You will see several symbols throughout the playbook. These symbols will help you find your way to information.

**Policy & Procedure**
Documented company directives

**Glossary**
Concentra acronym and abbreviation list for definitions you should know

**If this, then consider**
Troubleshooting guide; provides options for solving common problems

**Reference Tools**
Quick reference guides and examples of completed forms

**Orange Book**
Behaviors to demonstrate the Concentra Way

**Methods Procedures**
Links back to Clinical Protocols in the GAN Playbook

**Process Guide**
Appears in process information; represents how a patient flows through the center at each step of the process
01 PATIENT JOURNEY
- About Multiple Sclerosis
- About Gilenya
- About GAN
- Service Objectives

02 INTRODUCTION
- Mission
- Purpose

03 PARTNERS IN CARE
- Neurologist
- Novartis
- Gilenya Go Program™
- Concentra
- GAN Provider
- CardioNet

04 GAN SITE SETUP
- Onboarding
- Site Readiness Evaluation Tool
  - Overview
  - Form
  - Required Forms and Training
  - Staffing, Equipment, and Center Aesthetics
- Site Validation

05 SITE OPERATIONS & PROCEDURES
- Starting on Gilenya
- Referral Process
- GAN Pre-Appointment Checklist
- Patient Discharge
- Reimbursement

06 COMMUNICATION
- Patient Medication History
- Patient Questions
- Customer Support

07 PATIENT VISIT
- Visit Guidelines
  - Initial Evaluation
  - Interval Checks
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  - Discharge Process

08 CLINICAL PROTOCOL
- Bradycardia and Atrioventricular Block
- 0.5 mg FDO Side Effects
- Contraindications
- Varicella Zoster Virus Antibody Testing/Vaccination
- Ketoconazole
- Hepatic Effects

APPENDIX
- Contacts
- Forms, Checklists, Sheets, and Links
- Glossary
PATIENT JOURNEY
As a clinician and provider at a Gilenya Assessment Network (GAN) location, it’s important you understand the disease you are treating — MS. This complex autoimmune disease (AD) disrupts the nervous system and can cause a wide range of symptoms including:

- Numbness or muscle weakness
- Vision problems
- Mobility impairment
- Difficulty speaking
- Bladder incontinence
- Vision problems

These symptoms can lead to communication problems between you and your patients, and it can provoke concerns about the long-term side effects and disabilities of MS. While it’s best to refer any clinical questions to a patient’s neurologist, it’s important you better understand MS and its treatment — specifically, Gilenya and how GAN sites administer this drug.
About Gilenya

Gilenya® (fingolimod) is the first oral agent that treats relapsing forms of MS. By keeping lymphocytes inside the lymph nodes, it helps limit the damage to the myelin sheath of nerve fibers. Furthermore, studies show Gilenya to be highly effective versus an active comparator and placebo.

A month after the FDA approved Gilenya in September 2010, Novartis, the maker of the drug, began working with Concentra to implement a clinical first dose observation (FDO) program and establish a network of FDO clinicians. During clinical trials, some patients experienced bradycardia, a low resting heart rate, leading to the creation of the GAN to provide first dose observation services lasting six hours.

**First dose side effects**
- Slow heart rate
- Low blood pressure

**Common side effects of Gilenya**
- Headache
- Diarrhea
- Abnormal liver function
- Back pain
- Cough
- Increased risk of flu
About GAN

To provide the best care for relapsing-remitting MS patients, Concentra and Novartis established GAN sites, a network of comprehensive medical centers. Complete with well-trained staff and state-of-the-art equipment, these sites offer the support needed to provide the FDO of Gilenya.

As well as having the right supplies and people, it’s integral to the success of GAN sites to have open communication and collaboration. That’s why our GAN site staff is committed to working one-on-one with prescribing neurologists to bring MS patients the care they deserve.

GAN sites

+ 300+ across the country
+ Most hosted by Concentra Urgent Care centers
+ Other sites subcontracted to join the network
Service Objectives for Referring Clinicians

| + Assist neurologists in providing the best care | + Help MS patients initiate therapy |
| + Focus on safety, comfort, and convenience | + Ensure a high-quality patient experience |
| | + Provide access to health programs and resources |

We achieve these objectives by:

1. Supporting neurologists and the MS population

GAN sites are set up to monitor and ensure a safe medical environment for the patient receiving a first dose of Gilenya. If the patient experiences any abnormal reactions to the drug, the GAN site will notify the neurologist and make arrangements for hospital transfer.

2. Setting up a repository for Concentra and Novartis service offerings and support

To ensure FDO sessions are properly monitored and implemented, all GAN sites have step-by-step instructions outlined by medical teams at Concentra and Novartis.

+ Through research and real-life applications, these instructions ensure the best possible patient experience while limiting potential risks and medical errors.
+ These steps, along with assistant resources from Concentra, have been streamlined through pilot testing to create the easiest and most efficient implementation process.
Our goal is to work with prescribing neurologists and their staff to ensure the best care for patients with MS. That being said, we’ve created this useful guide complete with resources and information for site and operations staff to use.
# Purpose of the GAN Playbook

<table>
<thead>
<tr>
<th>01 DEFINE</th>
<th>Define roles and responsibilities for GAN site owners</th>
</tr>
</thead>
<tbody>
<tr>
<td>02 REINFORCE</td>
<td>Reinforce <em>Network Management and Quality Improvement (NMQI)</em> initiative</td>
</tr>
<tr>
<td>03 STANDARDIZE</td>
<td>Standardize activities of clinicians and GAN field personnel</td>
</tr>
<tr>
<td>04 DISCUSS</td>
<td>Discuss resources and best practices available to GAN staff and neurologists</td>
</tr>
</tbody>
</table>
GAN sites work with a number of partners to provide patients the expert care and attention they need during the entire MS treatment process. It’s important that these partners work one-on-one with patients and each other to ensure the FDO process runs smoothly.

**PATIENT PROCESS**

- **NEUROLOGIST**
  - Diagnosed with MS
  - Presented with treatment option
  - Hears clinical value of Gilenya
  - Prescribed Gilenya

- **NEUROLOGIST**
  - Asks questions by phone and in person

- **CUSTOMER SUPPORT**
  - Schedules appointments at GAN
  - Completes forms for GAN
  - Expresses any health concerns
  - Checks out from GAN site
  - Gets Gilenya prescription filled after FDO

- **GO PROGRAM**
  - Goes to GAN site for baseline evaluation if not performed by neurologist
  - Goes to GAN site for FDO

- **NOVARTIS NGN**
- **CARDIONET**
  - (some sites)
As partners in care of the patient journey, neurologists are actively engaged throughout the entire FDO process. First guiding the MS patient in selecting Gilenya as a disease modifying therapy. Then referring the patient to a GAN site for FDO — always remaining engaged in patient care decisions.

In fact, Concentra’s customer support and the Go Program team update results, obtain clearances, and report patient issues to neurologists. GAN clinicians also update neurologists on changes in patient condition or care.

Note
Clinicians experiencing issues connecting with neurologists should call Pharma Customer Support immediately at 1-877-876-4912 or e-mail them at novartiscss@concentra.com.
Novartis

Novartis is an international pharmaceutical company that produces Gilenya. Committed to providing excellent care for patients with relapsing forms of MS, Novartis partnered with Concentra to establish GAN sites for the FDO of Gilenya treatment.

Novartis has a brand team that works closely with Concentra management to ensure that the program runs successfully and meets patient needs.

The Gilenya Brand Teams include:
+ Brand leaders
+ Brand medical director

The Gilenya Patient Specialty Service Teams include:
+ Operations personnel
+ Development and quality assurance personnel
Novartis Field Teams

Novartis Gilenya Nurse (NGN): NGNs help patients start on Gilenya by performing these roles:

- Visiting GAN sites regularly and sitting in on patient visits
- Serving as the case manager for patients
- Developing relationships with neurologists and GAN staff
- Working with patients from the first dose of Gilenya to the last
- Serving as experts on MS, Gilenya, and MS patients
- Maintaining relationships between multiple GAN sites
- Serving as communication liaisons for neurologists, patients, Go Program staff, and GAN site employees

Gilenya Business Relationship Manager (BRM): The BRM works with the NGN and sales representatives to perform these roles:

- Finds solutions for patients who need baseline services or FDO
- Works with offices to address reimbursement questions
- Assists in onboarding GAN sites
- Serves as a GAN advocate through relationships with health care facilities

Gilenya Sales

The Novartis Gilenya sales force performs these roles:

- Develops relationships with neurologists
- Promotes Gilenya's clinical value
- Markets services available to prescribers and patients, including GAN

Note
GAN site staff members are encouraged to meet with their area NGN to assist in patient and neurologist communication.
Novartis contracted the LASH Group to administer a patient support team — Gilenya Go Program. A dedicated Go Program representative works with patients, health care providers, and NGN from the initial prescription all the way through the therapy process.

