Aetna Better Health®

Pharmacy Prior Authorization
Multiple Sclerosis – Clinical Guideline

Glatiramer acetate	**Ocrevus (ocrelizumab)**	Bafiertam (monomethyl fumarate)
Aubagio (teriflunomide)	**Avonex (interferon beta-1a)**	Tysabri (natalizumab)
Dimethyl fumarate	Copaxone(glatiramer acetate)	Vumerity (diroximel fumarate)
Glatopa (glatiramer acetate)	Mavenclad (cladribine)	Plegridy (peginterferon beta-1a)
Extavia (interferon beta-1b)	Mayzent (siponimod)	Kesimpta (Ofatumumab)
Gilenya (fingolimod)	Mitoxantrone	Lemtrada (alemtuzumab)
Rebif/Rebidose (interferon beta-1a)	Betaseron (interferon beta-1b)	Zeposia (ozanimod)
		Tecfidera (dimethyl fumarate)

Preferred Products:
Glatiramer, Glatopa, Extavia, Rebif, Aubagio, Dimethyl fumarate, Gilenya, Avonex, Ocrevus

Non-preferred products:
Will be considered with documentation to support trial and failure or contraindication to two (2) preferred agents

General Authorization Criteria for all Agents:
- Member is 18 years of age or older for all agents except Gilenya (10 years of age or older)
- Medication is prescribed by a Neurologist
- Other disease modifying multiple sclerosis therapies (not including Ampyra) will be, or have been discontinued

Additional Criteria for Specific Medications:

- **INJECTABLE AGENTS**
  - Copaxone 40mg, **Glatopa 20mg, Extavia, Rebif/Rebidose, Avonex:**
    - Diagnosis of relapsing form of multiple sclerosis (for example, relapsing-remitting or active secondary progressive multiple sclerosis), or
    - Member has clinically isolated syndrome suggestive of multiple sclerosis (for example, persons who have experienced first clinical episode, and have magnetic resonance imaging (MRI) features consistent with multiple sclerosis)
    - Copaxone 40mg requires member to have had inadequate response, intolerable side effects, or contraindication to two (2) formulary agents, one of which must be an interferon, or glatiramer acetate
  - Betaseron:
    - Diagnosis of relapsing form of multiple sclerosis (for example, relapsing-remitting or active secondary progressive multiple sclerosis), or
    - Member has clinically isolated syndrome suggestive of multiple sclerosis (for example, persons who have experienced a first clinical episode and have magnetic resonance imaging (MRI) features consistent with multiple sclerosis)
    - Member had inadequate response, intolerable side effects, or contraindication to two (2) formulary agents, one of which must be an interferon, or glatiramer acetate
  - Kesimpta:
    - Diagnosis of relapsing form of multiple sclerosis (for example, relapsing-remitting or active secondary progressive multiple sclerosis), or
    - Member has clinically isolated syndrome suggestive of multiple sclerosis (for example, persons who have experienced a first clinical episode and have magnetic resonance imaging (MRI) features consistent with multiple sclerosis)

- Baseline (within 3 months) MRI scan is obtained prior to starting treatment course due to risk of progressive multifocal leukoencephalpathy (PML)
- Member has been screened for Hepatitis B and does not have an active Hepatitis B infection
- Females of reproductive potential are not pregnant prior to start of therapy, and will be using effective contraception during treatment
- Members Immunoglobulins level have been reviewed and will be monitored during treatment
- There was inadequate response, intolerable side effects, or contraindication to two (2) formulary agents, one of which must be an interferon, or glatiramer acetate
- Plegridy: Diagnosis of relapsing form of multiple sclerosis (for example, relapsing-remitting or active secondary progressive multiple sclerosis), or
- Member has clinically isolated syndrome suggestive of multiple sclerosis (for example, persons who have experienced a first clinical episode and have magnetic resonance imaging (MRI) features consistent with multiple sclerosis)
- There was inadequate response, intolerable side effects, or contraindication to two (2) formulary agents, one of which must be an interferon or glatiramer acetate

- **ORAL AGENTS**
  - **Aubagio:**
    - Diagnosis of relapsing form of multiple sclerosis (for example, relapsing-remitting or active secondary progressive multiple sclerosis), or
    - Member has clinically isolated syndrome suggestive of multiple sclerosis (for example, persons who have experienced a first clinical episode and have magnetic resonance imaging (MRI) features consistent with multiple sclerosis)
    - Females of reproductive potential are not pregnant prior to start of therapy, and will be using effective contraception during treatment
    - All the following labs have been completed within the last six (6) months
      - Complete Blood Count
      - Liver Function Tests and bilirubin levels
      - Tuberculin skin test
  - Bafiertam:
    - Diagnosis of relapsing form of multiple sclerosis (for example, relapsing-remitting or active secondary progressive multiple sclerosis), or
    - Member has clinically isolated syndrome suggestive of multiple sclerosis (for example, persons who have experienced a first clinical episode and have magnetic resonance imaging (MRI) features consistent with multiple sclerosis)
    - Baseline (within 3 months) MRI scan is obtained prior to starting treatment course due to risk of progressive multifocal leukoencephalpathy (PML)
    - Documented history of chicken pox, or varicella zoster vaccination, or evidence of immunity (positive antibodies)
    - All the following labs have been completed within the last six (6) months
      - Complete Blood Count and lymphocyte count
      - Liver Function Tests and bilirubin levels
    - There was inadequate response, intolerable side effects, or contraindication to two (2) formulary agents, one of which must be an interferon or glatiramer acetate
  - **Gilenya:**

- Diagnosis of relapsing form of multiple sclerosis (for example, relapsing-remitting or active secondary progressive multiple sclerosis), or
- Member has clinically isolated syndrome suggestive of multiple sclerosis (for example, persons who have experienced a first clinical episode and have magnetic resonance imaging (MRI) features consistent with multiple sclerosis)
- All the following labs have been completed within the last six (6) months
  - Complete Blood Count
  - Liver Function Tests and bilirubin levels
  - Electrocardiogram evaluation performed
  - Ophthalmic examination
- Member 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 any of the following:
  - Myocardial Infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or class III/IV heart failure within the past six (6) months
  - Corrected QT (QTc) greater than or equal to 500 msec
  - History of Mobitz type II (2nd or 3rd degree atrioventricular block), or sick sinus syndrome, unless member has a pacemaker
  - Treatment with Class Ia or Class III anti-arrhythmic drugs

- Mayzent:
  - Diagnosis of relapsing form of multiple sclerosis (for example, relapsing-remitting or active secondary progressive multiple sclerosis), or
  - Member has clinically isolated syndrome suggestive of multiple sclerosis (for example, persons who have experienced a first clinical episode and have magnetic resonance imaging (MRI) features consistent with multiple sclerosis)
  - Member has been tested for CYP2C9 variants to determine CYP2C9 genotype, and is not positive for CYP2C9*3/*3
  - There was inadequate response, intolerable side effects, or contraindication to two (2) formulary agents, one of which must be an interferon or glatiramer acetate
  - All the following labs have been completed within the last six (6) months
    - Complete Blood Count
    - Liver Function Tests and bilirubin levels
    - Electrocardiogram evaluation performed
    - Ophthalmic examination
  - Documented history of chicken pox, or has had the varicella zoster vaccination, or has evidence of immunity (positive antibodies)
  - There is no history of any of the following:
    - Myocardial Infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or class III/IV heart failure within the past six (6) months
    - History of Mobitz type II (2nd or 3rd degree atrioventricular block), or sick sinus syndrome, unless member has a pacemaker
- Mavenclad:
  - Diagnosis of relapsing form of multiple sclerosis (for example, relapsing-remitting or active secondary progressive multiple sclerosis)
  - Member does not have a diagnosis of clinically isolated syndrome

- Member had inadequate response, intolerable side effects, or contraindication to two (2) formulary agents, one of which must be an interferon or glatiramer acetate
- Baseline (within 3 months) MRI scan is obtained prior to starting treatment course due to risk of progressive multifocal leukoencephalpathy (PML)
- Females of reproductive potential are not pregnant prior to start of therapy, and will be using effective contraception during treatment
- Member is not infected with Human Immunodeficiency Virus and has no active chronic infections (for example, hepatitis or tuberculosis), or is breastfeeding (during treatment or for 10 days after last dose)
- Lifetime maximum of 2 courses (4 cycles) of therapy

- **Tecfidera**, Vumerity:
  - Diagnosis of relapsing form of multiple sclerosis (for example, relapsing-remitting or active secondary progressive multiple sclerosis), or
  - Member has clinically isolated syndrome suggestive of multiple sclerosis (for example, persons who have experienced a first clinical episode and have magnetic resonance imaging (MRI) features consistent with multiple sclerosis
  - Vumerity: Member had inadequate response, intolerable side effects, or contraindication to two (2) formulary agents, one of which must be an interferon or glatiramer acetate
  - All the following labs have been completed within the last 6 months:
    - Complete blood count
    - Liver function tests and bilirubin levels
- Zeposia:
  - Diagnosis of relapsing form of multiple sclerosis (for example, relapsing-remitting or active secondary progressive multiple sclerosis), or
  - Member has clinically isolated syndrome suggestive of multiple sclerosis (for example, persons who have experienced a first clinical episode and have magnetic resonance imaging (MRI) features consistent with multiple sclerosis
  - Member does not have any of the following:
    - History (within the last 6 months) of myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or NYHA Class III/IV heart failure
    - History or presence of Mobitz Type II second- or third-degree AV block , sick sinus syndrome, or sino-atrial block (unless member has a functioning pacemaker)
    - Severe untreated sleep apnea
  - All the following labs have been completed within the last six (6) months
    - Complete Blood Count
    - Liver Function Tests and bilirubin levels
    - Electrocardiogram
    - Ophthalmic examination
  - Documented history of chicken pox, or varicella zoster vaccination, or evidence of immunity (positive antibodies)
  - Baseline (within 3 months) MRI scan is obtained prior to starting treatment course due to risk of progressive multifocal leukoencephalpathy (PML)
  - Females of reproductive potential are not pregnant prior to start of therapy, and will be using effective contraception during treatment

  - There was inadequate response, intolerable side effects, or contraindication to two (2) formulary agents, one of which must be an interferon or glatiramer acetate

- **INFUSIONS**
  - **Ocrevus:**
    - Member has been screened for Hepatitis B and does not have an active Hepatitis B infection
    - Diagnosis of relapsing form of multiple sclerosis (for example, relapsing-remitting or active secondary progressive multiple sclerosis), or
    - Member has clinically isolated syndrome suggestive of multiple sclerosis (for example, persons who have experienced a first clinical episode, and have magnetic resonance imaging (MRI) features consistent with multiple sclerosis), or
    - Diagnosis of Primary-Progressive Multiple Sclerosis (PPMS)
  - Lemtrada:
    - Diagnosis of relapsing form of multiple sclerosis (for example, relapsing-remitting or active secondary progressive multiple sclerosis)
    - Will not exceed five (5) days of treatment the first year, and three (3) days of treatment the 2nd year. (subsequent treatment courses of 12mg per day on 3 consecutive days (36mg total dose) may be administered, as needed, at least 12 months after the last dose of any prior treatment course)
    - Member is not infected with Human Immunodeficiency Virus (HIV)
    - All the following have been completed prior to initiating treatment:
      - Complete blood count
      - Serum creatinine levels
      - Complete any necessary immunizations at least 6 weeks prior to treatment
      - History of varicella, or had varicella zoster vaccination, or has evidence of immunity (positive antibodies)
      - Member has been screened for tuberculosis. If screening was positive for latent tuberculosis, member has received treatment for latent tuberculosis
      - Thyroid function test such as a thyroid stimulating hormone level (TSH)
    - There was inadequate response, intolerable side effects, or contraindication to two (2) formulary agents, one of which must be an interferon or glatiramer acetate
  - Tysabri:
    - Diagnosis of relapsing form of multiple sclerosis (for example, relapsing-remitting or active secondary progressive multiple sclerosis), or
    - Member has clinically isolated syndrome suggestive of multiple sclerosis (for example, persons who have experienced a first clinical episode and have magnetic resonance imaging (MRI) features consistent with multiple sclerosis)
    - Anti-JCV (John Cunningham virus) antibody test (ELISA [enzyme-linked immunosorbent assay]) has been completed (those with positive anti-JCV [John Cunningham Virus] antibody have a higher risk for developing progressive multifocal leukoencephalopathy [PML]).
    - There was inadequate response, intolerable side effects, or contraindication to two (2) formulary agents, one of which must be an interferon or glatiramer acetate
  - Mitoxantrone:
    - Member has one of the following diagnoses:
      - Secondary (chronic) progressive multiple sclerosis
      - Progressive relapsing multiple sclerosis

- Worsening relapsing-remitting multiple sclerosis to reduce neurologic disability and/or frequency of clinical relapse
- Mitoxantrone is not indicated for treatment of primary progressive multiple sclerosis
- Cumulative lifetime dose is less than 140 mg/m^2
- There was inadequate response, intolerable side effects, or contraindication to two (2) formulary agents, one of which must be an interferon or glatiramer acetate
- All the following labs were completed within the last six (6) months:
  - LVEF (left ventricular ejection fraction) greater than 50% (not below lower limit of normal)
  - Absolute neutrophil count (ANC) greater than 1500 cells/mm3
  - CBC (complete blood count) including platelets
  - LFTs (liver functions tests)

Initial Approval Duration:

- All injections: 12 months
- All orals: six (6) months
- Tysabri and mitoxantrone: three (3) months
- Ocrevus: six (6) months
- Lemtrada: 12 months
- Mavenclad is limited to a total of 2 courses per lifetime

Renewal Criteria:

- Documentation and lab results to support response to treatment, and no serious toxicity as result of treatment
- All required testing listed in criteria for initial therapy are completed and continuously monitored as clinically appropriate
  - For example, left ventricular ejection fraction (LVEF), complete blood count (CBC), absolute neutrophil count (ANC), electrocardiogram (ECG), immunoglobulins level, contraception use for females of reproductive potential

Renewal Approval Duration:

- All orals: 12 months
- Lemtrada: 12 months
- Mitoxantrone: three (3) months
- Tysabri and Ocrevus: six (6) months
- Mavenclad is limited to a total of 2 courses per lifetime

Additional information:

- Examples of treatment failure (over 1 year period of using disease-modifying therapies):
  - 1 or more relapses
  - Magnetic resonance imaging (MRI) lesion progression (for example, increase in T1, T2, or gadolinium lesions)
  - Worsening disability or Expanded Disability Status Scale (EDSS) score

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

Multiple Sclerosis Agent	Max Dose	Strength	Frequency and Quantity

Aubagio	14mg/day	7mg; 14mg	Daily: Up to 30 tablets in 30 days
Gilenya	Children weighing more than 40kg & adults: 0.5 mg/day Children weighing less than 40kg: 0.25mg	0.25mg, 0.5mg	Daily: Up to 30 capsules in 30 days
Tecfidera	480mg/day	120mg 240mg	Up to 14 delayed release capsules or 1 starter pack in 30 days (for taper) Up to 60 delayed release capsules in 30 days
Vumerity	462 mg twice daily	231mg	Initial: 231 mg twice daily Maintenance: 462 mg twice daily
Avonex	30mcg/week	30mcg/0.5ml	Up to 4 syringes per month
Betaseron	250mcg/every other day	0.3mg	Up to 15 syringes per month
Kesimpta	20mg/month	20 mg/0.4 mL	Initial: 20 mg once weekly for 3 weeks Maintanace: 20 mg, 0.4ml pen per month
Copaxone/Glatopa Glatiramer acetate,	20mg/day 40mg three times per week	20mg/ml, 40mg/ml	Daily (subcutaneous [SQ]): 20 mg, up to 30 ml per month 20mg: QLL = 1ml per day 3 times per week (subcutaneous [SQ]): 40 mg- up to 12 ml per 28 days 40mg: QLL = 12ml per 28 days
Extavia	250mcg every other day	0.3mg	Up to 15 syringes per 30 days
Plegridy	125mcg every 14 days	125mcg/0.5ml	Up to 2 syringes per month
Rebif	44mcg every 48 hours	22mcg/0.5ml,44 mcg/0.5ml	Three times a week (subcutaneous [SQ]):22mcg-44 mcg. Titration 4.2 ml/28 days, Regular injectable 6ml/28days
Lemtrada	12mg/day for 5 days	12mg/1.2ml	Year 1: 5 days of 12mg (60mg total: 5 vials) Year 2 and beyond: 3 days of 12mg (36mg total: 3 vials)
Tysabri	300mg every 4 weeks	300mg/15ml	Up to 1 vial per month
Mitoxantrone	Lifetime cumulative dose limit of (140 mg/m2)	2mg/ml	Every 3 months (intravenous [IV]):12 mg/m^2
Mavenclad	Lifetime cumulative dosage of 3.5 mg/kg	10mg	Course 1/cycle 1: start any time Course 1/cycle 2: 23 – 27 days after last dose of course 1/cycle 1

			Course 2/cycle 1:at least 34 weeks after last dose of course 1/cycle 2 Course 2/cycle 2: 23 – 27 days after last dose of course 2/cycle 1
Ocrevus	600mg every 6 months	300mg/10ml	300mg intravenous [IV] infusion followed by another 300mg 2 weeks later. Subsequent doses 600mg every 6 months.
Mayzent	2mg/day	0.25mg; 2mg	Daily: Up to 30 tablets in 30 days
Bafiertam	190 mg twice a day	95mg	Up to 120 capsules per month
Zeposia	0.92 mg/day	0.23 mg or 0.46 mg or 0.92 mg	Daily: Up to 30 capsules in 30 days

Forms of Multiple Sclerosis:

Form	Description
Relapsing-Remitting Multiple Sclerosis	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 multiple sclerosis are initially diagnosed with relapsing-remitting multiple sclerosis
Secondary Progressive Multiple Sclerosis	The name for this course comes from the fact that it follows after the relapsing-remitting course. Most people who are initially diagnosed with Relapsing-Remitting Multiple Sclerosis will eventually transition to Secondary Progressive Multiple Sclerosis, which means that the disease will begin to progress more steadily (although not necessarily more quickly), with or without relapses.
Primary-Progressive Multiple Sclerosis	Primary-Progressive Multiple Sclerosis 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 multiple sclerosis are diagnosed with Primary-Progressive Multiple Sclerosis.

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