PREFERRED SPECIALTY MANAGEMENT POLICY

POLICY: Multiple Sclerosis Preferred Specialty Management Policy

Beta Interferon Products (Self-Injectable)
• Avonex® (interferon beta-1a intramuscular injection– Biogen) • Betaseron® (interferon beta-1b subcutaneous injection – Bayer) • Extavia® (interferon beta-1b subcutaneous injection – Novartis) • Plegridy® (peginterferon beta-1a subcutaneous injection – Biogen) • Rebif® (interferon beta-1a subcutaneous injection – Serono)
CD20-Directed Cytolytic Antibody (Self-Injectable)
• Kesimpta® (ofatumumab subcutaneous injection – Novartis)
Fumarate Products (Oral)
• Bafiertam® (monomethyl fumarate delayed-release capsules – Banner Life Sciences) • Tecfidera® (dimethyl fumarate delayed-release capsules – Biogen, generic) • Vumerity® (diroximel fumarate delayed-release capsules – Biogen)
Glatiramer Products (Self-Injectable)
• Copaxone® (glatiramer subcutaneous injection – Teva, generic) • Glatopa® (glatiramer subcutaneous injection – Sandoz, generic)
Purine Antimetabolite (Oral)
• Mavenclad® (cladribine tablets – EMD Serono)
Pyrimidine Synthesis Inhibitor (Oral)
• Aubagio® (teriflunomide tablets – Genzyme/Sanofi, generic)
Sphingosine 1-Phosphate Receptor Modulator
• Gilenya® (fingolimod capsules – Novartis, generic) • Mayzent® (siponimod tablets – Novartis) • Ponvory® (ponesimod tablets – Janssen) • Tascenso ODT® (fingolimod orally disintegrating tablets – Handa/Cycle) • Zeposia® (ozanimod capsules – Celgene/Bristol Myers Squibb)

REVIEW DATE: 11/08/2023

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Cigna National Formulary Coverage:

OVERVIEW

This Preferred Specialty Management policy involves the use of self-administered injectable products and oral disease-modifying agents used for multiple sclerosis.[1-19] All products are indicated for use in adults. Of note, fingolimod and Tascenso ODT are the only agents specifically indicated for children ≥ 10 years of age for the treatment of relapsing forms of multiple sclerosis.[9,19] Mayzent has an indication for use in active secondary progressive multiple sclerosis and its pivotal data involved this patient population.[12] Glatiramer injection and dimethyl fumarate only have limited data in this patient subset. Zeposia is also indicated for use in adults with moderately to severely active ulcerative colitis.[15] A practice guideline recommendation regarding disease-modifying agents for adults with multiple sclerosis from the American Academy of Neurology (2018) includes fingolimod as one of the agents to consider for patients with multiple sclerosis who have highly active disease.[20]

POLICY STATEMENT

The Multiple Sclerosis Preferred Specialty Management Program has been developed to encourage the use of the Preferred Products. For all medications (Preferred and Non-Preferred), the patient is required to meet the respective standard *Prior Authorization Policy* criteria. The Program also directs the patient to try one Preferred Product prior to the approval of a Non-Preferred Product. Requests for Non-Preferred Products will also be reviewed using the exception criteria (below). All approvals are provided for 1 year. If a patient requesting a Non-Preferred Product meets the standard *Prior Authorization Policy* criteria but has not tried one Preferred Product (generic glatiramer injection, generic dimethyl fumarate delayed-release capsules, generic fingolimod capsules, or generic teriflunomide tablets), an offer to review for the Preferred Products will be made.

The Tecfidera (Brand) Preferred Specialty Management Program has been developed to encourage the use of generic dimethyl fumarate delayed-release capsules. For all medications (Preferred and Non-Preferred) the patient is required to meet the respective standard *Prior Authorization Policy* criteria. Requests for the Non-Preferred Product will also be reviewed using the exception criteria (below). All approvals are provided for 1 year. If a patient requesting the Non-Preferred Product (Tecfidera [brand]) meets the standard *Prior Authorization Policy* criteria but has not tried the Preferred Product, an offer to review for the Preferred Product will be made.