The Gilenya Go Program team fulfills these functions:

+ Collects prescriptions which authorize services and drugs for patients
+ Investigates benefits including researching financial benefits of treatment
+ Schedules baseline patient assessments and FDO appointments
+ Sends appointment confirmations to patients and neurologists
+ Sets appointments, reschedules appointments, and handles exceptions and special requests
+ Follows up with physicians for approval and advancement to next step of initiation
+ Handles issues and concerns of patients and health care providers (HCPs)
+ Supports NGNs regarding patient status including HCP approvals
+ Answers inbound calls from patients to support NGNs
+ Leads patients to pharmacy fulfillment after their first doses of Gilenya
Concentra serves in a dual capacity as the network manager for the GAN program as well as an active, participating provider within the GAN.

Concentra Customer Support is responsible for:

- Coordinating product and brand agencies
- Scheduling patients and obtaining the appropriate paperwork and forms
- Conducting the program’s billing and reimbursement process
- Investigating and resolving patient issues

Concentra management is responsible for:

- Managing 300+ sites
- Handling GAN development and ongoing maintenance as well as relationship management
- Maintaining day-to-day operations of GAN sites
- Ensuring overall network quality
- Upholding patient experience and prescriber satisfaction
- Onboarding new GAN sites
- Training and updating existing sites
- Ensuring compliance with clinical protocols

Questions
Contact: 1-877-876-4912 | Mon.– Fri., 8 a.m. – 5 p.m. CT
Patient documents fax: 1-877-876-4912
Complete with well-trained staff and state-of-the-art equipment including EKG machines, GAN providers offer the support needed to implement the FDO of Gilenya. They also work one-on-one with Concentra customer support to ensure MS patients are getting the care they deserve.

**GAN sites**

+ 300+ across the country
+ Most hosted by Concentra Urgent Care centers
+ Others hosted by subcontracted medical offices working with Concentra as part of the GAN
CardioNet

The Gilenya Electrocardiography Access Program through CardioNet is for GAN sites that do not have EKG capabilities and those that need EKG over-read services.

This program also provides backup machines to GAN sites with malfunctioning EKG machines. See the “Methods and Procedures” document in the appendix to use this service if your GAN site is not part of the program.
GAN SITE SETUP
## Onboarding a New Site

<table>
<thead>
<tr>
<th>STEP 1</th>
<th>STEP 2</th>
<th>STEP 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Concentra submits “Next Steps Email” to site contact</td>
<td>Site contact submits a credentialing application for each provider, certificates of insurance, and a site profile information form</td>
<td>Concentra processes credentialing application, approves certificate of insurance, and prepares agreement</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>STEP 4</th>
<th>STEP 5</th>
<th>STEP 6</th>
</tr>
</thead>
<tbody>
<tr>
<td>GAN site reviews, signs, and returns agreement</td>
<td>Concentra orders equipment and enrolls staff for training</td>
<td>NGN completes in-service</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>STEP 7</th>
<th>STEP 8</th>
<th>STEP 9</th>
</tr>
</thead>
<tbody>
<tr>
<td>GAN site completes readiness evaluation</td>
<td>Concentra activates site</td>
<td>Site begins seeing patients</td>
</tr>
</tbody>
</table>

Network sites complete steps 1–8. Concentra sites complete steps 2, 6, 7, and 8.

**Note**
Send all forms to GAN@concentra.com or fax to 1-800-203-7720.
Gilenya FDO Site Readiness Evaluation Overview

Sites must go through a Site Readiness Evaluation to become part of the GAN network. This evaluation checks a site’s ability to meet patient needs and to provide outstanding service during the FDO.

Before GAN sites can provide patient FDO, these steps must be completed:

+ Complete the Site Readiness Evaluation Form provided by a Network Relationship Specialist
+ Conduct a follow-up phone call regarding the readiness evaluation

Questions
Contact a Network Relationship Specialist at 972-372-5324.
Gilene FDO Site Readiness Evaluation Form

Gilenya FDO Site Readiness Evaluation
(To be conducted prior to first patient visit)

Date: ___________ Evaluation Completed By: ___________

Fields:
☐ All required staff have completed the GAN FDO Training modules listed below:
  - Gilene First Dose Observation eLearning Course
  - Novartis Drug Safety & Epidemiology
  - Concentra Medication Administration course
  - EKG Standard Operating Procedure (Non-Concentra Network Sites Only)
  - Spoken Patient Consent recorded and reviewed with all staff
  - Required staff demonstrates proficiency on EKG’s and FDO clinical protocol

Equipment:
☐ All Equipment to conduct FDO visit has been received in good working order and set-up:
  - Television/DVD
  - Refrigerator
  - FDO Chair
  - iPad

☐ Site is equipped to conduct Lab tests prior to FDO if needed:
  - Refrigerator, iPad, and Chair have been set up and functional
  - Space and walking available for patient to bring one

Center Information:
  - Concentra Pharma Customer Support has your most up to date days of the week and time slot that your site is available to conduct FDO visits. Any updates can be sent to novartiscss@concentra.com.

Evaluation Completed By: _______________________

Spirit Level Staffing:
☐ All required staff have sufficient Aesthetics
☐ A patient will not be able to be seen if staffing is insufficient

Space and Seating Availability:
☐ FDO room is clean and all equipment (TV, Refrigerator, iPad, and Chair) has been set-up and functional

Training:
☐ All required staff have completed the GAN FDO Training modules listed below:
  - Gilene First Dose Observation eLearning Course
  - Novartis Drug Safety & Epidemiology
  - Concentra Medication Administration course
  - EKG Standard Operating Procedure (Non-Concentra Network Sites Only)
  - Spoken Patient Consent recorded and reviewed with all staff
  - Required staff demonstrates proficiency on EKG’s and FDO clinical protocol

Site Readiness Evaluation Form:
Please fax completed checklist and results of Dry Run EKG to novartiscss@concentra.com. A patient will not be able to be seen if staffing is insufficient.

Please fax completed checklist and results of Dry Run EKG to novartiscss@concentra.com. A patient will not be able to be seen if staffing is insufficient.

Please ensure that Concentra Pharma Customer Support has your most up to date days of the week and time slot that your site is available to conduct FDO visits. Any updates can be sent to novartiscss@concentra.com.

Site has completed all credentialing and insurance paperwork and has received copy of their signed contract (Non-Concentra Network Sites Only)

Required staff demonstrates proficiency on EKG’s and FDO clinical protocol

Go to form
Gilenya FDO Site Readiness Evaluation

Required Forms and Training

All physicians, nurses, medical assistants, and new staff members involved in the care of patients during the FDO process are required to fully understand and complete specified forms, training, and courses.

Operations directors of each GAN site must verify all personnel have received, reviewed, and completed these requirements:

Forms
+ Contracts (network sites only)
+ Credentialing and insurance paperwork

Training
+ Sample patient charts
+ EKG standard operating procedure
+ Learning Management System (MyLearning) training and annual refresher courses
  - Gilenya FDO Course (click to see course description)
  - Adverse Events Training: Gilenya Drug Safety and Epidemiology Course (click to see course description)

Please inform the Network Relationship Specialist of staff changes so new staff members can complete forms and training and be enrolled in MyLearning courses.

Questions
Contact a Network Relationship Specialist at 972-372-5324.
After forms and training are complete, GAN site physicians, nurses, medical assistants, and new staff members must verify staff scheduling, complete an inventory check of supplies, and conduct equipment tests prior to an FDO visit.

**Staffing**

+ Designate backup staff for additional coverage.

**Equipment**

+ Set up and make sure the following equipment is in good working order:
  - Television/DVD
  - Refrigerator
  - FDO chair
+ Conduct EKG equipment tests prior to FDO:
  - EKG machine is fully operational and user understands machine
  - If using CardioNet for EKG, make sure equipment is set up and functional and staff is trained
  - Forms for EKG machine is available to conduct FDO visit

**Center Aesthetics**

+ FDO room and equipment are clean
+ Space and seating are available for patient to bring one guest

**Note**

Notify a Network Relationship Specialist at 972-372-5324 if any equipment is missing. E-mail novartiscss@concentra.com with the EKG equipment lab test results.
Site Validation

This is the last step of the Gilenya FDO Checklist, completing all GAN onboarding.

