This Coverage Policy applies to Individual Health Insurance Marketplace benefit plans only.

**Multiple Sclerosis Agents**

Ampyra®, Aubagio®, Avonex®, Betaseron®, Copaxone®, Extavia®, Gilenya®, Glatopa™, Plegridy™, Rebif®, Tysabri®

**COVERAGE POLICY**

Note: The provision of physician samples does not guarantee coverage under the provisions of the pharmacy benefit. All criteria below must be met in order to obtain coverage of Ampyra, Aubagio, Avonex, Betaseron, Copaxone, Extavia, Gilenya, Glatopa, Rebif, Tysabri

For **Ampyra**

- A documented diagnosis of multiple sclerosis AND ALL of the following:
  - Member is 18 years or older, and
  - Normal creatinine clearance (> 50 ml/ min), and
  - No past medical history of seizures, and
  - Member has sustained walking impairment, and
  - Member is able to walk 25 feet without assistance

- For renewal at 3 months and every 12 months thereafter:
  - Member has continued therapeutic response to Ampyra

For **Aubagio**

- A documented diagnosis of relapsing remitting multiple sclerosis **AND** documentation of **ALL** of the following:
- Discontinuation of other therapies used for treating multiple sclerosis (Note: This does NOT require having to discontinue Ampyra)
- Recent (within 6 months) complete blood count (CBC)
- Recent (within 6 months) liver transaminase and bilirubin levels
- Recent Tuberculin skin test (within 6 months) to check for latent Tuberculosis
- Blood pressure monitoring at initiation and during treatment
- If Female, confirmation of negative pregnancy test at initiation of therapy and confirmation that reliable contraception will be used during treatment with Aubagio
- A documented contraindication or intolerance or allergy or failure of an adequate trial* of 3 preferred alternatives, including Glatopa or Copaxone 40mg, Rebif, and Gilenya

* For purposes of this policy, failure of an adequate trial of therapy for multiple sclerosis is defined as follows:
  o The member has increasing relapses (defined as two or more relapses in a year, or one severe relapse associated with either poor recovery or MRI lesion progression); OR
  o The member has lesion progression by MRI (increased number or volume of gadolinium-enhancing lesions, T2 hyperintense lesions or T1 hypointense lesions); OR
  o The member has worsening disability (sustained worsening of Expanded Disability Status Scale (EDSS) score or neurological examination findings)

Intolerance is defined as intolerable side effects despite optimized management strategies.

For **Avonex**
  o A documented diagnosis of relapsing remitting multiple sclerosis AND documentation of all of the following:
    - Discontinuation of other therapies used for treating multiple sclerosis (Note: This does NOT require having to discontinue Ampyra)
    - A documented contraindication or intolerance or allergy or failure of an adequate trial* of 3 preferred alternatives, including Glatopa or Copaxone 40mg and Rebif and Gilenya

* For purposes of this policy, failure of an adequate trial of therapy for multiple sclerosis is defined as follows:
  o The member has increasing relapses (defined as two or more relapses in a year, or one severe relapse associated with either poor recovery or MRI lesion progression); OR
  o The member has lesion progression by MRI (increased number or volume of gadolinium-enhancing lesions, T2 hyperintense lesions or T1 hypointense lesions); OR
  o The member has worsening disability (sustained worsening of Expanded Disability Status Scale (EDSS) score or neurological examination findings)

Intolerance is defined as intolerable side effects despite optimized management strategies.

For **Betaseron, Extavia,** and **Plegridy**
  o A documented diagnosis of relapsing remitting multiple sclerosis AND documentation of all of the following:
- Discontinuation of other therapies used for treating multiple sclerosis (Note: This does NOT require having to discontinue Ampyra)
- A documented contraindication or intolerance or allergy or failure of an adequate trial* of 3 preferred alternatives, including Glatopa or Copaxone 40mg and Rebif and Gilenya

* For purposes of this policy, failure of an adequate trial of therapy for multiple sclerosis is defined as follows:
  - The member has increasing relapses (defined as two or more relapses in a year, or one severe relapse associated with either poor recovery or MRI lesion progression); OR
  - The member has lesion progression by MRI (increased number or volume of gadolinium-enhancing lesions, T2 hyperintense lesions or T1 hypointense lesions); OR
  - The member has worsening disability (sustained worsening of Expanded Disability Status Scale (EDSS) score or neurological examination findings)

Intolerance is defined as intolerable side effects despite optimized management strategies.