The Fingolimod Preferred Specialty Management Program has been developed to encourage the use of the Preferred Products (generic dimethyl fumarate delayed-release capsules and generic fingolimod capsules). For all medications (Preferred and Non-Preferred) the patient is required to meet the respective standard *Prior Authorization Policy* criteria. Requests for the Non-Preferred Product will also be reviewed using the exception criteria (below). All approvals are provided for 1 year. If a patient requesting a Non-Preferred Product meets the standard *Prior Authorization Policy* criteria but has not tried the Preferred Products, an offer to review for the Preferred Products will be made.

The Aubagio Preferred Specialty Management Program has been developed to encourage the use of the Preferred Products (generic glatiramer injection, generic dimethyl fumarate delayed-release capsules, generic fingolimod capsules, and generic teriflunomide tablets). For all medications (Preferred and Non-Preferred), the patient is required to meet the respective standard *Prior Authorization Policy* criteria. Requests for the Non-Preferred Product will also be reviewed using the exception criteria (below). All approvals are provided for 1 year. If a patient requesting a Non-Preferred Product meets the standard *Prior Authorization Policy* criteria but has not tried the Preferred Products, an offer to review for the Preferred Products will be made.

Documentation: Documentation is required for Tecfidera (brand), Gilenya (brand), and Aubagio (brand) as noted in the criteria as **[documentation required]**. Documentation may include, but is not limited to, chart notes, prescription claims records, prescription receipts, and magnetic resonance imaging (MRI) reports and/or other information.

Multiple Sclerosis Preferred Specialty Management Program

Preferred Products: generic glatiramer injection, OR generic dimethyl fumarate delayed-release capsules, OR generic fingolimod capsules, OR generic teriflunomide tablets

Non-Preferred Products: Avonex, Bafiertam, Betaseron, Copaxone, Extavia, Glatopa, Kesimpta, Mavenclad, Mayzent, Plegridy, Ponvory, Rebif, Vumerity, Zeposia

Tecfidera (Brand) Preferred Specialty Management Program

Preferred Product: generic dimethyl fumarate delayed-release capsules

Non-Preferred Product: Tecfidera (brand)

Fingolimod Preferred Specialty Management Program

Preferred Products: generic fingolimod capsules and generic dimethyl fumarate delayed-release capsules

Non-Preferred Products: Gilenya (brand), Tascenso ODT

Aubagio Preferred Specialty Management Program

Preferred Products: generic teriflunomide tablets and generic glatiramer injection and generic dimethyl fumarate delayed-release capsules and generic fingolimod capsules

Non-Preferred Product: Aubagio (brand)

Multiple Sclerosis non-preferred product(s) is(are) covered as medically necessary when the following non-preferred product exception criteria is(are) met. Any other exception is considered not medically necessary.

NON-PREFERRED PRODUCT EXCEPTION CRITERIA

I. Multiple Sclerosis Preferred Specialty Management Program

Non-Preferred Product	Exception Criteria
Avonex	**1.** Approve for 1 year if the patient meets the following (A and B): **A)** Patient meets the standard *Multiple Sclerosis – Avonex Prior Authorization Policy* criteria; AND **B)** Patient meets one of the following (i, ii, iii, iv, or v): **i.** Patient has been established on Avonex for ≥ 120 days; OR **ii.** Patient meets both of the following (a and b): **a)** Patient has tried generic dimethyl fumarate delayed-release capsules; AND **b)** Patient has experienced inadequate efficacy or significant intolerance, according to the prescriber; OR Note: Prior use of Tecfidera, Bafiertam, or Vumerity with inadequate efficacy or significant intolerance (according to the prescriber) also counts. **iii.** Patient meets both of the following (a and b): **a)** Patient has tried generic glatiramer injection; AND **b)** Patient has experienced inadequate efficacy or significant intolerance, according to the prescriber; OR Note: Prior use of Copaxone or Glatopa with inadequate efficacy or significant intolerance (according to the prescriber) also counts. **iv.** Patient meets both of the following (a and b): **a)** Patient has tried generic fingolimod capsules; AND **b)** Patient has experienced inadequate efficacy or significant intolerance, according to the prescriber; OR Note: Prior use of Gilenya or Tascenso ODT with inadequate efficacy or significant intolerance (according to the prescriber) also counts. **v.** Patient meets both of the following (a and b): **a)** Patient has tried generic teriflunomide tablets; AND **b)** Patient has experienced inadequate efficacy or significant intolerance, according to the prescriber. Note: Prior use of Aubagio with inadequate efficacy or significant intolerance (according to the prescriber) also counts. **2.** If the patient meets the standard *Multiple Sclerosis – Avonex Prior Authorization Policy* criteria, but does not meet criterion 1B, offer to review for the Preferred Product(s).