Before and after a GAN site becomes active, an NGN will:

+ Check in with the site
+ Answer GAN site onboarding questions
+ Provide information on GAN site best practices
+ Follow up with the prescribing neurologist
+ Help resolve any issues informally or through the Feedback Log
SITE OPERATIONS AND PROCEDURES
Starting on Gilenya

**STEPS TO STARTING GILENYA**

**STEP 1**
Neurologist faxes service request form (SRF)

**STEP 2**
Benefit Investigation (BI) is performed to ensure Gilenya is covered under insurance at the patient’s pharmacy

**STEP 3**
Patient appointment is scheduled

**STEP 4**
Baseline tests are run (blood test, EKG, eye exam)

**STEP 5**
FDO (monitoring of heart rate and other side effects for first 6 hours)
## Referral Process

<table>
<thead>
<tr>
<th>NEUROLOGIST</th>
<th>Fills out SRF</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>GO PROGRAM</strong></td>
<td>Receives SRF</td>
</tr>
<tr>
<td><strong>GO PROGRAM</strong></td>
<td>Conducts BI</td>
</tr>
<tr>
<td><strong>GO PROGRAM</strong></td>
<td>Schedules patient assessment labs and FDO appointment</td>
</tr>
<tr>
<td><strong>GO PROGRAM</strong></td>
<td>Ships starter dose to GAN site</td>
</tr>
<tr>
<td><strong>GO PROGRAM</strong></td>
<td>Faxes patient forms to Pharma Customer Support</td>
</tr>
<tr>
<td><strong>CUSTOMER SUPPORT</strong></td>
<td>Confirms all forms have been received and completed</td>
</tr>
<tr>
<td><strong>CUSTOMER SUPPORT</strong></td>
<td>Completes the scheduling process in Appointment Plus and Occusource (Concentra sites only)</td>
</tr>
<tr>
<td><strong>CUSTOMER SUPPORT</strong></td>
<td>Sends patient forms to GAN site</td>
</tr>
<tr>
<td><strong>CUSTOMER SUPPORT</strong></td>
<td>Calls GAN site to confirm receipt of forms, starter drug, MD coverage, and overall readiness for appointment</td>
</tr>
</tbody>
</table>

### Questions regarding patient appointments
Pharma Customer Support: 1-877-876-4912
Mon.–Fri., 7:30 a.m.– 5:00 p.m. CT
To ensure the patient intake process is clearly defined and followed, GAN sites will use the **Gilenya FDO Checklist** before and during the FDO process.

### GAN Pre-Appointment Checklist

<table>
<thead>
<tr>
<th>5 days prior to appointment:</th>
<th>Adequate supplies? (paper, ink, leads)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 days prior to appointment:</td>
<td>(email <a href="mailto:novartiscss@concentra.com">novartiscss@concentra.com</a> if missing items or not received)</td>
</tr>
<tr>
<td>1 day prior to appointment:</td>
<td></td>
</tr>
</tbody>
</table>

**iPad Process (if available):**

- iPad Release signed by patient
- Patient signs iPad log to indicate receipt
- Clear and charge iPad per instructions
- Log out iPad and present to patient in FDO room
- Collect iPad from patient at end of visit
- Colleague co-signs log to indicate receipt
- Secure iPad in designated location

---

**Notes:**

- EKG machine functional?
- Adequate supplies? (paper, ink, leads)
- Date Verified:
- Date of Service:
- Verified By:

---

**Revised 03/12/14**

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**Image:**

[Image showing the checklist form with relevant sections filled in and unchecked boxes, indicating completion of tasks or information available].

---

**Table:**

<table>
<thead>
<tr>
<th><strong>Gilenya FDO Checklist (for GAN sites)</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Date Verified:</strong></td>
</tr>
<tr>
<td><strong>Verified By:</strong></td>
</tr>
<tr>
<td><strong>2 days prior to appointment:</strong></td>
</tr>
<tr>
<td><strong>1 day prior to appointment:</strong></td>
</tr>
<tr>
<td><strong>iPad Process (if available):</strong></td>
</tr>
</tbody>
</table>

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**Contact:**

- 866-623-6857

---
Transfer the patient to the ER if any of the following occur:

+ Pulse is <50 and <80% of baseline value
+ Pulse rate at 6 hours post dose is at its lowest value measured during observation period
+ Patient has symptoms associated with bradycardia
+ EKG post dose shows new onset second degree or higher Atrioventricular (AV) block
+ Prolonged QT Interval (QTc) interval (>450 msec males, >470 msec females) at any time during the observation period
+ Patient required pharmacologic intervention for symptomatic bradycardia

Follow the ER protocol below before transfer:

+ Notify the neurologist
+ Fill out the ER Transfer Form
+ Make arrangements to transfer the patient to the hospital
+ Send remaining does of Gilenya with transferred patient to ER for second dose FDO

---

**ER Protocol Form**

Gilenya FDO Emergency Department Transfer Form

<table>
<thead>
<tr>
<th>Field</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Name</td>
<td>Name of patient being transferred.</td>
</tr>
<tr>
<td>DOB</td>
<td>Date of birth of patient.</td>
</tr>
<tr>
<td>Case #</td>
<td>Case number for patient.</td>
</tr>
<tr>
<td>Transported With</td>
<td>Name and title of individual accepting medication for transfer to receiving facility.</td>
</tr>
<tr>
<td>Name of Receiving Facility</td>
<td>Name and address of facility accepting patient.</td>
</tr>
<tr>
<td>Transferring Physician Name</td>
<td>Name and title of physician transferring patient.</td>
</tr>
<tr>
<td>Transported by</td>
<td>Name and title of individual transporting patient.</td>
</tr>
</tbody>
</table>

**Physician Certification:** I certify that I have examined the patient and based on the information available to me at the time of transfer, the medical benefits reasonably expected from the provision of emergency medical care in a facility managing complications of Gilenya and the outcomes of continued medical observation and treatment to the patient is the same as those expected at the time of the transfer. This certification is based upon the following:

1. Risk(s) of transfer:
   - Prolonged QTc interval (>450 msec males, >470 msec females) at any time during the observation period
   - Patient is being transferred for continued observation in accordance with the first dose protocol
   - Prolonged QTc interval (>450 msec males, >470 msec females) at any time during the observation period
   - Patient required pharmacologic intervention for symptomatic bradycardia

2. Benefit(s)
   - GILENYA is 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
   - GILENYA may delay the progression of disability related to primary progressive MS
   - GILENYA is being transferred with the patient. The remaining doses of GILENYA are being transferred with the patient. The patient should not resume taking GILENYA until cleared by the prescribing neurologist

3. Risk(s) of transport: All transfers have the inherent risks of traffic delays, accident during transport, inclement weather, rough terrain or turbulence (if air) and the limitations of equipment and personnel present at the time of transport. I certify that these risks and benefits have been explained to the patient.

4. I hereby authorize the Receiving Facility listed above to release of my Emergency Department Discharge Summary to Concentra. This authorization is valid only for the release of my Emergency Department Discharge Summary to Concentra. This authorization is valid only for the release of my Emergency Department Discharge Summary to Concentra. This authorization is valid only for the release of my Emergency Department Discharge Summary to Concentra. This authorization is valid only for the release of my Emergency Department Discharge Summary to Concentra. This authorization is valid only for the release of my Emergency Department Discharge Summary to Concentra. This authorization is valid only for the release of my Emergency Department Discharge Summary to Concentra. This authorization is valid only for the release of my Emergency Department Discharge Summary to Concentra. This authorization is valid only for the release of my Emergency Department Discharge Summary to Concentra.

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**Release of Limited Medical Records Statement:** I hereby authorize the Receiving Facility listed above to release of my Emergency Department Discharge Summary to Concentra. This authorization is valid only for the release of my Emergency Department Discharge Summary to Concentra.

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Reimbursement for Services
(Non-Concentra sites only)

+ Receipt of completed patient files will initiate payment.
+ Payments are reconciled during the first week of the new month.
  - For example, January services will be submitted for payment and paid to the GAN site by the 15th of the new month.

