

## Multiple Sclerosis Agents Prior Authorization

<b>Drug(s) Applied:</b>	<b>Betaseron</b> (Interferon beta-1b), <b> fingolimod (0.5mg only)</b> , <b>glatiramer acetate</b> , <b>glatopa</b> (glatiramer acetate)
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### Criteria:

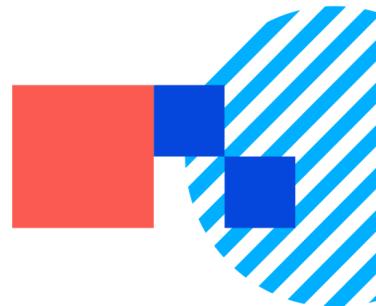
Drug(s) Applied will be approved when the requested medication is being used for an FDA approved indication and all of the following criteria are met:

#### I. Initial Therapy Criteria

**A. Clinically Isolated Syndrome (CIS), Relapsing Remitting Multiple Sclerosis (RRMS) or Active Secondary Progressive Multiple Sclerosis (SPMS)** as indicated by chart notes within past 90 days

1. Patient's age is within FDA labeling for the requested indication for the requested agent **and**
2. If the requested agent is fingolimod and the patient is a female of reproductive potential then the prescriber notes the patient is not pregnant prior to initiation of treatment with requested agent and the patient will use effective contraception throughout treatment **and**
3. If the requested agent is fingolimod, then chart notes do not indicate that the patient has any of the following:
  - a) Recent myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure with hospitalization, or Class III/IV heart failure
  - b) History of Mobitz Type II 2nd degree or 3rd degree AV block or sick sinus syndrome, unless patient has a pacemaker
  - c) A baseline QTc interval  $\geq$  500 msec
  - d) Cardiac arrhythmias requiring anti-arrhythmic treatment with Class Ia or Class III anti-arrhythmic drugs
  - e) Patient does not have Progressive Multifocal Leukoencephalopathy (PML) **and**
4. Patient will NOT be using the requested agent in combination with an additional disease modifying therapy (DMT) for the requested indication; with exception of an agent used in combination with Mavenclad (cladribine) and the prescriber has provided justification for combination use (e.g., using DMT for relapse between cycles of Mavenclad) **and**
5. Prescriber is a specialist, or has consulted with a specialist, in the area of the





patient's diagnosis (e.g., neurology)

**Approval Duration:** 12 months

## II. Continued Therapy Criteria

**A. Clinically Isolated Syndrome (CIS), Relapsing Remitting Multiple Sclerosis (RRMS) or Active Secondary Progressive Multiple Sclerosis (SPMS) as indicated by chart notes within past 12 months**

1. Chart notes indicate patient has been on requested drug as continuation of therapy with documented clinical benefit **and**
2. Prescriber is monitoring patient for adverse effects (e.g., PML development, liver dysfunction, cardiovascular dysfunction) **and**
3. Patient's age is within FDA labeling for the requested indication for the requested agent **and**
4. Patient will NOT be using the requested agent in combination with an additional disease modifying therapy (DMT) for the requested indication; with exception of an agent used in combination with Mavenclad (cladribine) and the prescriber has provided justification for combination use (e.g., using DMT for relapse between cycles of Mavenclad) **and**
5. Prescriber is a specialist, or has consulted with a specialist, in the area of the patient's diagnosis (e.g., neurology)

**Approval Duration:** 12 months

**Policy Owned by:** Curative PBM team

