#### WEST COL



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

To develop and implement a safe and effective protocol for initiation and maintenance of fingolimod.

The protocol developed emphasizes Gilenya education, including risks and benefits. Particular attention placed on face-to-face patient education; outlining patient responsibilities for Gilenya initiation and ongoing adherence.

Over one hundred patients have participated in this process that resulted in significant increased adherence, as it is related to ongoing safety monitoring.

Vigilant monitoring and adherence to safety protocol has resulted in better understanding and satisfaction for patients, as well as early recognition of potentially unfavorable drug effects.

## of Gilenya

- MD Order/Insurance Approval 2 Patient Education Pre-testing First Dose Observation 5 Ongoing Evaluation

#### 1. MD Order and Insurance Approval

Affordability of the medication is top priority before moving ahead with the patient education, as we find we often need to advocate for the patient.



#### 2. Patient Education

All patients are required to come into the MS Center for a Gilenya Patient Education visit prior to initiation of drug/pre-testing. This is a face to face visit in which patients receive verbal and written instruction for required testing. The following is an outline for that visit:

- Review of Medication
- Risks and Adverse Reactions

- Required Ongoing Evaluation
- Patient Responsibilities
- Review of Office Contacts and Patient Signs Consent

Patients must consent to all required pre-testing and follow-up testing, before starting pre-testing.

# **Best Practice for Education and Ongoing Evaluation** of Patients on Gilenya (fingolimod)

#### **5** Step Process for Initiation and Maintenance

- Benefits and Efficacy
- Pre-Dose Screening and Testing
- First Dose Observation

### 3. Pre-testing

Patients receive an individualized Gilenya folder during their education visit with instructions to call throughout the pre-testing process if they have any questions. Patients call to confirm once all prescreening/testing is complete.

#### Pre-screening/testing includes:

- 12 lead EKG
- CBC w/diff, CMP, VZV IgG (within the last 30 days)
- Recent MRI (within 3 months of FDO)
- An eye exam from ophthalmologist
- If indicated on EKG, patients are referred to cardiology
- Patients call to confirm once all pre-screening/ testing is complete.
- Final pre-testing results are reviewed and approved by MD/APN

#### 4. First Dose Observation

- FDOs are conducted in the MS Center infusion room under close supervision of APN (with MD on site at all times).
- Cardionet services are utilized for both pre and post dosing EKG
- Majority of our FDOs are done at the Center
- At risk patients are first dosed at the Mercy Heart Hospital IVC

#### 5. On-Going Evaluation

Although patients are given the responsibility to adhere to ongoing follow-up, we keep a detailed spreadsheet that allows us to track patients and remind them of needed tests/exams. Patients also receive a follow-up schedule and are encouraged to keep this up to date.





#### Since initiation of this 5 step process, total patient adherence to ongoing safety monitoring

has improved by over 50%. This safety monitoring process has been successful for our patients and MS Center staff.

**Conclusion:** 

## Sample Follow-Up **Guide Given Patients**

<b>DATE</b> <b>DUE</b> 01/01/2013	DATE COMPLETED
01/01/2013	
	01/01/2013
Feb-2013	02/04/2013
April-2013	04/10/2013
April-2013	04/12/2013
April-2013	04/10/2013
July-2013	
July-2013	
Oct-2013	
Jan-2014	
Jan-2014	
Jan-2014	
Per MD	
July-2014	
July-2014	
Jan-2015	
Jan-2015	
Jan-2015	
	April-2013         April-2013         July-2013         July-2013         Oct-2013         Jan-2014         Jan-2014         Jan-2014         July-2014         July-2014         Jan-2014         Jan-2014         Jan-2014         Jan-2014         Jan-2014         July-2014         July-2014         Jan-2015         Jan-2015







West County MS Center

