curative

Multiple Sclerosis Agents Prior Authorization

Drug(s) Applied:	**Avonex** (Interferon beta-1a) **Betaseron** (Interferon beta-1b) **Fingolimod (0.5mg only)** **Glatiramer Acetate** **Glatopa** (Glatiramer Acetate) **Kesimpta** (Ofatumumab)

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 Approval 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 Kesimpta, then **one** of the following applies:
   a) Patient has had an inadequate response to rituximab **or**
   b) A noted adverse reaction, or contraindication to rituximab that is not expected to occur with use of requested agent **and**
3. 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**
4. 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 ≥ 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**

5. If the requested agent is Kesimpta, then chart notes do not indicate that the patient has active hepatitis B viral infection **and**
6. If the requested agent is Avonex, must have documented failure of betaseron **and**
7. 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**
8. 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 Approval

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. If the requested agent is Kesimpta, then chart notes do not indicate that the patient has active hepatitis B viral infection **and**
5. If the requested agent is Avonex, must have documented failure of betaseron **and**
6. 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**
7. 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