GUIDELINES FOR USE

1. Does the patient have a diagnosis of relapsing-remitting multiple sclerosis (RRMS), secondary-progressive multiple sclerosis, or progressive-relapsing multiple sclerosis?

   If yes, continue to #2.
   If no, do not approve.

   **DENIAL TEXT:** See the denial text at the end of the guideline.

2. Has the patient tried Copaxone AND an interferon (Rebif or Avonex or Extavia or Betaseron)?

   If yes, continue to #3.
   If no, do not approve.

   **DENIAL TEXT:** See the denial text at the end of the guideline.

3. Does the patient have any of the following contraindications to Gilenya?
   a.) recent (within past 6 months) occurrence of myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or Class III/IV heart failure;
   b.) history or presence of Mobitz Type II 2nd degree or 3rd degree AV block or sick sinus syndrome, unless patient has pacemaker;
   c.) baseline QTC interval 500ms or above; or
   d.) treatment with Class Ia (quinidine, procainamide, or disopyramide) or Class III anti-arrhythmic drugs (amiodarone, dofetilide, dronedarone, ibutilide, or sotalol)

   If yes, do not approve.

   **DENIAL TEXT:** See the denial text at the end of the guideline.

   If no, **Approve for 12 months by HICL with a quantity limit of #28 capsules per 28 days.**

**DENIAL TEXT:** Our guideline for **FINGOLIMOD** requires a diagnosis of relapsing-remitting, secondary-progressive, or progressive-relapsing multiple sclerosis and a trial of Copaxone AND an interferon (Rebif, Avonex, Extavia or Betaseron), or the patient has experienced rapid progression of disease while on interferon therapy, and the absence of medical history or cardiac events that are contraindicated with the use of Gilenya (those that may increase risk of cardiac events associated with Gilenya).
FINGOLIMOD

RATIONALE
To prevent inappropriate utilization of fingolimod for clinically isolated syndrome (CIS) or in those patients for whom Gilenya is contraindicated and to encourage the use of Copaxone and preferred interferons.

Cardiovascular adverse effects, including bradycardia and heart block, have been associated with Gilenya, especially early in therapy. Bradycardia was observed in fingolimod clinical trials (4% in fingolimod group versus 1% in placebo group), although patients at high risk of bradycardia were excluded from the clinical trials. When Gilenya was approved, initial product labeling included information on first dose monitoring and instructed health care professionals to observe patients for at least 6 hours after the first dose. Patients exhibiting symptomatic bradycardia should obtain continuous ECG monitoring until symptoms resolve. The manufacturer has recently updated labeling information to include a list of cardiovascular contraindications for Gilenya, including recent (within past 6 months) occurrence of myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or Class III/IV heart failure; history or presence of Mobitz Type II 2nd degree or 3rd degree AV block or sick sinus syndrome, unless patient has pacemaker; baseline QTC interval 500ms or above; or treatment with Class Ia or Class III anti-arrhythmic drugs.

FDA APPROVED INDICATIONS
Fingolimod is 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.

REFERENCES