Billing of Patient Services

<table>
<thead>
<tr>
<th>COMMERCIAL PAY</th>
<th>GOVERNMENT PAY</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Concentra</em> reimburses network sites</td>
<td><em>Network</em> to bill Medicare, Tricare, or Medicaid as appropriate</td>
</tr>
</tbody>
</table>

Questions regarding billing issues contact:
E-mail GAN Customer Support Team Program Manager Agnes Pina at agnes.pina@concentra.com or call 972-372-5313 or 877-876-4912.
Patient Medication History

The NGN will obtain a medication list from the patient and provide it to the Gilenya Go Program, Pharma Customer Support, and the GAN site. If a medication list is not available, the GAN site clinician will consult with the patient and make a clinical judgment regarding moving forward with the FDO.

<table>
<thead>
<tr>
<th><strong>NEUROLOGIST</strong></th>
<th>Sends patient to the GAN site for FDO</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>NOVARTIS NGN</strong></td>
<td>Gathers patient medication list prior to FDO</td>
</tr>
<tr>
<td><strong>NOVARTIS NGN</strong></td>
<td>Faxes or e-mails the medication list to both the Gilenya Go Program and Pharma Customer Support</td>
</tr>
<tr>
<td><strong>CUSTOMER SUPPORT</strong></td>
<td>Transfers the medication list to the GAN site</td>
</tr>
<tr>
<td><strong>CUSTOMER SUPPORT</strong></td>
<td>Collects any comments or concerns about the medication list for the GAN site clinician</td>
</tr>
<tr>
<td><strong>NEUROLOGIST</strong></td>
<td><strong>NOVARTIS NGN</strong></td>
</tr>
</tbody>
</table>

**Note**
If GAN clinicians are unable to reach a neurologist regarding medication concerns, the GAN physician will contact the GAN medical director, Dr. Michael Rowe, at 412-720-3708.
## Patient Questions

**Whom should you refer patients to when they have questions regarding:**

<table>
<thead>
<tr>
<th>Gilenya</th>
<th>MS Treatment</th>
<th>FDO Protocols and Procedures</th>
</tr>
</thead>
<tbody>
<tr>
<td>NEUROLOGIST</td>
<td>NEUROLOGIST</td>
<td>PHARMA CUSTOMER SUPPORT</td>
</tr>
</tbody>
</table>

**Note**

The Pharma Customer Support number is 1-877-876-4912.
GAN site roles:
+ GAN site staff doesn’t recommend Gilenya. Only neurologists recommend and prescribe Gilenya
+ GAN site provides FDO service only to patients with appointments set through the Gilenya Go Program
+ GAN site staff follows protocols, manages complications, and records information
+ GAN site physicians serve as supportive partners to neurologists

GAN site EKG process:
+ GAN site staff performs EKGs, not complete cardiac evaluations
+ GAN site physicians can recommend cardiology consults
+ GAN site physicians don’t discuss EKG results with patients before consulting neurologists
+ GAN site physicians contact neurologists to discuss concerns about pre- and/or post-dose EKGs
+ GAN sites can cancel FDOs even if neurologists are comfortable with EKG results

Note
If a GAN physician cannot reach a neurologist, Concentra’s GAN medical director, Dr. Michael Rowe, can be consulted at 412-720-3708.
Initial Evaluation

STEP 1
Review baseline labs and EKG if provided

STEP 2
Perform pre-FDO EKG
+ Do not proceed with FDO if QTc interval is
  - >450 msec for males
  - >470 msec for females

STEP 3
Perform orientation assessment and obtain cardiac history, including medications

STEP 4
Validate that there are no contraindications or high risks prior to the FDO
+ History or presence of Mobitz Type II second-degree or third-degree AV or sick sinus syndrome (unless patient has a pacemaker)
+ Treatment with Class Ia or Class III anti-arrhythmic drugs
+ Heart-rate-lowering drugs that can potentially prolong the QT interval with risk of torsades

STEP 5
Call and review any abnormal results with neurologist

Refer the patient back to the neurologist for further evaluation with a cardiologist if contraindications exist

Note
Notify the neurologist if the FDO can’t be initiated or the patient shows symptomatic bradycardia.

Questions
After initial assessment, please call Dr. Michael Rowe at 412-720-3708.
Interval Checks

1. Check and sign off on vital signs every 30 minutes for first hour, every hour thereafter
2. Check sitting and standing blood pressure of ambulatory patients at first and last vital signs check
3. Have interval checks with patient each hour
4. Perform discharge evaluation and post EKG after 6 hours

Note
Notify the neurologist if the FDO can’t be initiated or the patient shows symptomatic bradycardia.

Questions
After initial assessment, please call Dr. Michael Rowe at 412-720-3708.
# Bradycardia Management

| **STEP 1** | Use clinical judgment — a decreased pulse at baseline is not bradycardia |
|**STEP 2** | Treat symptomatic bradycardia only |
|**STEP 3** | Assist the patient in walking when there’s a moderate decrease in pulse (positive chronotropic and inotropic effects of activity may improve the rate) |
|**STEP 4** | Follow these guidelines for symptomatic bradycardia and pulse (P) < 55  
+ Assess ABCs (airway, breathing, circulation)  
+ Check EKG and provide 2L O₂  
+ Monitor VS q 30 minutes with pulse oximetry  
+ Administer atropine 0.5–1 mg by IV or simple butterfly per standard ACLS protocols if significant symptoms or altered mental status are observed (a single dose should be sufficient)  
+ Run a rhythm strip before and after administration of atropine (most GAN sites have rhythm monitors)  
+ Follow the ER transfer protocol on page 43 should pharmacologic intervention be required |
Discharge Criteria

After 6 hours of monitoring, patient will be released if all apply:

+ P > 50 or P > 80% baseline value
+ Pulse rate not at lowest value measured during FDO
+ No symptoms associated with decreased pulse
+ EKG shows no new onset of second degree or higher AV block
+ QTC interval <450 msec for males and <470 msec for females

If discharge criteria are not met, continue monitoring the patient for another 2 hours. Follow the ER transfer protocol on page 31 when a patient has a QTC interval >450 msec for males and >470 msec for females.

Discharge Process

+ Complete final Treating Physician Report
+ Assist staff with completing of AE form if indicated
+ Place courtesy call to neurologist’s office with any unexpected findings

The Treating Physician Report needs to be completed even if the FDO cannot be performed. Indicate on this form the clinical findings and rationale for not performing the FDO.

Note
All discharge forms should be completed and faxed the same day of the appointment to Pharma Customer Support at 1-866-623-6857. If you have any questions, please call Pharma Customer Support at 1-877-876-4912.
Discharge Process

**STEP 1**
Complete final Treating Physician Report

**STEP 2**
Assist staff with completion of AE form, if indicated

**STEP 3**
Place courtesy call to neurologist’s office with any unexpected findings

The Treating Physician Report needs to be completed even if the FDO cannot be performed. Indicate on this form the clinical findings and rationale for not performing the FDO.

**Note**
All discharge forms should be completed same day and faxed to Pharma Customer Support at 1-877-876-4912. No forms should be sent directly to a neurologist’s office.
Transfer the patient to the ER if any of the following occur:

+ Pulse is < 50 and < 80% of baseline value
+ Pulse rate at 6 hours post dose is at its lowest value measured during observation period
+ Patient has symptoms associated with bradycardia
+ EKG post dose shows new onset second degree or higher AV block
+ Prolonged QTc interval (>450 msec males, >470 msec females) at any time during the observation period
+ Patient required pharmacologic intervention for symptomatic bradycardia

Follow the ER protocol before transfer:

+ Notify the neurologist
+ Download and fill out the ER Transfer Form
+ Make arrangements to transfer the patient to the hospital
+ Send remaining doses of Gilenya with transferred patient to ER for second dose FDO

**ER Protocol Form**

- **PHYSICIAN CERTIFICATION:** I hereby certify that I have examined the patient and, based on the information available to me at the time of transfer, I authorize the release of my Emergency Department Discharge Summary to Concentra, an affiliated entity of Concentra Health Management Corporation, to any other medical facility or organization for continued medical care.

- **Transfer the patient to the ER if any of the following occur**
  - Pulse is < 50 and < 80% of baseline value
  - Pulse rate at 6 hours post dose is at its lowest value measured during observation period
  - Patient has symptoms associated with bradycardia
  - EKG post dose shows new onset second degree or higher AV block
  - Prolonged QTc interval (>450 msec males, >470 msec females) at any time during the observation period
  - Patient required pharmacologic intervention for symptomatic bradycardia

- **Follow the ER protocol before transfer**
  - Notify the neurologist
  - Download and fill out the ER Transfer Form
  - Make arrangements to transfer the patient to the hospital
  - Send remaining doses of Gilenya with transferred patient to ER for second dose FDO

**Additional Information**

- **Transported With**
  - _Patient Name_ ___________________________________________________________________
  - _Name and Title (print)_ ____________________________________________________________________
  - _Name of Receiving Facility:_ ____________________________________________________________________

- **Transport and By**
  - _Name of Receiving Facility:_ ____________________________________________________________________
  - _Name of Transport:_ ____________________________________________________________________
  - _Number of Transfer:_ ____________________________________________________________________
  - _Reason:_ ____________________________________________________________________

- **Additional Information**
  - _Medical Records:_ ____________________________________________________________________
  - _Laboratory Results:_ ____________________________________________________________________
  - _EKG Results:_ ____________________________________________________________________

- **Release of Limited Medical Records Statement**
  - I certify that the information contained in this Emergency Department Discharge Summary to Concentra is confidential. I authorize the release of this medical information, including, but not limited to, the names of physicians and hospitals, to any other facility authorized to treat the patient.

- **Signature of Transferring Physician**
  - ____________________________  Date: ____________________________

- **Signature of Receiving Facility**
  - ____________________________  Date: ____________________________

- **Signature of Receiving Facility**
  - ____________________________  Date: ____________________________

- **Release of Limited Medical Records Statement**
  - I certify that the information contained in this Emergency Department Discharge Summary to Concentra is confidential. I authorize the release of this medical information, including, but not limited to, the names of physicians and hospitals, to any other facility authorized to treat the patient.

- **Signature of Transferring Physician**
  - ____________________________  Date: ____________________________

- **Signature of Receiving Facility**
  - ____________________________  Date: ____________________________

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- **Signature of Transferring Physician**
  - ____________________________  Date: ____________________________

- **Signature of Receiving Facility**
  - ____________________________  Date: ____________________________
Bradyarrhythmia and Atrioventricular Block

Gilenya, in controlled studies, was shown to induce a dose-dependent reduction in heart rate and has been associated with AV conduction delays including first- or second-degree AV block following administration of the initial dose.

After the first dose of Gilenya, the heart rate decrease starts within an hour and is maximal after approximately 6 hours. In clinical studies, the average decrease in heart rate was approximately 13 beats per minute (bpm). Heart rates below 40 bpm were rarely observed. Patients who experienced bradycardia were generally asymptomatic, but some patients experienced mild to moderate symptoms, including dizziness, fatigue, palpitations, and chest pain, which resolved within the first 24 hours on treatment.

At initial FDO of Gilenya 0.5 mg, the frequency of first- and second-degree AV blocks was 0.1% for each. Frequency of all bradycardia was 3.5% with 1% in the placebo group. One case of complete AV block occurred in a patient taking 1.25 mg of Gilenya (complete recovery within 24 hours) but none in the 0.5 mg groups. Mean decline was 8 bpm. One asymptomatic patient was inappropriately given isoproterenol.

Note: Read the full clinical protocols: Highlights from Prescribing Information.
Summary of 0.5 mg FDO side effects in 1,176 patients

+ Bradycardia with mean decrease of 8 bpm in 3.5% vs. 1% in placebo group
+ 4 cases of symptomatic bradycardia were seen (none required treatment)
  – 3 had mild dizziness
  – 1 had moderate somnolence later that evening
  – Symptoms in all 4 resolved in 24 hours
+ All bradycardia resolved in 30 days
Contraindications

+ Patients who in the last 6 months experienced myocardial infarction, unstable angina, stroke, Transient Ischemic Attack (TIA), decompensated heart failure requiring hospitalization, or Class III/IV heart failure

+ Mobitz Type II second-degree or third-degree AV block or sick sinus syndrome, unless patient has a functioning pacemaker

+ Baseline QTc > 500 msec

+ Treatment with Class Ia or Class III anti-arrhythmic drugs
Varicella zoster virus antibody testing/vaccination

As for any immune modulating drug, before initiating Gilenya therapy, patients without a history of chickenpox or without vaccination against varicella zoster virus (VZV) should be tested for antibodies to VZV.

VZV vaccination of antibody-negative patients should be considered prior to commencing treatment with Gilenya, following which initiation of treatment with Gilenya should be postponed for 1 month to allow the full effect of vaccination to occur.
Ketoconazole

The blood levels of fingolimod and fingolimod-phosphate increase by 1.7 times when used concomitantly with ketoconazole. Patients who use Gilenya and systemic ketoconazole concomitantly should be closely monitored, as the risk of adverse reactions is greater.
Hepatic Effects

Elevations of liver enzymes may occur in patients receiving Gilenya. Recent (within the last 6 months) transaminase and bilirubin levels should be available before initiation of Gilenya therapy. In clinical trials, Gilenya was discontinued if the elevation exceeded 5 times the upper limit of normal (ULN).

Elevations 3 times the ULN or greater in liver transaminases occurred in:
- 8% of patients treated with Gilenya 0.5 mg
- 2% of patients on placebo

Elevations 5 times the ULN occurred in:
- 2% of patients on Gilenya
- 1% of patients on placebo

Recurrence of liver transaminase elevations occurred with challenge in some patients, supporting a relationship to the drug. The majority of elevations occurred within 6–9 months. Serum transaminase levels returned to normal within approximately 2 months after discontinuation of Gilenya.

Liver enzymes should be monitored in patients who develop symptoms suggestive of hepatic dysfunction:
- Unexplained nausea
- Vomiting
- Abdominal pain
- Fatigue
- Anorexia
- Jaundice and/or dark urine

Patients with pre-existing liver disease may be at increased risk of developing elevated liver enzymes when taking Gilenya. Because Gilenya exposure is doubled in patients with severe hepatic impairment, these patients should be closely monitored, as the risk of adverse reactions is greater.
Contacts
Concentra GAN Management Team

Thomas Abraham
National Program Manager
214-326-9913
thomas_abraham@concentra.com
Questions regarding:
+ Program and operational management
+ Clinical operations and support
+ Project governance
+ Relationship management
+ Process development and administration
+ Network and vendor management
+ Program quality and customer service oversight

Dr. Michael Rowe
Medical Director
412-720-3708
michael_rowe@concentra.com
Questions regarding:
+ Clinical protocol
+ Patient adverse events
+ EKG abnormalities
+ Medication contraindications
+ Vital sign abnormalities
+ Incomplete FDOs
+ ER transfers

Agnes Pina
GAN Customer Support Team Program Manager
972-372-5313
agnes_pina@concentra.com
Questions regarding:
+ ER transfers
+ Scheduling
+ Billing/Reimbursements
+ Patient paperwork
+ Medication kits
+ Staffing issues
+ Patient issues

Matthew Gorman
Network Relationship Specialist
972-372-5324
matthew_gorman@concentra.com
Questions regarding:
+ Training
+ Onboarding
+ Contract issues
+ Credentialing issues
+ Equipment issues

Pharma Customer Support
general question or concerns
877-876-4912
novartiscss@concentra.com
# Forms, Checklists, Sheets, and Links

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<th>FORMs</th>
<th>CHECKLISTS</th>
<th>SHEETS</th>
<th>LINKS</th>
</tr>
</thead>
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<tr>
<td>+ Treating Provider Form</td>
<td>+ Cardiac Drug List</td>
<td>+ Gilenya Package Insert</td>
<td><strong>General Links</strong></td>
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<tr>
<td>+ AE Forms</td>
<td>+ Site Readiness Checklist</td>
<td>+ Nursing Flow Sheets</td>
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<td><strong>MS Organization Links</strong></td>
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<td>+ Post Assessment Form</td>
<td>+ Patient Readiness Checklists</td>
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<td><strong>MyMSTeam, the social network for those living with MS</strong></td>
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<td>+ ER Transfer Form</td>
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<td><strong>Can Do Multiple Sclerosis</strong></td>
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<td><strong>Accelerated Cure Project for MS</strong></td>
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<td><strong>Multiple Sclerosis Research Center of New York</strong></td>
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<td><strong>Myelin Repair Foundation</strong></td>
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<td><strong>National Multiple Sclerosis Society of the United States</strong></td>
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<td><strong>Nancy Davis Foundation for Multiple Sclerosis</strong></td>
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<td><strong>NARCOMS Registry</strong></td>
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<td><strong>Bike the US for MS</strong></td>
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<td><strong>Multiple Sclerosis Research Institute</strong></td>
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Glossary

AV — Atrioventricular
The atrial and ventricular chambers of the heart or the connection or coordination between them.

