AETNA BETTER HEALTH®
Prior Authorization guideline for Multiple Sclerosis Agents

Multiple Sclerosis Agents –Preferred Agents in Bold
- Avonex®, Rebif® (Interferon Beta-1a),
- Betaseron®, Extavia® (Interferon Beta-1b)
- Copaxone® (Glatiramer), Glatopa (Glatiramer)
- Tysabri® (natalizumab)
- Novantrone® (mitoxantrone)
- Gilenya® (Fingolimod)
- Tecfidera (dimethyl fumerate)
- Aubagio (teriflunomide)
- Ampyra (dalfampridine)
- Lemtrada® (alemtuzumab)
- Plegridy® (peginterferon beta-1a)

Authorization guidelines
Glatopa, Rebif, Aubagio, Copaxone, Extavia, and are the preferred MS agents. Non-preferred product will be considered with documentation to support trial and failure or contraindication to 2 preferred agents.

Discontinuation of treatment of other MS therapies is required before initiating new MS therapy, except for Ampyra.

For patients who have the following:
1. Must be prescribed for an FDA approved indication
2. Must be 18 years of age or older (except Lemtrada)
3. Prescribed by a Neurologist
4. Meet the additional requires for the requested drug as noted in the following:

(Injectables)

Copaxone/Glatopa (glatiramer acetate)
- Diagnosis of Relapsing Remitting Multiple Sclerosis or
- Clinically Isolated Syndrome suggestive of MS (i.e. persons who have experienced a first clinical episode and have magnetic resonance imaging (MRI) features consistent with MS) and
- Discontinuation of other MS therapies
**Extavia** (interferon-beta1b)
- Diagnosis of Relapsing Remitting Multiple Sclerosis
- Clinically Isolated Syndrome suggestive of MS (i.e. persons who have experienced a first clinical episode and have magnetic resonance imaging (MRI) features consistent with MS) and
- Discontinuation of other MS therapies

**Rebif** (interferon-beta1a)
- Diagnosis of Relapsing Remitting Multiple Sclerosis and
- Discontinuation of other MS therapies

**Avonex** (interferon-beta1a)
- Diagnosis of Relapsing Remitting Multiple Sclerosis
- Discontinuation of other MS therapies
- Trial and failure of or contraindication to 2 formulary agents (i.e., Glatopa, Copaxone, Extavia, Rebif, or Aubagio)

**Plegridy** (peg-interferon-beta1a)
- Diagnosis of Relapsing Remitting Multiple Sclerosis
- Discontinuation of other MS therapies
- Trial and failure of or contraindication to 2 formulary agents (i.e., Glatopa, Copaxone, Extavia, Rebif, or Aubagio)

**Betaseron** (Interferon-beta1b)
- Diagnosis of Relapsing Remitting Multiple Sclerosis
- Discontinuation of other MS therapies
- Trial and failure of or contraindication to 2 formulary agents (i.e., Glatopa, Copaxone, Extavia, Rebif, or Aubagio)

(ORAL Agents)

**Aubagio** (teriflunamide)
- Diagnosis of Relapsing Remitting Multiple Sclerosis
- Discontinuation of other MS therapies
- All of the following labs within the last 6 months
  - CBC
  - LFT’s and bilirubin levels
  - Negative pregnancy if female
  - Recent Tuberculin skin test
**Gilenya** (fingolimod)
- Diagnosis of Relapsing Remitting Multiple Sclerosis
- Discontinuation of other MS therapies
- All of the following labs within the last 6 months
  - CBC
  - LFT’s and bilirubin levels
  - Negative pregnancy if female
  - EKG evaluation (i.e., has not had MI, unstable angina, TIA, QTc ≥500 msec, Mobitz type II (2nd or 3rd degree AV block)
  - Ophthalmic examination
  - No hx of chicken pox or evidence of vaccination
- Trial and failure of or contraindication to 2 formulary alternatives (i.e., Glatopa, Copaxone, Extavia, Rebif or Aubagio; one of the agents must include Aubagio)

**Tecfidera** (dimethyl fumarate)
- Diagnosis of Relapsing Remitting Multiple Sclerosis
- Discontinuation of other MS therapies
- CBC done within the past 6 months
- Trial and failure of or contraindication to 2 formulary alternatives (i.e., Glatopa, Copaxone, Extavia, Rebif or Aubagio; one of the agents must include Aubagio)

(Infusions)

**Lemtrada** (alemtuzumab)
- Patient is 17 years of age and older
- Diagnosis of Relapsing Remitting Multiple Sclerosis
- Discontinuation of other MS therapies
- Will not exceed 5 days of treatment the first year and 3 days of treatment the 2nd year
- Not infected with HIV
- Trial and failure of or contraindication to 2 formulary agents (i.e., glatopa, Copaxone, Extavia, Rebif or Aubagio)

**Tysabri** (natalizumab)
- Diagnosis of Relapsing Remitting Multiple Sclerosis
- Discontinuation of other MS therapies (excluding Ampyra)
- Anti-JCV antibody test (ELISA) performed (those with positive anti-JCV antibody have a higher risk for developing progressive multifocal leukoencephalopathy (PML)
- Trial and failure of or contraindication 2 formulary alternatives (i.e., glatopa, Copaxone, Extavia, Rebif, or Aubagio)

**Mitoxantrone**
- Diagnosis is secondary (chronic) progressive (SPMS), progressive relapsing (PRMS), or worsening relapsing-remitting multiple sclerosis to reduce neurologic disability and/or frequency of clinical Relapse
- All of the following labs within the last 6 months:
  - Cumulative dose is less than 140 mg/m²
  - LVEF (left ventricular ejection fraction) > 50% (not below the lower limit of normal)
  - ANC > 1500 cells/mm³
- Trial and failure of or contraindication to 2 formulary alternatives (i.e., Glatopa, Copaxone, Extavia, Rebif or Aubagio)

**Authorization and Limitations**

**Approval Duration:**
- All injections: Indefinite
- Tysabri- 3 months
- Lemtrada-12 months (2 years maximum allowed)
- Mitoxantrone-3 months

**Renewal:**
- Documentation and lab results to support response to treatment (i.e., LVEF, CBC, ANC, ECG, etc.)
- Lemtrada-12 months (2 year maximum allowed)
- Mitoxantrone-3 months
- Tysabri- 6 months

**Additional Information:**
Multiple Sclerosis agents are NOT covered for members with the following criteria:
- Use not approved by the FDA; **AND**
- The use is unapproved and not supported by the literature or evidence as an accepted off-label use.

**Medically Necessary** — A service or benefit is Medically Necessary if it is compensable under the MA Program and if it meets any one of the following standards:

- The service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.
• The service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.

• The service or benefit will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

Determination of Medical Necessity for covered care and services, whether made on a Prior Authorization, Concurrent Review, Retrospective Review, or exception basis, must be documented in writing.

The determination is based on medical information provided by the Member, the Member’s family/caretaker and the Primary Care Practitioner, as well as any other Providers, programs, agencies that have evaluated the Member.

All such determinations must be made by qualified and trained Health Care Providers. A Health Care Provider who makes such determinations of Medical Necessity is not considered to be providing a health care service under this Agreement.

References:


