, I authorize NPAF, Novartis Pharmaceuticals Corporation, and its affiliates, business partners, and agents to forward as my agent for these limited purposes these prescriptions electronically, by facsimile, or by mail to the appropriate dispensing pharmacies.

Cannot process form without this completed

X _____ _____ / / _____

Prescriber Signature (Dispense as Written) (Brand Exchange Permissible) **Date of Signature (MM/DD/YYYY)**

☐ I have read and agree to the Prescriber Authorization for the NPAF on page 2. (if applicable)

Click here for full Prescribing Information.

GILENYA go program®

GILENYA™ (fingolimod) capsules 0.5 mg

Patient Authorization. I give permission for my health care providers (HCPs), pharmacies, health insurer(s), third party contractors, and service providers to disclose my personal information, including information about my insurance, prescriptions, medical condition, and health ("Personal Information") to Novartis Pharmaceuticals Corporation, its affiliates, business partners, and agents (the "Novartis Group") and to the Novartis Patient Assistance Foundation, Inc. ("NPAF") so that the Novartis Group and NPAF can (i) help verify or coordinate insurance coverage or otherwise obtain payment for my treatment with GILENYA, (ii) coordinate my receipt of and payment for GILENYA, (iii) facilitate my access to GILENYA, (iv) provide me with information about GILENYA, disease awareness, management programs, and educational materials, (v) manage the GILENYA *Go Program*, (vi) provide me with adherence reminders and support, (vii) conduct quality assurance, surveys, and other internal business activities in connection with the GILENYA *Go Program*, and (viii) if I choose to apply to programs offered by the NPAF, to administer those programs, to send me information about programs that might help me pay for my medicines, and to coordinate and share my Personal Information with my health care providers, other programs that might help me pay for medicines, government agencies, and insurance companies for purposes of providing or facilitating this assistance.

I give permission to the Novartis Group and NPAF to disclose my Personal Information to my health care providers, pharmacies, health insurer(s), caregivers, and other third-party contractors or service providers for the purposes described above. I also give permission to the Novartis Group and NPAF to combine or aggregate any information collected from me with information the Novartis Group and NPAF may collect about me from other sources for the purpose of providing or administering Program services.

I understand that my pharmacy, health insurer(s), and health care providers may receive remuneration (payment) from the Novartis Group in exchange for disclosing my personal information to the Novartis Group and/or for providing me with therapy support services. I understand that once my Personal Information is disclosed it may no longer be protected by federal and state privacy law. I understand that I may refuse to sign this authorization. I also may revoke (withdraw) this authorization with respect to the GILENYA *Go Program* at any time in the future by calling 1-888-NOW-NOVA (1-888-669-6682) or by writing to the Customer Interaction Center, Novartis Pharmaceuticals Corporation, One Health Plaza, East Hanover, NJ 07936-1080. I also may revoke (withdraw) this authorization with respect to NPAF at any time in the future by calling 1-800-277-2254.

My refusal or future revocation will not affect the commencement or continuation of my treatment by my doctors; however, if I revoke this authorization, I may no longer be able to participate in the GILENYA *Go Program* and/or programs administered by NPAF. If I revoke this authorization, the Novartis Group and/or NPAF will stop using or sharing my information (except as necessary to end my participation in the program and/or NPAF) but my revocation will not affect uses and disclosures of Personal Information previously disclosed in reliance upon this authorization. I understand that this authorization will remain valid for five (5) years after the date of my signature, unless I revoke it earlier. I also understand that the GILENYA *Go Program* and/or programs administered by NPAF may change or end at any time without prior notification. I understand that I may receive a copy of this authorization.

I agree to be contacted by the Novartis Group and NPAF by mail, e-mail, telephone calls, and text messages at the number(s) and address(es) provided on the Start Form for all purposes described in this Patient Authorization. I also agree to be contacted by the Novartis Group, NPAF, and others on its behalf by telephone calls and text messages made by or using an automatic telephone dialing system or pre-recorded voice, at the number(s) provided on this form, for all non-marketing purposes, including but not limited to sending me materials and asking for my participation in surveys. I confirm that I am the subscriber for the telephone number(s) provided and the authorized user for the e-mail address(es) provided, and I agree to notify the Novartis Group and/or NPAF promptly if any of my numbers or addresses change in the future. I understand that my wireless service provider's message and data rates may apply.

