Rancho Los Amigos National Rehabilitation Center

ADMINISTRATIVE POLICY AND PROCEDURE

SUBJECT: **Fingolimod (Gilenya ®) First Dose Monitoring**

Policy No.: B879
Supersedes: 10/15/15
Reviewed: 10/17/18

PURPOSE:

To delineate the procedure for clinical management of outpatients receiving the first dose of fingolimod (Gilenya®). This medication 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. Initiation of fingolimod treatment may result in a decrease in heart rate which usually occurs within the first 6 hours after drug administration. Per FDA requirements, the patient should be monitored during the initial dose. A patient who skips one or more doses may be required to repeat the monitoring process.

Refer to FDA or drug manufacturer product information for additional information including updated recommendations and contraindications.

Contraindications for this medication:

1. Baseline QTc interval 500ms
2. Treatment with Class Ia or Class III anti-arrhythmic drugs
3. Pregnancy
4. Pediatric patients
5. Patients who experienced the following within the past 6 months:
   - Myocardial infarction
   - Unstable angina
   - Stroke
   - Transient Ischemic Attack
   - Decompensated heart failure requiring hospitalization or Class III/IV Heart Failure
   - History of Mobitz Type II Second-degree or Third-degree Atrioventricular (AV) Block or Sick Sinus Syndrome, unless patient has a functioning pacemaker.

PROCEDURE:

A. **Assessment and Procedure**
   1. In outpatient clinic, provider identifies potential candidate appropriate for fingolimod
      a. Orders diagnostic tests, including ECG, labs, ophthalmology assessment, etc.
      b. Provides initial patient education about medication and monitoring session.
   2. History and Physical completed by ordering provider within 30 days of the monitoring session includes
      a. Reason for starting Fingolimod
      b. Pertinent medical and cardiac history

c. Physical exam
d. Review of ECG
e. Absence of contraindications: recent MI, unstable angina, stroke, TIA, etc.

3. Provider submits the DHS Prior Authorization Medication Request Form via email to RLANRC Pharmacy. This form will be forwarded to DHS Core Pharmacy & Therapeutics Committee for documentation.
4. RLANRC Pharmacy informs drug manufacturer liaison to coordinate medication delivery.

5. When RLANRC Pharmacy receives the initial dose of fingolimod
   a. The drug, dose, quantity, lot number, and expiration date shall be recorded on an inventory sheet
   b. Notify ordering provider that medication has arrived
   c. Notify the drug manufacturer liaison
   d. Notify Outpatient Holding Area Scheduling Staff to schedule appointment.

6. Arrange Monitoring Appointment

   a. Outpatient Holding Area Scheduling Staff contacts patient and books the appointment

   b. When the appointment has been scheduled, Pre-operative Area Scheduling staff notifies the following:
      i. Ordering provider
      ii. On-call providers (Neurology Attending Physicians and Resident)
      iii. Pharmacy
      iv. Nutrition Department

   c. Scheduling staff informs patient of appointment logistics
      i. Check-in location: Outpatient Holding
      ii. Appointment time 8:00 a.m. Estimated discharge time: 5:00 p.m.
      iii. Activity level during observation period: rest in monitoring center
      iv. Diet: regular. Lunch provided by RLANRC
      v. Medications: bring home medications to the appointment
      vi. Driving: no restrictions
      vii. Education: expect heart rate decrease with first dose, HR will decrease within first 4-5 hours and gradually increase
      viii. Discharge criteria: heart rate stable and at least 55 bpm

B. First Dose Observation

1. Physician coverage during observation provided by:
   a. On-call: Neurology Resident
   b. Back-up: Contact Attending Neurologist for additional consultation as needed
   c. After-hours: Intensivist

2. Patient checks in at the Pre-operative Holding Area.

3. The Outpatient Holding Area Nursing Staff oversees the monitoring session.

4. Notify the following of the patient's arrival:
    a. On-call provider meets and clears patient for medication administration and writed the order on the EMR, eg. EKG, IV insertion, etc.
    b. Pharmacy

5. Initiate pre-dose actions
    a. Obtain baseline vital signs
    b. Obtain baseline ECG 12-lead
    c. Women of child-bearing age: urine pregnancy test
    d. Infuse intravenous fluid as ordered

6. On-call provider shall
    a. Examine patient
    b. Write a brief note
    c. Sign order set

7. Dispense medication:
    d. Deliver the medication order to Pharmacy
    e. Pharmacist shall dispense medication

8. Monitor vital signs hourly for minimum 6 hours: heart rate, blood pressure, respiratory rate, temperature every hour.

9. Continuous telemetry monitoring during monitoring session.

10. Contact physician if patient demonstrates symptomatic bradycardia:
    a. HR < 45 bpm
    b. HR < 20% baseline
    c. New dysrhythmia not present on admission
    d. Abnormal ECG results per computerized interpretation
    e. Other symptoms: chest pain, dizziness, pre-syncope, syncope, nausea, vomiting, etc.

11. Consult with provider regarding ACLS protocol for symptomatic bradycardia
    a. Atropine 1 mg IV
    b. Dopamine IV infusion at bedside

12. Post-dose ECG 12-lead is completed 6-hours after medication administration

13. Discharge criteria:
    a. Heart rate > 55 bpm
    b. Heart rate > 80% of baseline value
    c. No signs of cardiac insufficiency or signs/symptoms including: chest pain, dizziness, palpitations, syncope, nausea, vomiting
    d. ECG results unchanged from baseline (other than sinus bradycardia). No new signs that were not observed at pre-dose ECG.
    e. Heart rate should not be the lowest value recorded during monitoring period (suggestive of progressive decline). Heart rate may not have returned to baseline but should be increasing.

14. If patient does not meet discharge criteria, consult with on-call physician. Provider may:
    a. Extend monitoring period
        i. Continue with hourly monitoring of vital signs for 1-2 hours
        ii. Evaluate resolution of symptomatic bradycardia
        iii. Re-assess for discharge
    b. If symptomatic bradycardia does not resolve in a timely manner, transfer patient to appropriate level of care

15. If discharge criteria have been met, on-call provider clears patient for discharge
    a. Review patient status, discharge criteria, and ECG results
    b. Order discharge
    c. Write brief note

16. Nursing staff provides discharge instructions
    a. Inform patient that drug manufacturer liaison will contact patient following discharge
    b. Provide patient education materials from fingolimod website
    c. Advise patient to take medication daily. Skipping one or more doses may require patient to repeat monitoring session.

C. Assessment and Process for LAC+USC Outpatients

1. Potential candidates may be identified in LAC+USC Neurology Clinic.
2. LAC+USC clinic staff and provider submit referral to RLANRC Referral Office for
    a. Financial screening
    b. Assignment of MRUN
3. RLANRC referral staff schedules patient for MS Evaluation Clinic.
4. Follow Section A above for "Assessment and Process"

REFERENCES:

Gilenya.
https://www.gilenya.com/index.jsp?utm_source=google&utm_medium=paid&utm_campaign=Gilenya.com_Branded_Google_5.2020&utm_term=Generic_Exact%20%7c%20fingolimod%20brand%20name&gclid=EAIaIQobChMI1KHv3Ne8-QIVXSCtBh1qIwUdEAAYASAAEgJXQvD_BwE&gclsrc=aw.ds
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Highlights of Prescribing Information.
https://www.novartis.com/us-en/sites/novartis_us/files/gilenya.pdf
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