Non-Preferred Product	Exception Criteria
Bafiertam	**1.** Approve for 1 year if the patient meets the following (A and B): **A)** Patient meets the standard *Multiple Sclerosis – Bafiertam Prior Authorization Policy* criteria; AND **B)** Patient meets one of the following (i, ii, iii, or iv): **i.** Patient meets both of the following (a and b): **a)** Patient has tried generic dimethyl fumarate delayed-release capsules; AND **b)** Patient has experienced inadequate efficacy or significant intolerance, according to the prescriber; OR Note: Prior use of Tecfidera with inadequate efficacy or significant intolerance (according to the prescriber) also counts. **ii.** Patient meets both of the following (a and b): **a)** Patient has tried generic glatiramer injection; AND **b)** Patient has experienced inadequate efficacy or significant intolerance, according to the prescriber; OR Note: Prior use of Copaxone or Glatopa with inadequate efficacy or significant intolerance (according to the prescriber) also counts. **iii.** Patient meets both of the following (a and b): **a)** Patient has tried generic fingolimod capsules; AND **b)** Patient has experienced inadequate efficacy or significant intolerance, according to the prescriber; OR Note: Prior use of Gilenya or Tascenso ODT with inadequate efficacy or significant intolerance (according to the prescriber) also counts. **iv.** Patient meets both of the following (a and b): **a)** Patient has tried generic teriflunomide tablets; AND **b)** Patient has experienced inadequate efficacy or significant intolerance, according to the prescriber. Note: Prior use of Aubagio with inadequate efficacy or significant intolerance (according to the prescriber) also counts. **2.** If the patient meets the standard *Multiple Sclerosis – Bafiertam Prior Authorization Policy* criteria, but does not meet criterion 1B, offer to review for the Preferred Product(s).

Non-Preferred Product	Exception Criteria
Betaseron	**1.** Approve for 1 year if the patient meets the following (A and B): **A)** Patient meets the standard *Multiple Sclerosis – Betaseron/Extavia Prior Authorization Policy* criteria; AND **B)** Patient meets one of the following (i, ii, iii, iv, or v): **i.** Patient has been established on Betaseron for ≥ 120 days; OR **ii.** Patient meets both of the following (a and b): **a)** Patient has tried generic dimethyl fumarate delayed-release capsules; AND **b)** Patient has experienced inadequate efficacy or significant intolerance, according to the prescriber; OR Note: Prior use of Tecfidera, Bafiertam, or Vumerity with inadequate efficacy or significant intolerance (according to the prescriber) also counts. **iii.** Patient meets both of the following (a and b): **a)** Patient has tried generic glatiramer injection; AND **b)** Patient has experienced inadequate efficacy or significant intolerance, according to the prescriber; OR Note: Prior use of Copaxone or Glatopa with inadequate efficacy or significant intolerance (according to the prescriber) also counts. **iv.** Patient meets both of the following (a and b): **a)** Patient has tried generic fingolimod capsules; AND **b)** Patient has experienced inadequate efficacy or significant intolerance, according to the prescriber; OR Note: Prior use of Gilenya or Tascenso ODT with inadequate efficacy or significant intolerance (according to the prescriber) also counts. **v.** Patient meets both of the following (a and b): **a)** Patient has tried generic teriflunomide tablets; AND **b)** Patient has experienced inadequate efficacy or significant intolerance, according to the prescriber. Note: Prior use of Aubagio with inadequate efficacy or significant intolerance (according to the prescriber) also counts. **2.** If the patient meets the standard *Multiple Sclerosis – Betaseron/Extavia Prior Authorization Policy* criteria, but does not meet criterion 1B, offer to review for the Preferred Product(s).