BI — Benefits Investigation
A list of benefits of Gilenya for MS patients.

BPM — Beats Per Minute
The process of counting how many times the heart beats per minute.

BRM — Novartis Business Relationship Manager
A person who helps with reimbursement, GAN site onboarding, and baseline FDO services.

EKG — Electrocardiography
A galvanometric device that detects and records the minute differences in electric potential caused by heart action and occurring between different parts of the body.

FDO — First Dose Observations
The first 6 hours patients are observed for bradycardia after taking Gilenya.

GAN — Gilenya Assessment Network
A network of comprehensive medical centers that provide care for MS patients.

MS — Multiple Sclerosis
Complex inflammatory disease that disrupts the nervous system.

NGN — Novartis Gilenya Nurse
A nurse who works with the MS patient from the first dose of Gilenya to the end. Serves as a communication liaison between all partners in care.

QTc — QT interval
A measure of time between the start of the Q wave and the end of the T wave in the heart’s electrical cycle.

SRF — Service Request Form
A referral form used to start MS patients on Gilenya.

Transient Ischemic Attack — TIA
A mini-stroke that occurs when a clot stops blood from flowing to part of the brain for a short time.

ULN — Upper Limit of Normal
A medical abbreviation, typically referring to the highest value of a physiological measurement that is considered normal.

VZV — Varicella Zoster Virus
A ubiquitous human alphaherpesvirus that causes varicella (chicken pox) and herpes zoster (shingles).
Gilenya FDO Site Readiness Evaluation
(To be conducted prior to first patient visit)

Date: ____________   Evaluation Completed By: _______________________

Training:
☐ All required staff have completed the GAN FDO Training modules listed below
  - Gilenya First Dose Observation eLearning Course
  - Novartis Drug Safety & Epidemiology
☐ Site has completed all credentialing and insurance paperwork and has received copy of their signed contract (Non-Concentra Network Sites Only)
☐ All required staff have received, read and understood EKG standard operating procedure
☐ All required Clinicians feel comfortable with EKG read
☐ Sample Patient Chart received and reviewed with all staff
☐ Required staff demonstrates proficiency on EKG’s and FDO clinical protocol

Equipment:
☐ All Equipment to conduct FDO visit has been received in good working order and set-up:
  - Television/DVD
  - Refrigerator
  - FDO Chair
  - iPad
☐ Site is equipped to conduct Lab tests prior to FDO if needed
☐ EKG machine is fully operational
☐ If site set up with CardioNet for EKG over reads, equipment is properly set up, functional and required staff trained on how to use equipment
☐ Appropriate leads and paper for EKG machine are available to conduct FDO visit
☐ Site to conduct a Dry Run EKG on a healthy control (i.e. fellow staff member) to ensure proper functionality of machine and test competency of user (Please fax results to e-mail address listed below)

Staffing:
☐ Trained back-up staff has been designated to provide additional coverage if needed

Center Aesthetics:
☐ FDO room is clean and all equipment (TV, Refrigerator, iPad, and Chair) has been set-up and functional
☐ Space and seating available for patient to bring one guest

Scheduling:
Please ensure that Concentra Pharma Customer Support has your most up to date days of the week and time slot that your site is available to conduct FDO visits. Any updates can be sent to novartiscss@concentra.com.

________________________________________   ______________________________________
Center Operations Director Signature/ Phone
GAN Provider (Network Sites)

________________________________________   ______________________________________
Print Center Operations Director Name/ E-mail
GAN Provider (Network Sites)

Please fax completed checklist and results of Dry Run EKG to novartiscss@concentra.com. A patient will not be able to be scheduled at your site until this checklist has been competed and received by Pharma Customer Support.

Revised 03/10/2012
# Gilenya FDO Checklist (for GAN sites)

**Patient Name:**

**Date of Service:**

## 5 days prior to appointment:

- □ EKG machine functional?
- □ Adequate supplies? (paper, ink, leads)

**Verified By:**

**Date Verified:**

## 2 days prior to appointment:

*(email novartiscss@concentra.com if missing items or not received)*

- □ Received Gilenya First Dose Observation Kit
- □ Received Medication (2 week supply)
- □ Received Patient Materials (literature, pen, bag)
- □ FDO Kit Locked in secure location for Meds

## 1 day prior to appointment:

- □ Patient chart created

  - □ Novartis FDO Nursing Flowsheets
  - □ Post Assessment Form
  - □ Adverse Events Fax Cover Sheet
  - □ Adverse Events Reporting Form

  □ Gilenya FDO Treating Provider Report
  □ Service Request Form
  □ Novartis First Dose Observation Checklist

## Patient Visit (MS=Medical Support, P=Physician/Provider):

- □ MS - Document Meds taken day of appt on OccuSource Patient Encounter
- □ P - Review of patient’s current med list if available
- □ P - Review of patient hx
- □ MS - Perform Pre FDO EKG
- □ P - Review of EKG results by Physician
- □ P - Concerns w EKG? Contact referring Neuro
- □ MS/P - Document vitals signs on FDO Nursing Flowsheet at indicated intervals
- □ Observe for Adverse Effects (check all that apply)

  - □ Referring Neuro Notified
  - □ Completed FDO
  - □ ER Transport

## Complete the Visit (MS=Medical Support, P=Physician/Provider):

- □ MS - Post FDO EKG performed, reviewed by provider and documented on Treating Provider Report
- □ MS - Review of FDO Treating Provider Report for accuracy and completion
- □ MS - Completion of the Patient Post-Assessment Form *(initialed and signed by patient and MS)*
- □ P - Completion of the Treating Provider Report Form
- □ P - Complete the Adverse Event Reporting Form *(complete only if adverse events were recorded)*
- □ MS - Fax all documents (day of appt) to 866-623-6857

  - □ Post Assessment Form
  - □ Adverse Event Form (if noted)
  - □ EKG’s
  - □ FDO Nursing Flowsheet
  - □ Treating Provider Report
  - □ Completed First Dose Observation Checklist

## iPad Process (if available):

- □ iPad Release signed by patient
- □ Log out iPad and present to patient in FDO room
- □ Patient signs iPad log to indicate receipt
- □ Collect iPad from patient at end of visit
- □ Patient signs log to indicate iPad returned
- □ Colleague co-signs log to indicate receipt
- □ Clear and charge iPad per instructions
- □ Secure iPad in designated location

**Verified By:**

**Date:**
Patient has received an initial dose of GILENYA, along with pre- and post- monitoring at our facility today. GILENYA is 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. GILENYA may produce symptomatic bradycardia in some patients. Patient is being transferred for continued observation for the following reason:

- Pulse is < 50 and < 80% of baseline value.
- Pulse rate at 6 hours post dose is at its lowest value measured during observation period.
- Patient has symptoms associated with bradycardia.
- EKG post dose shows new onset second degree or higher AV block.
- Prolonged QTc interval (>450 msec males, >470 msec females) at any time during the observation period.
- Patient required pharmacologic intervention for symptomatic bradycardia.

Additional information about GILENYA, the dose received today, and discharge criteria, is noted on the last page of this document.

**Transfer Notes** (to be completed by Physician)

---

Transported By:  
___ Ambulance  ___ Declined Ambulance*  

Transported With (if not by Ambulance*):  
Family/Friend ____________________________

___ Other* _______________________________  

Other _________________________________

*Transport by ambulance is recommended and any other form of transport would be against medical advice.

Documentation Sent: ___ Medical Records  ___ Laboratory Results  ___ EKG Results

Revised 3/12/14
PHYSICIAN CERTIFICATION: I hereby certify that I have examined the patient and, based on the information available to me at the time of transfer, the medical benefits reasonably expected from the provision of appropriate medical care at another facility outweigh the increased risk to the patient from effecting the transfer. This certification is based upon the following:

1. **Benefit(s)** of transfer:
   Patient is being transferred for continued observation in accordance with the first dose protocol.

2. **Risk(s)** of transfer (in addition to deterioration of patient’s condition/clinically specific): _________________

3. **Risk(s)** of transport: All transfers have the inherent risks of traffic delays, accident during transport, inclement weather, rough terrain or turbulence (if air) and the limitations of equipment and personnel present in the vehicle.