For **Copaxone 20 mg**
- A documented diagnosis of one of the following **AND** discontinuation of other therapies used for treating multiple sclerosis (Note: This does NOT require having to discontinue Ampyra)
  - Clinically isolated syndrome (CIS) suggestive of multiple sclerosis (MS) (i.e. persons who have experienced a first clinical episode and have magnetic resonance imaging (MRI) features consistent with MS))
  - Relapsing, remitting multiple sclerosis (Note: Does not include diagnosis of chronic progressive multiple sclerosis (MS))
  - A documented contraindication or intolerance or allergy or failure of an adequate trial* of the preferred alternative Glatopa

For **Copaxone 40 mg**
- A documented diagnosis of one of the following **AND** discontinuation of other therapies used for treating multiple sclerosis (Note: This does NOT require having to discontinue Ampyra)
  - Clinically isolated syndrome (CIS) suggestive of multiple sclerosis (MS) (i.e. persons who have experienced a first clinical episode and have magnetic resonance imaging (MRI) features consistent with MS))
  - Relapsing, remitting multiple sclerosis (Note: Does not include diagnosis of chronic progressive multiple sclerosis (MS))

For **Gilenya**
For new starts or restarts after 6 months or more of treatment interruption:
- A documented diagnosis of relapsing, remitting multiple sclerosis **AND** documentation of **ALL** of the following:
  - Discontinuation of other therapies used for treating multiple sclerosis (Note: This does NOT require having to discontinue Ampyra)
  - Recent (within 6 months) complete blood count (CBC)
  - Recent (within 6 months) liver transaminase and bilirubin levels
- A documented EKG (i.e. electrocardiogram that measures rate and regularity of heartbeats) prior to the first dose **AND** a documented EKG at the end of the observation period **AND** documented to have **NONE** of the following:
  - Recent (within the last 6 months) occurrence of myocardial infarction (i.e. heart attack), unstable angina, stroke, transient ischemic attack (i.e. mini stroke), 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 (these are specific types of heart rhythm problems), unless patient has a pacemaker
  - Baseline QTc interval ≥500 ms (as measured on most recent EKG)
  - Treatment with Class Ia or Class III anti-arrhythmic drugs**
- A documented baseline ophthalmologic examination
- A documented history of chicken pox or administration of the varicella zoster vaccine (VZV) (If history of chicken pox or administration of VZV is unknown then titers should be drawn and if low VZV should be considered)
- If female, a documented negative pregnancy test

For restarts after treatment interruption of less than 6 months:
  - If re-initiating Gilenya after treatment interruption of less than 6 months, then a documented EKG prior to the first re-initiated dose **AND** a documented EKG at the end of the observation period will be required

For **Glatopa**
  - A documented diagnosis of one of the following **AND** discontinuation of other therapies used for treating multiple sclerosis (Note: This does NOT require having to discontinue Ampyra)
    - Clinically isolated syndrome (CIS) suggestive of multiple sclerosis (MS) (i.e. persons who have experienced a first clinical episode and have magnetic resonance imaging (MRI) features consistent with MS))
    - Relapsing, remitting multiple sclerosis (Note: Does not include diagnosis of chronic progressive multiple sclerosis(MS))

For **Rebif**
  - A documented diagnosis of relapsing remitting multiple sclerosis **AND** discontinuation of other therapies used for treating multiple sclerosis (Note: This does NOT require having to discontinue Ampyra)

For **Tecfidera**
  - A documented diagnosis of relapsing remitting multiple sclerosis **AND** documentation of all of the following:
    - Discontinuation of other therapies used for treating multiple sclerosis while on therapy with Tecfidera (Note: This does NOT require having to discontinue Ampyra)
    - Recent (within 6 months) complete blood count (CBC)
    - A documented contraindication or intolerance or allergy or failure of an adequate trial* of 3 preferred alternatives, including Glatopa or Copaxone 40mg and Rebif and Gilenya
* For purposes of this policy, failure of an adequate trial of therapy for multiple sclerosis is defined as follows:
  - The member has increasing relapses (defined as two or more relapses in a year, or one severe relapse associated with either poor recovery or MRI lesion progression); **OR**
  - The member has lesion progression by MRI (increased number or volume of gadolinium-enhancing lesions, T2 hyperintense lesions or T1 hypointense lesions); **OR**
  - The member has worsening disability (sustained worsening of Expanded Disability Status Scale (EDSS) score or neurological examination findings)

Intolerance is defined as intolerable side effects despite optimized management strategies.

### AUTHORIZATION PERIOD AND LIMITATIONS

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<tr>
<th>MS Agent</th>
<th>Initial Approval</th>
<th>Extended Approval</th>
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<tbody>
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<td>Ampyra</td>
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<td>Six months</td>
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### NON-COVERAGE

1. Use not approved by the FDA; and
2. The use is unapproved and not supported by the literature or evidence as an accepted off-label use. (see Off-Label Use Policy for determining ‘accepted use’)
3. Combination use of interferons and/or glatiramer, and/or Gilenya and/or Aubagio and/or Tysabri

### REFERENCES


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