Non-Preferred Product	Exception Criteria
Copaxone 20 mg/mL and 40 mg/mL	**1.** Approve for 1 year if the patient meets the following (A and B): **A)** Patient meets the standard *Multiple Sclerosis – Glatiramer Products Prior Authorization Policy* criteria; AND **B)** Patient meets one of the following (i, ii, iii, or iv): **i.** Patient meets both of the following criteria (a and b): **a)** Patient has tried generic dimethyl fumarate delayed-release capsules; AND **b)** Patient has experienced inadequate efficacy or significant intolerance, according to the prescriber; OR Note: Prior use of Tecfidera, Bafiertam, or Vumerity with inadequate efficacy or significant intolerance (according to the prescriber) also counts. **ii.** Patient meets both of the following (a and b): **a)** Patient has tried generic glatiramer injection; AND **b)** Patient cannot continue to use generic glatiramer injection due to a formulation difference in the inactive ingredient(s) [e.g., preservatives] between the brand and the bioequivalent generic product which, per the prescriber, would result in a significant allergy or serious adverse reaction; OR **iii.** Patient meets both of the following (a and b): **a)** Patient has tried generic fingolimod capsules; AND **b)** Patient has experienced inadequate efficacy or significant intolerance, according to the prescriber; OR Note: Prior use of Gilenya or Tascenso ODT with inadequate efficacy or significant intolerance (according to the prescriber) also counts. **iv.** Patient meets both of the following (a and b): **a)** Patient has tried generic teriflunomide tablets; AND **b)** Patient has experienced inadequate efficacy or significant intolerance, according to the prescriber. Note: Prior use of Aubagio with inadequate efficacy or significant intolerance (according to the prescriber) also counts. **2.** If the patient meets the standard *Multiple Sclerosis – Glatiramer Prior Authorization Policy* criteria, but does not meet criterion 1B, offer to review for the Preferred Product(s).

Non-Preferred Product	Exception Criteria
Extavia	**1.** Approve for 1 year if the patient meets the following (A and B): **A)** Patient meets the standard *Multiple Sclerosis – Betaseron/Extavia Prior Authorization Policy* criteria; AND **B)** Patient meets one of the following (i, ii, iii, iv, or v): **i.** Patient has been established on Extavia for ≥ 120 days; OR **ii.** Patient meets both of the following (a and b): **a)** Patient has tried generic dimethyl fumarate delayed-release capsules; AND **b)** Patient has experienced inadequate efficacy or significant intolerance, according to the prescriber; OR Note: Prior use of Tecfidera, Bafiertam, or Vumerity with inadequate efficacy or significant intolerance (according to the prescriber) also counts. **iii.** Patient meets both of the following (a and b): **a)** Patient has tried generic glatiramer injection; AND **b)** Patient has experienced inadequate efficacy or significant intolerance, according to the prescriber; OR Note: Prior use of Copaxone or Glatopa with inadequate efficacy or significant intolerance (according to the prescriber) also counts. **iv.** Patient meets both of the following (a and b): **a)** Patient has tried generic fingolimod capsules; AND **b)** Patient has experienced inadequate efficacy or significant intolerance, according to the prescriber; OR Note: Prior use of Gilenya or Tascenso ODT with inadequate efficacy or significant intolerance (according to the prescriber) also counts. **v.** Patient meets both of the following (a and b): **a)** Patient has tried generic teriflunomide tablets; AND **b)** Patient has experienced inadequate efficacy or significant intolerance, according to the prescriber. Note: Prior use of Aubagio with inadequate efficacy or significant intolerance (according to the prescriber) also counts. **2.** If the patient meets the standard *Multiple Sclerosis – Betaseron/Extavia Prior Authorization Policy* criteria, but does not meet criterion 1B, offer to review for the Preferred Product(s).

Non-Preferred Product	Exception Criteria
Glatopa 20 mg/mL and 40 mg/mL	**1.** Approve for 1 year if the patient meets the following (A and B): **A)** Patient meets the standard *Multiple Sclerosis – Glatiramer Products Prior Authorization Policy* criteria; AND **B)** Patient meets one of the following (i, ii, iii, or iv): **i.** Patient meets both of the following criteria (a and b): **a)** Patient has tried generic dimethyl fumarate delayed-release capsules; AND **b)** Patient has experienced inadequate efficacy or significant intolerance, according to the prescriber; OR Note: Prior use of Tecfidera, Bafiertam, or Vumerity with inadequate efficacy or significant intolerance (according to the prescriber) also counts. **ii.** Patient meets both of the following (a and b): **a)** Patient has tried generic glatiramer injection; AND **b)** Patient cannot continue to use generic glatiramer injection due to a formulation difference in the inactive ingredient(s) [e.g., preservatives] between the brand and the bioequivalent generic product which, per the prescriber, would result in a significant allergy or serious adverse reaction; OR **iii.** Patient meets both of the following (a and b): **a)** Patient has tried generic fingolimod capsules; AND **b)** Patient has experienced inadequate efficacy or significant intolerance, according to the prescriber; OR Note: Prior use of Gilenya or Tascenso ODT with inadequate efficacy or significant intolerance (according to the prescriber) also counts. **iv.** Patient meets both of the following (a and b): **a)** Patient has tried generic teriflunomide tablets; AND **b)** Patient has experienced inadequate efficacy or significant intolerance, according to the prescriber. Note: Prior use of Aubagio with inadequate efficacy or significant intolerance (according to the prescriber) also counts. **2.** If the patient meets the standard *Multiple Sclerosis – Glatiramer Prior Authorization Policy* criteria, but does not meet criterion 1B, offer to review for the Preferred Product(s).

Non-Preferred Product	Exception Criteria
Kesimpta	**1.** Approve for 1 year if the patient meets the following (A and B): **A)** Patient meets the standard *Multiple Sclerosis – Kesimpta Prior Authorization Policy* criteria; AND **B)** Patient meets one of the following (i, ii, iii, iv, v, or vi): **i.** Patient has been established on Kesimpta for ≥ 120 days; OR **ii.** Patient meets both of the following (a and b): **a)** Patient has tried generic dimethyl fumarate delayed-release capsules; AND **b)** Patient has experienced inadequate efficacy or significant intolerance, according to the prescriber; OR Note: Prior use of Tecfidera, Bafiertam, or Vumerity with inadequate efficacy or significant intolerance (according to the prescriber) also counts. **iii.** Patient meets both of the following (a and b): **a)** Patient has tried generic glatiramer injection; AND **b)** Patient has experienced inadequate efficacy or significant intolerance, according to prescriber; OR Note: Prior use of Copaxone or Glatopa with inadequate efficacy or significant intolerance (according to the prescriber) also counts. **iv.** Patient meets both of the following (a and b): **a)** Patient has tried generic fingolimod capsules; AND **b)** Patient has experienced inadequate efficacy or significant intolerance, according to the prescriber; OR Note: Prior use of Gilenya or Tascenso ODT with inadequate efficacy or significant intolerance (according to the prescriber) also counts. **v.** Patient meets both of the following (a and b): **a)** Patient has tried generic teriflunomide tablets; AND **b)** Patient has experienced inadequate efficacy or significant intolerance, according to the prescriber; OR Note: Prior use of Aubagio with inadequate efficacy or significant intolerance (according to the prescriber) also counts. **vi.** Patient has previously received one of Tysabri (natalizumab intravenous infusion), Ocrevus (ocrelizumab intravenous infusion), Briumvi (ublituximab-xiiy intravenous infusion), Mavenclad (cladribine tablets), Lemtrada (alemtuzumab intravenous infusion), or Kesimpta. **2.** If the patient meets the standard *Multiple Sclerosis – Kesimpta Prior Authorization Policy* criteria, but does not meet criterion 1B, offer to review for the Preferred Product(s).

