**FINGOLIMOD**

| Generic | Brand | HICL | GCN | Exception/Other |
|---|---|---|---|---|
| FINGOLIMOD | GILENYA | 37180 | | |

**GUIDELINES FOR USE**

1. Does the patient have the diagnosis of a relapsing form of multiple sclerosis to include clinically isolated syndrome, relapsing-remitting disease and active secondary progressive disease **AND** meet the following criterion?
   - The patient is 10 years of age and older

   If yes, continue to #2.
   If no, do not approve.
   **DENIAL TEXT:** See the denial text at the end of the guideline.

2. 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
   - A history or presence of Mobitz Type II 2$^{nd}$ degree or 3$^{rd}$ degree AV block or sick sinus syndrome, unless patient has a functioning pacemaker
   - A baseline QTC interval 500 msec or above
   - Current 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 #1 capsule per day.**

**DENIAL TEXT:** The guideline named **FINGOLIMOD (Gilenya)** requires the diagnosis of a relapsing form of multiple sclerosis, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in patients 10 years of age and older. In addition, approval requires 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), which includes any of the following criteria:
- 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
- A history or presence of Mobitz Type II 2nd degree or 3rd degree AV block or sick sinus syndrome, unless the patient has a functioning pacemaker
- A baseline QTC interval 500 msec or above
- Current treatment with Class Ia (quinidine, procainamide, or disopyramide) or Class III anti-arrhythmic drugs (amiodarone, dofetilide, dronedarone, ibutilide, or sotalol)

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## FINGOLIMOD

### RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Review for Gilenya.

### REFERENCES


- Novartis Pharmaceutical Corporation. Gilenya package insert. East Hanover, NJ. August 2019.


| Library | Commercial | NSA |
|---|---|---|
| Yes | Yes | No |

Part D Effective: N/A
Commercial Effective: 10/07/19
Created: 11/10
Client Approval: 09/19
P&T Approval: 07/18