Custom Criteria for
BlueCross Blue Shield of Rhode Island Commercial

catamaran™

GILENYA™ (fingolimod)

GPI CODING:

62407025100120

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:

Approval duration: lifetime
Quantity limit: 28 capsules per 28 days

CRITERIA FOR GILENYA

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 Class Ia antiarrhythmic agent (disopyramide, procainamide, quinidine) or a Class III antiarrhythmic agent (amiodarone, bretylium, dofetilide, ibutilide, sotalol) **AND**
IV. Patient has not experienced any of the following in the last 6 months: myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or Class III/IV heart failure **AND**
V. Patient does not have a baseline QTc interval ≥500 ms **AND**
VI. Patient does not have current or past history of Mobitz Type II 2nd-degree or 3rd-degree AV block or sick sinus syndrome (unless patient has a functioning pacemaker) **AND**
VII. Patient has immunity to varicella from one of the following:
   A. History of chickenpox
   B. Patient has been vaccinated against varicella zoster virus (VZV)
   C. Immunity confirmed with positive VZV antibody testing

AND

VIII. Patient has all of the following tests performed within 6 months of starting Gilenya with normal results:
   A. Complete blood count (CBC)
   B. Liver function tests (LFTs)
   C. Ophthalmologic examination in patients with diabetes or a history of uveitis

AND

IX. The first dose of Gilenya will be administered under health care provider supervision **AND**
X. Patient will be observed for a minimum of six hours after the first dose of Gilenya to monitor for signs and symptoms of bradycardia with hourly pulse and blood pressure measurement **AND**
XI. ECG will be/was obtained prior to dosing and at the end of the observation period

AND

XII. For patients who are not currently stable on therapy (naïve to treatment):

A. Patient has had an inadequate response to a previous trial of interferon beta (Avonex, Betaseron, Extavia, Rebif) or glatiramer (Copaxone) **OR**
B. Patient has a documented contraindication to interferon beta or glatiramer **OR**
C. Patient is intolerant to or had a confirmed adverse event with interferon beta or glatiramer