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

Please complete all fields to prevent any delays. 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

First Name _____ Last Name _____

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

Address _____

City _____ State _____ ZIP _____

Home Phone _____ Cell Phone _____

E-mail Address _____

OK to leave a message on: ☐ Cell Phone ☐ 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 _____

X _____ / / _____

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

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

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

2. Prescriber Information

FOR OFFICE USE ONLY

First Name _____ Last Name _____

Site Name _____

Address _____

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*

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

☐ ECG BLOOD TESTS: ☐ CBC ☐ LFTs and bilirubin ☐ VZV antibody serology

☐ First-dose observation (FDO) ☐ Patient is cleared for FDO scheduling

☐ ECG through CardioNet in prescriber office ☐ Co-pay support only

*A benefit investigation to determine co-pay support will be completed even if assistance for treatment initiation is not requested. Ophthalmologic evaluation is not offered through the GAN.

†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 [MA, MI, or 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, or for [MA, MI, or RI] residents. This program is subject to termination or modification at any time.

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, one 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 ☐ Patient's address

☐ 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: Acro Pharmaceutical Services

Alternate instructions: Please fax to Acro at 877-381-3806

Additional notes:

I certify that the prescribed 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 this prescription, I authorize Novartis Pharmaceuticals Corporation, and its affiliates, business partners, and agents, to forward as my agent for these limited purposes, this prescription electronically, by facsimile, or by mail to a dispensing pharmacy chosen by the above-named patient.

X _____ / / _____

Prescriber Signature **Date of Signature (MM/DD/YYYY)**

Click here for full Prescribing Information, including Patient Medication Guide.

GILENYA go program

GILENYA™ (fingolimod) capsules 0.5mg

GILENYA Start Form and Prescriptions

Fax 1-877-428-5889 **Phone** 1-800-GILENYA (1-800-445-3692)

Please read the following carefully, then sign and date where indicated on the previous page.

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 (together, the "Novartis Group") so that the Novartis Group can (i) help to 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 and management programs and educational materials, (v) manage the GILENYA *Go Program*, (vi) provide me with adherence reminders and support, and (vii) conduct quality assurance, surveys and other internal business activities in connection with the GILENYA *Go Program*.

I give permission to the Novartis Group to disclose my Personal Information to my HCPs, pharmacies, health insurer(s), caregivers, and other third party contractors or service providers for the purposes described above.

I understand that my pharmacy, health insurer(s), and HCPs may receive remuneration (payment) from the Novartis Pharmaceuticals Corporation in exchange for disclosing my Personal Information to Novartis Pharmaceuticals Corporation 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 privacy law. I understand that I may refuse to sign this authorization. I also may revoke (withdraw) this authorization 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. My refusal or future revocation will not affect the commencement or continuation of my treatment by my doctor(s); however, if I revoke this authorization, I may no longer be eligible to participate in the GILENYA *Go Program*. If I revoke this authorization, the Novartis Group will stop using or sharing my information (except as necessary to end my participation in the program) but my revocation will not affect uses and disclosures of my 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* 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 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 and on its behalf by telephone calls and text messages made by using an automatic telephone dialing system or prerecorded voice, at the number(s) provided on the Start 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 promptly if any of my number(s) or address(es) change in the future. I understand that my wireless service provider's message and data rates may apply.

I understand that Novartis Pharmaceuticals Corporation does 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.

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. Finally, Novartis requires patients to annually re-enroll and re-attest to the program Terms and Conditions. We 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.

Click here for full Prescribing Information, including Patient Medication Guide.

Indication

GILENYA® is a prescription medicine used to treat relapsing forms of multiple sclerosis (MS) in adults. GILENYA can decrease the number of MS flare-ups (relapses). GILENYA does not cure MS, but it can help slow down the physical problems that MS causes.

Important Safety Information

You should not take GILENYA if in the last 6 months you experienced heart attack, unstable angina, stroke or warning stroke, or certain types of heart failure. Do not take GILENYA if you have an irregular or abnormal heartbeat (arrhythmia), including a heart finding called prolonged QT as seen on an ECG, or if you take medicines that change your heart rhythm. Do not take GILENYA if you are allergic to fingolimod or any of the other ingredients.

