

**Pharmacy Prior Authorization
Multiple Sclerosis Clinical Guidelines**

Aubagio® (teriflunomide)
Avonex® (interferon beta-1a)
Betaseron® (interferon beta-1b)
Copaxone® (glatiramer acetate)

Extavia® (interferon beta-1b)
Gilenya® (fingolimod)
Lemtrada® (alemtuzumab)
Mitoxantrone glatiramer acetate

Plegridy® (peginterferon beta-1a)
Rebif® (interferon beta-1a)
Tecfidera® (dimethyl fumarate)
Tyasbri® (natalizumab)

Preferred Product:

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

Criteria for Approval:

For patients who meet all of the following:

- 18 years of age or older (except for Lemtrada)
- Prescribed by a Neurologist
- Discontinuation of other disease modifying MS therapies (not including Ampyra)

Injectables

- **Copaxone/Glatopa** (glatiramer acetate) and **Extavia** (interferon-beta1b)
 - 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)
- **Rebif** (interferon-beta1a)
 - Diagnosis of Relapsing Remitting Multiple Sclerosis
- **Avonex** (interferon-beta1a), **Plegridy** (peg-interferon-beta1a), and **Betaseron** (Interferon-beta1b)
 - Diagnosis of Relapsing Remitting Multiple Sclerosis
 - 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
 - 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
 - All of the following labs within the last 6 months
 - CBC
 - LFT's and bilirubin levels
 - Negative pregnancy if female
 - EKG evaluation [i.e., QTc ≥500 msec, Mobitz type II (2nd or 3rd degree AV block)]
 - Ophthalmic examination

**Pharmacy Prior Authorization
Multiple Sclerosis Clinical Guidelines**

- Patient has documented history of chicken pox OR has had the varicella zoster vaccination OR has evidence of immunity (positive antibodies)
- No history of MI, unstable angina, stroke, or TIA within the past 6 months
- Trial and failure of or contraindication to 2 formulary alternatives; one of the agents must include Aubagio (i.e., glatopa, Copaxone, Extavia, Rebif or Aubagio)
- **Tecfidera** (dimethyl fumarate)
 - Diagnosis of Relapsing Remitting Multiple Sclerosis
 - CBC done within the past 6 months
 - Trial and failure of or contraindication to 2 formulary alternatives; one of the agents must include Aubagio (i.e., glatopa, Copaxone, Extavia, Rebif or Aubagio)

Infusions

- **Lemtrada** (alemtuzumab)
 - Patient is 17 years of age and older
 - Diagnosis of Relapsing Remitting Multiple Sclerosis
 - 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
 - Anti-JCV antibody test (ELISA) performed [those with positive anti-JCV antibody have a higher risk for developing progressive multifocal leukoencephalopathy (PML)]. NOTE: This is required to be reported to the TOUCH program before each infusion.
 - Trial and failure of or contraindication 2 formulary alternatives (i.e., glatopa, Copaxone, Extavia, Rebif, or Aubagio)
- **Mitoxantrone**
 - Patient has ONE of the following diagnoses:
 - Secondary (chronic) progressive (SPMS)
 - Progressive relapsing (PRMS)
 - Worsening relapsing-remitting multiple sclerosis to reduce neurologic disability and/or frequency of clinical relapse
 - Cumulative lifetime dose is less than 140 mg/m²
 - Trial and failure of or contraindication to 2 formulary alternatives (i.e., glatopa, Copaxone, Extavia, Rebif or Aubagio)
 - All of the following labs within the last 6 months:
 - LVEF (left ventricular ejection fraction) > 50% (not below the lower limit of normal)
 - ANC > 1500 cells/mm³

Initial Approval Duration:

- All injections: Indefinite
- All orals: 6 months
- Tysabri: 3 months

Pharmacy Prior Authorization Multiple Sclerosis Clinical Guidelines

- Lemtrada: 12 months (2 years maximum allowed)
- Mitoxantrone: 3 months

Renewals:

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

Additional information:

*Dosing Table serves as a guidance and not always updated. Please confirm details in Clinical Pharmacology or the PI.

MS Agent	Max Dose	Strength	Frequency and Quantity
Aubagio	14 mg/day	7mg; 14mg	Daily: Up to 30 tablets in 30 days
Gilenya	0.5 mg/day	0.5mg	Daily: Up to 30 capsules in 30 days
Tecfidera	480 mg/day	120 mg 240 mg	Up to 14 delayed release capsules or 1 starter pack in 30 days (for taper) Up to 60 delayed release capsules in 30 days
Avonex	30mcg/week	30 mcg/0.5ml	Once weekly (IM): up to 30 mcg
Betaseron	250 mcg/QOD	0.3mg	Every other day (SQ): 250 mcg
Copaxone/Glatopa	20mg/day 40 mg/week	20-40mg/ml	Daily (SQ): 20 mg 3x week (SQ): 40 mg
Extavia	250 mcg/QOD	0.3mg	Every other day (SQ): 250mcg
Plegridy	125mcg/q14 days	125 mcg/0.5ml	Every 14 days (SQ): 125 mcg
Rebif	44 mcg/q48 hrs	22mcg-44mcg/0.5ml	Three times a week (SQ):22mcg-44 mcg.
Lemtrada	12mg/day x 5 days	12mg/1.2ml	(IV) Year 1: 5 days of 60mg Year 2: 3 days of 36mg
Tysabri	300mg/q 4 weeks	See CP	Every four weeks by (IV)- 300 mg.
Mitoxantrone	Lifetime cumulative dose limit of approximately 8–12 doses over 2–3 years (140 mg/m ²)	12 mg/ m ²	Every 3 months (IV): 12 mg/ m ²

Pharmacy Prior Authorization Multiple Sclerosis Clinical Guidelines

Forms of MS:

Form	Description
RRMS	the most common disease course — is characterized by clearly defined attacks of worsening neurologic function. These attacks — also called relapses, flare-ups or exacerbations — are followed by partial or complete recovery periods (remissions), during which symptoms improve partially or completely and there is no apparent progression of disease. Approximately 85 percent of people with MS are initially diagnosed with relapsing-remitting MS
SPMS	The name for this course comes from the fact that it follows after the relapsing-remitting course. Most people who are initially diagnosed with RRMS will eventually transition to SPMS, which means that the disease will begin to progress more steadily (although not necessarily more quickly), with or without relapses.
PPMS	PPMS is characterized by steadily worsening neurologic function from the beginning. Although the rate of progression may vary over time with occasional plateaus and temporary, minor improvements, there are no distinct relapses or remissions. About 10 percent of people with MS are diagnosed with PPMS.
PRMS	The least common of the four disease courses — is characterized by steadily progressing disease from the beginning and occasional exacerbations along the way. People with this form of MS may or may not experience some recovery following these attacks; the disease continues to progress without remissions.

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Pharmacy Prior Authorization Multiple Sclerosis Clinical Guidelines

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