

## Specialty Pharmacy Program

### Gilenya™ (fingolimod)

#### DESCRIPTION

Gilenya is an oral disease-modifying treatment for multiple sclerosis (MS). Gilenya is indicated for the treatment of patients with relapsing forms of MS to reduce the frequency of clinical exacerbations and to delay the accumulation of physical disability.

#### APPROVAL DURATION AND QUANTITY LIMITS

Approval duration: lifetime

Quantity limit: 28 capsules per 28 days

#### APPROVAL CRITERIA

Gilenya will be approved if the patient meets the following criteria:

- I. Patient has a relapsing form of multiple sclerosis (MS) **AND**
- II. Patient will not receive Gilenya concurrently with antineoplastic, immunosuppressive, or immune modulating therapy **AND**
- III. Patient will not receive Gilenya concurrently with a biologic agent for MS (eg, interferon beta, Copaxone, Tysabri) **AND**
- IV. Patient has had the following tests performed within 6 months of starting Gilenya with normal results:
  - A. Electrocardiogram (ECG) **AND**
  - B. Complete blood count (CBC) **AND**
  - C. Liver function tests (LFTs) **AND**
  - D. Ophthalmologic examination in patients with diabetes or a history of uveitis**AND**
- V. Patient has immunity to varicella:
  - A. History of chickenpox **OR**
  - B. Patient has been vaccinated against varicella zoster virus (VZV) **OR**
  - C. Immunity confirmed with positive VZV antibody testing **AND**
- VI. The first dose of Gilenya will be administered under health care provider supervision **AND**
- VII. Patient will be observed for a minimum of six hours after the first dose of Gilenya to monitor for signs and symptoms of bradycardia **AND**
- VIII. The prescribed quantity does not exceed 28 capsules per 28 days.