4. I certify that these risks and benefits have been explained to the patient.

Transferring Physician Signature: ___________________________ Date: __________________________

Transferring Physician Name: ___________________________ Phone Number: __________________________
(Printed)

**Medication:**
The remaining doses of GILENYA are being transferred with the patient. The patient should not resume taking GILENYA until cleared by the prescribing neurologist.

**Individual Accepting Medication for Transfer to Receiving Facility:**

Name and Title (printed): ___________________________

Name of Receiving Facility: ___________________________
Release Of Limited Medical Records Statement:

I hereby authorize the Receiving Facility listed above to release of my Emergency Department Discharge Summary to Concentra. This authorization is valid only for the release of my Emergency Department Discharge Summary for the visit related to this Emergency Department Transfer Form, and does not extend to any other medical records or information the Receiving Facility may have.

I understand that authorizing the release of my Emergency Department Discharge Summary to Concentra and Novartis is voluntary. I can refuse to sign this authorization. I need not sign this form in order to assure treatment. I understand that I may inspect or obtain a copy of the information to be released, as provided in CFR 164.524. I understand that any disclosure of information carries with it the potential for an unauthorized re-disclosure and the information may not be protected by federal confidentiality rules.

Patient Signature: ___________________________ Date: ________________________
GILENYA

INDICATIONS AND USAGE
GILENYA is 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.

DOSAGE AND ADMINISTRATION
Recommended Dose
- The recommended dose of GILENYA is 0.5 mg orally once daily. Fingolimod doses higher than 0.5 mg are associated with a greater incidence of adverse reactions without additional benefit. GILENYA can be taken with or without food.

First Dose Monitoring
- Initiation of GILENYA treatment results in a decrease in heart rate. After the first dose of GILENYA, the heart rate decrease starts within an hour and the Day 1 nadir generally occurs within approximately 6 hours, although the nadir can be observed up to 24 hours after the first dose in some patients.
- The first dose of GILENYA should be administered in a setting in which resources to appropriately manage symptomatic bradycardia are available. In order to assess patient response to the first dose of fingolimod, observe all patients for 6 hours for signs and symptoms of bradycardia with hourly pulse and blood pressure measurement. Obtain in all patients an electrocardiogram prior to dosing, and at the end of the observation period.

DISCHARGE CRITERIA
After 6 hours of monitoring:
Additional observation should be instituted until the finding has resolved in the following situations:
1) Pulse should be > 50 or at least > 80% of baseline value,
2) Pulse rate at 6 hours not at lowest value measured during observation period (may be hypothetically reflective of continuing decline in pulse),
3) Patients must have no symptoms associated with bradycardia.
4) EKG post dose does not show any new onset second degree or higher AV block,
5) No prolonged QTc interval (>450 msec males, >470 msec females) at any time during the observation period. These patients should be observed overnight with continuous ECG monitoring as per label,
6) Should a patient require pharmacologic intervention for symptomatic bradycardia, continuous overnight ECG monitoring in a medical facility should be instituted, and the first dose monitoring strategy should be repeated after the second dose of GILENYA.
## Gilenya FDO Nursing Flowsheet

<table>
<thead>
<tr>
<th>Time</th>
<th>Position</th>
<th>Apical Pulse</th>
<th>Blood Pressure</th>
<th>Patient Comments</th>
<th>Back Office Specialist Comments</th>
<th>Provider Comments/Signature</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vital Signs: To be taken prior to medication</td>
<td>Sitting</td>
<td>AP=___</td>
<td>BP_/_/</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time: ___</td>
<td>Standing</td>
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<tr>
<td>30 min - 1st</td>
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<td>30 min - 2nd</td>
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<td>Time: ___</td>
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<tr>
<td>Complete hour 2</td>
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<td>Time: ___</td>
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<tr>
<td>Complete hour 3</td>
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<td>Time: ___</td>
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<td>Complete hour 4</td>
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</table>

Completed by: Print Name: __________________________ Medical Support Signature: __________________________ Date: ________________
### Gilenya FDO Nursing Flowsheet

<table>
<thead>
<tr>
<th>Time</th>
<th>Position</th>
<th>Apical Pulse</th>
<th>Blood Pressure</th>
<th>Patient Comments</th>
<th>Back Office Specialist Comments</th>
<th>Provider Comments/Signature</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complete hour 5</td>
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<tr>
<td>Complete hour 6 -</td>
<td>Sitting</td>
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<tr>
<td>Discharge</td>
<td>Standing</td>
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<td>Time: ______________</td>
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<td>Extended Monitoring</td>
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**Completed by:** Print Name: ___________________  **Medical Support Signature:** ___________________  **Date:** ___________________
<table>
<thead>
<tr>
<th>Time</th>
<th>Position</th>
<th>Apical Pulse AP=</th>
<th>Blood Pressure BP</th>
<th>Patient Comments</th>
<th>Back Office Specialist Comments</th>
<th>Provider Comments/Signature</th>
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</tbody>
</table>

Completed by: Print Name: ___________________________ Medical Support Signature: ___________________________ Date: ___________________________
GILENYA FDO TREATING PROVIDER REPORT

Patient Name: _________________________________  Date of Observation: _________________________________

Patient Address: _______________________________  Observation Period Start Time: ____________________

Referring Physician: ____________________________  Observation Period End Time: ________________________

Phone Number: _________________________________  Dose Administered: _______________________________

Results – Entire Flow Sheet Attached

Initial BP/Pulse: ________________________________ Discharge BP/Pulse: ________________________________

Pre FDO EKG: _________________________________ Post FDO EKG: _________________________________

Adverse Effects: Y / N  AE Report Filed: Y / N

_________________________________________________________________________________________

_________________________________________________________________________________________

Extend FDO: Y / N  Comments _______________________________ ____________________________

Treatments:

O₂: Y / N  Comments: _______________________________________________________________________

IV: Y / N  Comments: _______________________________________________________________________

Meds: Comments: _______________________________________________________________________

Other: Comments: _______________________________________________________________________

Disposition:

____ Home  Comments: _______________________________________________________________________

____ Friend/Family Comments: _______________________________________________________________________

Transferred/Referred to (name of Hospital):

(If patient has to be transferred from site for further monitoring or any related adverse event, the
Concentra/Network GAN Clinician must contact prescribing neurologist ASAP)

Follow up:  As directed by Neurologist

_________________________________________________________________________________________

Provider Name / Signature            Date

_________________________________________________________________________________________

Center Name / Number             Provider Phone Number
**FAX coversheet**

Re: Adverse Events obtained from a Post-Marketing program

Fax within 24 hours

<table>
<thead>
<tr>
<th>To: CST</th>
<th>Name of program: Gilenya FDO</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-866-623-6857</td>
<td>Name of Vendor: Concentra</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Pages (including coversheet): 2</th>
<th>Name of Contact Person at Vendor:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Phone:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Novartis Drug: Gilenya</th>
<th>Date Received by Vendor:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Contact information for patient's treating physician: Name: Address:</th>
<th>Information was received in response to an outbound communication:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phone:</td>
<td></td>
</tr>
</tbody>
</table>

The following Adverse Event information was obtained from a post-marketing program such as those targeting patient use patterns, voucher programs, quality of life questionnaires and caregiver programs, etc.
**Adverse Event Reporting Form - Drug Safety & Epidemiology**

Fax to DS&E within 24 hours at 888-299-4565 OR call 888 NOW-NOVA (669-6682)

---

### Novartis Employee Information

<table>
<thead>
<tr>
<th>Name:</th>
<th>Title:</th>
<th>Territory #:</th>
</tr>
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<tbody>
<tr>
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</table>

<table>
<thead>
<tr>
<th>Voice mail #:</th>
<th>Date event reported to Novartis employee:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>day</td>
</tr>
</tbody>
</table>

**Example:** 01 DEC 2008

### Patient Information

<table>
<thead>
<tr>
<th>Patient initials:</th>
<th>Sex:</th>
<th>Male</th>
<th>Female</th>
<th>Age:</th>
<th>yrs</th>
<th>Date of birth:</th>
</tr>
</thead>
<tbody>
<tr>
<td>I. L.</td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td>day</td>
</tr>
</tbody>
</table>