I understand that the Novartis Group and NPAF do not permit my Personal Information to be used by its business partners for their own separate marketing purposes. I understand and agree that Personal Information transmitted by e-mail and cell phone cannot be secured against unauthorized access.

Telephone Consumer Protection Act (TCPA) Consent
I consent to receive marketing and non-marketing calls and texts from and on behalf of the Novartis Group and NPAF, made with an autodialer or pre-recorded voice, at the phone number(s) provided. I understand that my consent is not required or a condition of purchase. Number of messages will vary based on your program selections; average of 3 to 10 messages per week. Message and data rates may apply. Privacy Policy at www.usprivacy.novartis.com. Text STOP to opt out and HELP for help.

Co-Pay Assistance Program Terms and Conditions I understand that this offer is only valid for those with commercial insurance and who have a valid prescription. I understand that this offer is not valid under Medicare, Medicaid, or any other federal or state program (eg, VA, DoD, Tricare), for cash-paying patients, where product is not covered by patient's commercial insurance, or where the plan reimburses the patient for the entire cost of his/her prescription drug. I also understand that this offer is not valid where prohibited by law and is only valid in the United States and Puerto Rico. Additional terms and conditions may apply. Novartis reserves the right to rescind, revoke, or amend the program without notice. Finally, Novartis may use the information you provide to contact you to remind you that your co-pay assistance is about to expire and to confirm your eligibility to continue participating in co-pay assistance.

Novartis Patient Assistance Foundation, Inc. (NPAF) and Fair Credit Reporting Act (FCRA) Authorization I understand that I am providing "written instructions" authorizing NPAF and its vendor, under the FCRA, to obtain information from my credit profile or other information from Experian Health, solely for the purpose of determining financial qualifications for programs administered by NPAF. I understand that I must affirmatively agree to these terms in order to proceed in this financial screening process. I promise that any information, including financial and insurance information that I provide are complete and true and, unless I have indicated otherwise, I have no drug insurance coverage, which includes Medicaid, Medicare, or any public or private assistance programs or any other form of insurance. If my income or health coverage changes, I will call NPAF at 1-800-277-2254. If eligible, I would like to be considered for programs administered by NPAF.

Prescriber Authorization for the Novartis Patient Assistance Foundation, Inc. (NPAF) I certify that any medication received will be used only for the patient named on this form and will not be offered for sale, trade, or barter. Further, no claim for reimbursement will be submitted concerning this medication, nor will any medication be returned for credit. I acknowledge that NPAF is exclusively for purposes of patient care and not for remuneration of any sort. I understand that NPAF may revise, change, or terminate programs at any time.

Click here for full Prescribing Information.

Indication

GILENYA® is a sphingosine 1-phosphate receptor modulator indicated for the treatment of patients with relapsing forms of multiple sclerosis (MS) to reduce the frequency of clinical exacerbations and to delay the accumulation of physical disability.

Important Safety Information

Contraindications

- Patients who in the last 6 months experienced myocardial infarction, unstable angina, stroke, TIA, decompensated heart failure (HF) requiring hospitalization or Class III/IV HF
- History or presence of Mobitz Type II second-degree or third-degree atrioventricular (AV) block or sick sinus syndrome, unless patient has a functioning pacemaker
- Baseline QTc interval ≥500 msec
- Treatment with Class Ia or Class III anti-arrhythmic drugs
- Patients who have had a hypersensitivity reaction to fingolimod or any of the excipients in GILENYA. Observed reactions include rash, urticaria, and angioedema upon treatment initiation

Bradyarrhythmia and Atrioventricular (AV) Block: Monitor patients during GILENYA initiation because of a risk of bradyarrhythmia and AV block. Observe all patients for signs and symptoms of bradycardia for at least 6 hours after first dose with hourly pulse and blood pressure (BP) measurement. Obtain an electrocardiogram (ECG) prior to dosing and at the end of the observation period. Patients who develop a heart rate (HR) <45 bpm or new onset second degree or higher AV block should be monitored until resolution. Patients at lowest post-dose HR at end of observation period should be monitored until HR increases. Begin continuous ECG monitoring in patients with symptomatic bradycardia, and if pharmacological intervention is needed, continue ECG monitoring overnight in a medical facility, and repeat first-dose monitoring for second dose. Some patients may experience a second decrease in HR within 24 hours after the first dose.

