

**Pharmacy Prior Authorization
Multiple Sclerosis – Clinical Guideline**

Copaxone® (glatiramer acetate)
Betaseron® (interferon beta-1b)
Avonex® (interferon beta-1a)
Tecfidera® (dimethyl fumarate)
 Mitoxantrone

Glatopa (glatiramer acetate)
Plegridy® (peginterferon beta-1a)
Aubagio® (teriflunomide)
Tysabri® (natalizumab)
Zinbryta™ (daclizumab)

Extavia® (interferon beta-1b)
Rebif/Rebifose® (interferon beta-1a)
Gilenya® (fingolimod)
Lemtrada® (alemtuzumab)

Preferred Product:

Glatiramer (Glatopa), Copaxone (40 mg), Extavia, Rebif and Aubagio, Tecfidera and Gilenya are the preferred MS agents. Non-preferred product will be considered with documentation to support trial and failure or contraindication to 2 preferred agents.

General Authorization Criteria for ALL Agents:

- Patient is 18 years of age or older (except for Lemtrada)
- Medication is prescribed by a Neurologist
- Other disease modifying MS therapies (not including Ampyra) will be, or have been discontinued

Additional Criteria For Specific Medications:

- **INJECTABLE Agents**
 - **Copaxone/Glatopa** (glatiramer acetate) and **Extavia** (interferon-beta1b)
 - Patient has a diagnosis of Relapsing Remitting Multiple Sclerosis **OR**
 - Patient has Clinically Isolated Syndrome suggestive of MS (e.g., persons who have experienced a first clinical episode and have magnetic resonance imaging (MRI) features consistent with MS)
 - **Rebif** (interferon-beta1a)
 - Patient has a diagnosis of Relapsing Remitting Multiple Sclerosis
 - **Avonex** (interferon-beta1a), **Plegridy** (peg-interferon-beta1a), and **Betaseron** (Interferon-beta1b)
 - Patient has a diagnosis of Relapsing Remitting Multiple Sclerosis
 - Patient has had an inadequate response, intolerable side effects, or a contraindication to 2 formulary agents, one of which must be an interferon or glatiramer acetate
 - **Zinbryta** (daclizumab)
 - Patient has a diagnosis of Relapsing Remitting Multiple Sclerosis
 - Patient has had an inadequate response, intolerable side effects, or a contraindication to 2 formulary agents, one of which must be an interferon or glatiramer acetate
- **ORAL Agents**
 - **Aubagio** (teriflunamide)
 - Patient has a diagnosis of Relapsing Remitting Multiple Sclerosis
 - All of the following labs have been completed within the last 6 months
 - CBC
 - LFT's and bilirubin levels
 - Negative pregnancy if female
 - Tuberculin skin test
 - **Gilenya** (fingolimod)
 - Patient has a diagnosis of Relapsing Remitting Multiple Sclerosis
 - All of the following labs have been completed within the last 6 months

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- CBC
 - LFT's and bilirubin levels
 - Negative pregnancy if female
 - EKG evaluation [i.e., QTc \geq 500 msec, Mobitz type II (2nd or 3rd degree AV block)]
 - Ophthalmic examination
 - Patient has documented history of chicken pox OR has had the varicella zoster vaccination OR has evidence of immunity (positive antibodies)
 - There is no history of MI, unstable angina, stroke, or TIA within the past 6 months
- **Tecfidera** (dimethyl fumarate)
 - Patient has a diagnosis of Relapsing Remitting Multiple Sclerosis
 - CBC was completed within the past 6 months
- **INFUSIONS**
 - **Lemtrada** (alemtuzumab)
 - Patient is 17 years of age and older
 - Patient has a diagnosis of Relapsing Remitting Multiple Sclerosis
 - Will not exceed 5 days of treatment the first year and 3 days of treatment the 2nd year
 - Patient is not infected with HIV
 - Patient has had an inadequate response, intolerable side effects, or a contraindication to 2 formulary agents, one of which must be an interferon or glatiramer acetate
 - **Tysabri** (natalizumab)
 - Patient has a diagnosis of Relapsing Remitting Multiple Sclerosis
 - Anti-JCV antibody test (ELISA) has been completed [those with positive anti-JCV antibody have a higher risk for developing progressive multifocal leukoencephalopathy (PML)].
 - Patient has had an inadequate response, intolerable side effects, or a contraindication to 2 formulary agents, one of which must be an interferon or glatiramer acetate
 - **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
 - Patient has had an inadequate response, intolerable side effects, or a contraindication to 2 formulary agents, one of which must be an interferon or glatiramer acetate
 - All of the following labs were completed 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 and mitoxantrone: 3 months

Lemtrada: 12 months (2 years maximum allowed)

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Renewals:

Requires 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	Up to 14 delayed release capsules or 1 starter pack in 30 days (for taper)
		240 mg	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	20-40mg/ml	Daily (SQ): 20 mg
	40 mg/week		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
Zinbryta	150mg/month	150mg/ml	monthly (SQ) inj 150mg

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

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following these attacks; the disease continues to progress without remissions.
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