### Suspect Product Information

<table>
<thead>
<tr>
<th>Suspect product(s):</th>
<th>Dose:</th>
<th>Frequency:</th>
<th>Route of admin:</th>
<th>Lot number (if known):</th>
<th>Exp. date (if known):</th>
</tr>
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<table>
<thead>
<tr>
<th>Therapy dates:</th>
<th>From:</th>
<th>day</th>
<th>month</th>
<th>year</th>
<th>To:</th>
<th>day</th>
<th>month</th>
<th>year</th>
<th>Indication:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>day</td>
<td></td>
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</tr>
</tbody>
</table>

**Concomitant medical products (exclude treatment of event):**

---

### Adverse Event Information

<table>
<thead>
<tr>
<th>Date adverse event started:</th>
<th>Date adverse event ended:</th>
</tr>
</thead>
<tbody>
<tr>
<td>day</td>
<td>month</td>
</tr>
</tbody>
</table>

Describe event and any necessary treatment:

---

Relevant medical history and significant lab/test data (including dates):

---

Please indicate if the patient experienced any of the outcomes below (check all that apply):

- [ ] Death
- [ ] Life-threatening
- [ ] Hospitalization - initial or prolonged
- [ ] Disability
- [ ] Congenital anomaly
- [ ] Required intervention to prevent permanent impairment/damage
- [ ] Other (specify) ______________

### Current Status of Patient

**Adverse event:**

- [ ] Resolved
- [ ] Improved
- [ ] Worsened
- [ ] No change
- [ ] Unknown

### Reporter Information

<table>
<thead>
<tr>
<th>Name:</th>
<th>Degree:</th>
<th>Institution/Office:</th>
<th>Street address:</th>
</tr>
</thead>
<tbody>
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<table>
<thead>
<tr>
<th>City:</th>
<th>State:</th>
<th>Zip:</th>
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</tbody>
</table>

**Telephone:**

**Fax:**

**Email:**

Submission of a report does not constitute an admission that medical personnel, user facility distributor, manufacturer or product caused or contributed to the event.

---

*FRM/FLDRS007 Rev.2 Version 2.0 2009-05-02*
Contraindicated/Precaution Medications

1. Treatment with Class Ia or Class III anti-arrhythmic drugs are contraindicated with Gilenya.

2. Heart Rate Lowering drugs

Experience with GILENYA is limited in patients receiving concurrent therapy with drugs that slow heart rate (e.g., beta blockers, heart-rate lowering calcium channel blockers such as Diltiazem or Verapamil, or Digoxin). Because the initiation of GILENYA treatment is also associated with slowing of the heart rate, concomitant use of these drugs during GILENYA initiation may be associated with severe bradycardia or heart block. The possibility to switch to non-heart-rate lowering drugs should be evaluated by the physician prescribing the heart-rate lowering drug before initiating GILENYA. In patients who cannot switch, overnight continuous EKG monitoring after the first dose is recommended.

3. QT prolonging drugs

GILENYA has not been studied in patients treated with drugs that prolong the QT interval. Drugs that prolong the QT interval have been associated with cases of torsades de pointes in patients with bradycardia. Since initiation of GILENYA treatment results in decreased heart rate and may prolong the QT interval, patients on QT prolonging drugs with a known risk of Torsades de pointes (e.g., citalopram, chlorpromazine, haloperidol, methadone, erythromycin) should be monitored overnight with continuous EKG in a medical facility. See list following.

Please click here to see an updated list of medications that cause QT Prolongation with a known risk of Torsades de Pointes.
Service Request 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 insurance card.

1. Patient and Insurance Information

<table>
<thead>
<tr>
<th>First Name</th>
<th>Last Name</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tr>
</tbody>
</table>

Sex:  [ ] M  [ ] F  Date of Birth (MM/DD/YYYY)

<table>
<thead>
<tr>
<th>Address</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

City  State  ZIP

Home Phone  Cell Phone (important)

E-mail address (can help speed up the process)

Contact me by:  [ ] Cell  [ ] Home Phone  [ ] E-mail

[ ] OK to leave a message

Primary Insurance Name

Beneficiary/Cardholder Name

Primary Insurance ID #  Group #

Primary Insurance Phone

Prescription Insurance Name

Prescription Insurance ID #  Phone

I have read and agree to the attached Patient Authorization and Program Consent.

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

2. Physician Information

<table>
<thead>
<tr>
<th>First Name</th>
<th>Last Name</th>
</tr>
</thead>
<tbody>
<tr>
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</tr>
</tbody>
</table>

Site Name

Address

City  State  ZIP

3. Patient Selection Assessment Completed

[ ] YES  [ ] NO  First-Dose Observation Date:

A. Patient Selection†

B. GILENYA treatment Initiation†

4. Assessment Assistance Required

[ ] YES (Assistance through the GILENYA Assessment Network—Check those that apply):

A. Patient Selection™

B. GILENYA Treatment Initiation‡

[ ] NO (Benefit Investigation and RX Only)

5. Starter Product Rx (14-Day Supply) (Optional, at no cost to patient)

Dispense 2 boxes GILENYA (7 capsules per box) followed by up to 3 refills

To be taken:

I certify that this 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 have provided the patient with a description of the GILENYA Go Program.

[ ]

Prescriber Signature  Date

6. Ongoing Rx (Please provide required prior authorization documents)

Dispense (check one):

[ ] 1 box (28 capsules per box) followed by 11 refills

[ ] 3 boxes (28 capsules per box) followed by 3 refills

To be taken:

I certify that this 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 have provided the patient with a description of the GILENYA Go Program.

[ ]

Prescriber Signature  Date

If you want assistance with the prior authorization, please answer the following:

[ ] YES  [ ] NO: Does the patient have a documented failure of an adequate trial of at least one month of Avonex, Copaxone, Fingolimod, Rebif, Betaseron, Aubagio, or Extavia? If YES, please indicate which drugs:

Notes:
I authorize my health care providers (including my doctor(s) and their staff), my pharmacies, my employer and my health insurer(s) to disclose my personal information, including information about my insurance, prescriptions, medical condition and health ("Personal Information") to Novartis Pharmaceuticals Corporation (including sales force representatives), 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 Support Program as described in the materials provided to me, and (vi) conduct market research, data analytics, quality assurance, resource allocation, and other internal business activities. I authorize the Novartis Group to disclose my Personal Information to any pharmacies, my insurance insurer(s), health care providers (including my doctor(s) and their staff) and other third parties for the purposes described above. I authorize the Novartis Group to contact me directly for the purposes described above. I understand that I may choose the dispensing pharmacy in accordance with my insurance and/or prescriber recommendation. I agree to receive telephone calls, e-mails, and mailing materials from the Novartis Group at the telephone number(s) and address(es) provided on this Service Request Form. If I check the box on page 1, I also agree to receive cell phone calls from the Novartis Group at the telephone number(s) provided. I understand that my cell phone carrier's standard rates may apply for calls to my cell phone. I understand and agree that Personal Information transmitted by e-mail and cell phone cannot be secured against unauthorized access. I understand and agree that my pharmacy, health insurance company and healthcare providers may receive remuneration 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 subsidized by Novartis Pharmaceuticals Corporation.

I understand that once my Personal Information is disclosed it may no longer be protected by federal or state law regarding patient privacy. I understand that I may refuse to sign this authorization or revoke it at any time in the future, and my refusal or future revocation will not affect the commencement, continuation, or quality 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 Support Program. 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 Support Program may be changed or ended at any time without prior notification. I understand that I may receive a copy of this authorization. Withdrawal of this authorization will end further uses and disclosures of my Personal Information by the Novartis Group, except to the extent those uses or disclosures have been made in reliance upon this authorization.

I also consent to receive marketing information, offers, and promotions from Novartis Pharmaceuticals Corporation regarding my disease and related conditions (the "Marketing Program") and to be contacted for my opinions regarding them. I understand that the Personal Information I supply to Novartis Pharmaceuticals Corporation will be shared with and among its business partners to bring me the Marketing Program and/or to conduct market research. 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 agree to receive telephone calls, e-mails, and other materials from Novartis Pharmaceuticals Corporation at the number(s) and address(es) provided on the Service Request Form. I understand that my cell phone carrier's standard rates may apply for calls to my cell phone. I understand and agree that Personal Information transmitted by e-mail and cell phone cannot be secured against unauthorized access. I may cancel my participation in the Marketing Program at any time and such cancellation will not affect my ability to participate in the Gilenya GO Support Program. I understand that Novartis Pharmaceuticals Corporation will use my Personal Information for the Marketing Program in accordance with this marketing consent and the privacy statement at www.pharma.us.novartis.com.

I understand that I may revoke my authorization and/or consent to participate in the Marketing Program 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.