Patients with pre-existing ischemic heart disease, history of MI or cardiac arrest, CHF, cerebrovascular disease, uncontrolled hypertension, history of symptomatic bradycardia or recurrent syncope, severe untreated sleep apnea, AV block, sinoatrial heart block, and patients on concomitant drugs that slow HR or AV conduction should be evaluated by a physician and, if treated with GILENYA, monitored overnight with continuous ECG in a medical facility after the first dose due to higher risk of symptomatic bradycardia or heart block. Patients with or at risk for QT prolongation or on concomitant QT-prolonging drugs with a known risk of torsades de pointes should also be monitored overnight with continuous ECG. If GILENYA is discontinued for >14 days after the first month of treatment, the effects on HR and AV conduction may recur on reintroduction of treatment and the same precautions for initial dosing should apply. Take the same precautions if treatment is interrupted ≥1 day within the first 2 weeks or for >7 days during weeks 3 and 4.

Infections: GILENYA may increase the risk of infections. Life threatening and fatal infections have occurred in association with GILENYA. A recent CBC should be available before initiating GILENYA. Consider suspending GILENYA if a patient develops a serious infection. Monitor for signs and symptoms of infection during treatment and up to 2 months after discontinuation. Do not start GILENYA in patients with active acute or chronic infections until infection is resolved. Two patients receiving a higher than recommended dose of GILENYA (1.25 mg) in conjunction with high-dose corticosteroid therapy died of herpetic infections. In the postmarketing setting with GILENYA, serious infections, some fatal, have been reported with opportunistic pathogens including viruses (eg, John Cunningham virus [JCV], herpes simplex viruses 1 and 2, varicella zoster virus [VZV]), fungi (eg, cryptococci), bacteria (eg, atypical mycobacteria), and Kaposi's sarcoma. Patients with symptoms and signs consistent with any of these infections should undergo prompt diagnostic evaluation and treatment. Concomitant use with antineoplastic, immunosuppressive, or immune-modulating therapies would be expected to increase the risk of immunosuppression. When switching to GILENYA from immune-modulating or immunosuppressive medications and to avoid additive immunosuppressive effects, consider the duration of effect and mode of action of such therapies.

Before initiating GILENYA, patients without a history of chickenpox or without vaccination against VZV should be tested for antibodies to VZV. VZV vaccination of antibody-negative patients is recommended prior to commencing GILENYA treatment, following which GILENYA initiation should be postponed for 1 month.

Please see next page for additional Important Safety Information.

Click here for full Prescribing Information.

Important Safety Information (cont)

Progressive Multifocal Leukoencephalopathy (PML): Cases of PML occurred in patients with MS who received GILENYA in the postmarketing setting. PML is an opportunistic viral infection of the brain caused by the JC virus (JCV) that typically only occurs in patients who are immunocompromised, and that usually leads to death or severe disability. PML has occurred in patients who had not been treated previously with natalizumab, which has a known association with PML and who were not taking concomitant immunosuppressive or immunomodulatory medications.

Typical symptoms associated with PML are diverse, progress over days to weeks, and include progressive weakness on one side of the body or clumsiness of limbs, disturbance of vision, and changes in thinking, memory, and orientation leading to confusion and personality changes.

MRI findings may be apparent before clinical signs or symptoms. Cases of PML, diagnosed based on MRI findings and the detection of JCV DNA in the cerebrospinal fluid in the absence of clinical signs or symptoms specific to PML, have been reported in patients treated with MS medications associated with PML, including GILENYA. Therefore, monitoring with MRI for signs that may be consistent with PML may be useful, and any suspicious findings should lead to further investigation to allow for an early diagnosis of PML, if present. Lower PML-related mortality and morbidity have been reported following discontinuation of another MS medication associated with PML in patients with PML who were initially asymptomatic compared to patients with PML who had characteristic clinical signs and symptoms at diagnosis. It is not known whether these differences are due to early detection and discontinuation of MS treatment or due to differences in disease in these patients.