GILENYA may cause serious side effects such as:

- Slow heart rate, especially after first dose. You will be monitored by a health care professional for at least 6 hours after your first dose. Your pulse and blood pressure will be checked hourly. You'll get an ECG before and 6 hours after your first dose. If any heart problems arise or your heart rate is still low, you'll continue to be monitored. If you have any serious side effects, especially those that require treatment with other medicines, or if you have certain types of heart problems, or if you're taking medicines that can affect your heart, you'll be watched overnight. If you experience slow heart rate, it will usually return to normal within 1 month. Call your doctor, or seek immediate medical attention if you have any symptoms of slow heart rate, such as feeling dizzy or tired or feeling like your heart is beating slowly or skipping beats. Symptoms can happen up to 24 hours after the first dose. Do not stop taking GILENYA without consulting with your doctor. Call your doctor if you miss 1 or more doses of GILENYA—you may need to repeat the 6-hour monitoring.
- Increased risk of serious infections. GILENYA lowers the number of white blood cells (lymphocytes) in your blood. This will usually go back to normal within 2 months of stopping GILENYA. Your doctor may do a blood test before you start GILENYA. GILENYA may decrease the way vaccines work in your body, especially the chicken pox vaccine. Increased risk of infection was seen with doses higher than the approved dose (0.5 mg). Two patients died who took higher-dose GILENYA (1.25 mg) combined with high-dose steroids. Call your doctor right away if you have fever, tiredness, body aches, chills, nausea, vomiting, or headache accompanied by fever, neck stiffness, sensitivity to light, nausea, and/or confusion. These may be symptoms of meningitis.
- Progressive multifocal leukoencephalopathy (PML). PML is a rare brain infection that usually leads to death or severe disability. If PML happens, it usually happens in people with weakened immune systems. It is important that you call your doctor right away if you have any new or worsening medical problems that have lasted several days, including problems with thinking, eyesight, strength, balance, weakness on 1 side of your body, or using your arms and legs.
- Macular edema, a vision problem that can cause some of the same vision symptoms as an MS attack (optic neuritis), or no symptoms. If it happens, macular edema usually starts in the first 3 to 4 months after starting GILENYA. Your doctor should test your vision before you start GILENYA; 3 to 4 months after you start GILENYA; and any time you notice vision changes. Vision problems may continue after macular edema has gone away. Your risk of macular edema may be higher if you have diabetes or have had an inflammation of your eye (uveitis). Call your doctor right away if you have blurriness, shadows, or a blind spot in the center of your vision; sensitivity to light; or unusually colored vision.

Please see next page for additional Important Safety Information.

Click here for full Prescribing Information, including Patient Medication Guide.

Important Safety Information (cont)

- Swelling and narrowing of the blood vessels in your brain. A condition called PRES (Posterior reversible encephalopathy syndrome) has occurred rarely in patients taking GILENYA®. Symptoms of PRES usually get better when you stop taking GILENYA. However, if left untreated, it may lead to a stroke. Call your doctor right away if you experience any symptoms, such as sudden headache, confusion, seizures, loss of vision, or weakness.
- Breathing problems. Some patients have shortness of breath. Call your doctor right away if you have trouble breathing.
- Liver problems. Your doctor should do blood tests to check your liver before you start GILENYA. Call your doctor right away if you have nausea, vomiting, stomach pain, loss of appetite, tiredness, dark urine, or if your skin or the whites of your eyes turn yellow.
- Increases in blood pressure (BP). BP should be monitored during treatment.
- A type of skin cancer called basal cell carcinoma (BCC). Talk to your doctor if you notice any skin nodules (shiny, pearly nodules), patches or open sores that do not heal within weeks. These may be signs of BCC.

GILENYA may harm your unborn baby. Talk to your doctor if you are pregnant or planning to become pregnant. Women who can become pregnant should use effective birth control while on GILENYA, and for at least 2 months after stopping. If you become pregnant while taking GILENYA, or within 2 months after stopping, tell your doctor right away. Women who take GILENYA should not breastfeed, as it is not known if GILENYA passes into breast milk. A pregnancy registry is available for women who become pregnant during GILENYA treatment. For more information, contact the GILENYA Pregnancy Registry by calling Quintiles at 1-877-598-7237, by e-mailing gpr@quintiles.com, or by going to www.gilenyapregnancyregistry.com.

Tell your doctor about all your medical conditions, including if you had or now have an irregular or abnormal heartbeat; heart problems; a history of repeated fainting; a fever or infection, or if you are unable to fight infections due to a disease or are taking medicines that lower your immune system, including corticosteroids, or have taken them in the past; eye problems; diabetes; breathing or liver problems; or uncontrolled high blood pressure. Also tell your doctor if you have had chicken pox or have received the chicken pox vaccine. Your doctor may test for the chicken pox virus, and you may need to get the full course of the chicken pox vaccine and wait 1 month before starting GILENYA.

If you take too much GILENYA, call your doctor or go to the nearest hospital emergency room right away.

Tell your doctor about all the medicines you take or have recently taken, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Tell your doctor if you have been vaccinated within 1 month before you start taking GILENYA. You should not get certain vaccines, called live attenuated vaccines, while taking GILENYA and for at least 2 months after stopping GILENYA treatment.

The most common side effects with GILENYA were headache, abnormal liver tests, diarrhea, cough, flu, sinusitis, back pain, abdominal pain, and pain in arms or legs.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

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GILENYA go program®

GILENYA™ (fingolimod) capsules 0.5 mg

Novartis Pharmaceuticals Corporation
East Hanover, New Jersey 07936-1080

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