At the first sign or symptom suggestive of PML, withhold GILENYA® and perform an appropriate diagnostic evaluation.

Macular Edema: Fingolimod increases the risk of macular edema, with or without visual symptoms. Perform an exam of the fundus, including the macula, before starting GILENYA and at 3 to 4 months after initiation. Monitor visual acuity at baseline, during routine patient evaluations, and after a patient reports visual disturbances while on GILENYA. Patients with diabetes mellitus or history of uveitis are at increased risk and should have regular ophthalmologic evaluations.

Posterior Reversible Encephalopathy Syndrome (PRES): Rare cases of PRES have been reported with GILENYA. Symptoms reported included sudden onset of severe headache, altered mental status, visual disturbances, and seizure. Symptoms of PRES are usually reversible but may evolve into ischemic stroke or cerebral hemorrhage. Delay in diagnosis and treatment may lead to permanent neurological sequelae. If PRES is suspected, GILENYA should be discontinued.

Respiratory Effects: Dose-dependent reductions in forced expiratory volume over 1 second (FEV1) and diffusion lung capacity for carbon monoxide (DLCO) were observed in GILENYA patients as early as 1 month after initiation. The changes in FEV1 appear to be reversible after discontinuing GILENYA; however, there is insufficient information to determine the reversibility of DLCO. Obtain spirometry and DLCO when clinically indicated.

Liver Injury: Recent liver transaminase and bilirubin levels should be available before initiating GILENYA. Elevations 3- and 5-fold the upper limit of normal have occurred with GILENYA. The majority occurred within 6 to 9 months and returned to normal within 2 months after discontinuing GILENYA. Recurrence of liver transaminase elevations occurred with rechallenge in some patients. Assess liver enzymes and bilirubin if symptoms suggestive of hepatic injury develop. Discontinue GILENYA if significant liver injury is confirmed. Postmarketing cases of liver injury with hepatocellular and/or cholestatic hepatitis have been reported.

Fetal Risk: GILENYA may cause fetal harm. Women of childbearing potential should use effective contraception during and for 2 months after stopping GILENYA. A registry for women who become pregnant during GILENYA treatment is available. Contact the GILENYA Pregnancy Registry by calling QUINTILES at 1-877-598-7237, sending an e-mail to gpr@quintiles.com, or visiting gilenyapregnancyregistry.com.

Increased Blood Pressure (BP): Should be monitored during treatment with GILENYA. An average increase over placebo of 3 mm Hg in systolic and 2 mm Hg in diastolic BP was observed in clinical trials.

Cutaneous Malignancies: The risk of basal cell carcinoma (BCC) and melanoma is increased in patients treated with GILENYA. Monitor and evaluate suspicious skin lesions.

Please see next page for additional Important Safety Information.

Click here for full Prescribing Information.

GILENYA® go program®

GILENYA™ (fingolimod) capsules 0.5 mg

Important Safety Information (cont)

Immune System Effects Following Discontinuation: Fingolimod remains in the blood and has pharmacodynamic effects, including decreased lymphocyte counts, for up to 2 months following the last dose. Lymphocyte counts generally return to normal range within 1 to 2 months of stopping therapy. Initiating other drugs during this period warrants the same considerations needed for concomitant administration.

Hypersensitivity Reactions: Hypersensitivity reactions including rash, urticaria, and angioedema have been reported with GILENYA.

Drug Interactions: Closely monitor patients receiving systemic ketoconazole. The use of live attenuated vaccines should be avoided during and for 2 months after stopping GILENYA.

Common Adverse Reactions: The most common adverse reactions with GILENYA 0.5 mg (incidence ≥10% and >placebo) were headache, liver transaminase elevations, diarrhea, cough, influenza, sinusitis, back pain, abdominal pain, and pain in extremity.

Please see previous page for additional Important Safety Information.

Click here for full Prescribing Information.

Novartis Pharmaceuticals Corporation
East Hanover, New Jersey 07936-1080

1/18

T-GYA-1350488-A