Non-Preferred Product	Exception Criteria
Mavenclad	**1.** Approve for 1 year if the patient meets the following (A and B): **A)** Patient meets the standard *Multiple Sclerosis – Mavenclad Prior Authorization Policy* criteria; AND **B)** Patient meets one of the following (i, ii, iii, iv, v, or vi): **i.** Patient has been established on Mavenclad for ≥ 120 days; OR **ii.** Patient meets both of the following (a and b): **a)** Patient has tried generic dimethyl fumarate delayed-release capsules; AND **b)** Patient has experienced inadequate efficacy or significant intolerance according to the prescriber; OR Note: Prior use of Tecfidera, Bafiertam, or Vumerity with inadequate efficacy or significant intolerance (according to the prescriber) also counts. **iii.** Patient meets both of the following (a and b): **a)** Patient has tried generic glatiramer injection; AND **b)** Patient has experienced inadequate efficacy or significant intolerance, according to the prescriber; OR Note: Prior use of Copaxone or Glatopa with inadequate efficacy or significant intolerance (according to the prescriber) also counts. **iv.** Patient meets both of the following (a and b): **a)** Patient has tried generic fingolimod capsules; AND **b)** Patient has experienced inadequate efficacy or significant intolerance, according to the prescriber; OR Note: Prior use of Gilenya or Tascenso ODT with inadequate efficacy or significant intolerance (according to the prescriber) also counts. **v.** Patient meets both of the following (a and b): **a)** Patient has tried generic teriflunomide tablets; AND **b)** Patient has experienced inadequate efficacy or significant intolerance, according to the prescriber; OR Note: Prior use of Aubagio with inadequate efficacy or significant intolerance (according to the prescriber) also counts. **vi.** Patient has previously received one of Tysabri (natalizumab intravenous infusion), Ocrevus (ocrelizumab intravenous infusion), Kesimpta (ofatumumab subcutaneous injection), Briumvi (ublituximab-xiiy intravenous infusion), Lemtrada (alemtuzumab intravenous infusion), or Mavenclad. **2.** If the patient meets the standard *Multiple Sclerosis – Mavenclad Prior Authorization Policy* criteria, but does not meet criterion 1B, offer to review for the Preferred Product(s).

Non-Preferred Product	Exception Criteria
Mayzent	**1.** Approve for 1 year if the patient meets the following (A and B): **A)** Patient meets the standard *Multiple Sclerosis – Mayzent Prior Authorization Policy* criteria; AND **B)** Patient meets one of the following (i, ii, iii, iv, v, or vi): **i.** Patient has been established on Mayzent for ≥ 120 days; OR **ii.** Patient has active secondary progressive multiple sclerosis; OR **iii.** Patient meets both of the following (a and b): **a)** Patient has tried generic dimethyl fumarate delayed-release capsules; AND **b)** Patient has experienced inadequate efficacy or significant intolerance, according to the prescriber; OR Note: Prior use of Tecfidera, Bafiertam, or Vumerity with inadequate efficacy or significant intolerance (according to the prescriber) also counts. **iv.** Patient meets both of the following (a and b): **a)** Patient has tried generic glatiramer injection; AND **b)** Patient has experienced inadequate efficacy or significant intolerance, according to the prescriber; OR Note: Prior use of Copaxone or Glatopa with inadequate efficacy or significant intolerance (according to the prescriber) also counts. **v.** Patient meets both of the following (a and b): **a)** Patient has tried generic fingolimod capsules; AND **b)** Patient has experienced inadequate efficacy or significant intolerance, according to the prescriber; OR Note: Prior use of Gilenya or Tascenso ODT with inadequate efficacy or significant intolerance (according to the prescriber) also counts. **vi.** Patient meets both of the following (a and b): **a)** Patient has tried generic teriflunomide tablets; AND **b)** Patient has experienced inadequate efficacy or significant intolerance, according to the prescriber. Note: Prior use of Aubagio with inadequate efficacy or significant intolerance (according to the prescriber) also counts. **2.** If the patient meets the standard *Multiple Sclerosis – Mayzent Prior Authorization Policy* criteria, but does not meet criterion 1B, offer to review for the Preferred Product(s).

Non-Preferred Product	Exception Criteria
Plegridy	**1.** Approve for 1 year if the patient meets the following (A and B): **A)** Patient meets the standard *Multiple Sclerosis – Plegridy Prior Authorization Policy* criteria; AND **B)** Patient meets one of the following (i, ii, iii, iv, or v): **i.** Patient has been established on Plegridy for ≥ 120 days; OR **ii.** Patient meets both of the following (a and b): **a)** Patient has tried generic dimethyl fumarate delayed-release tablets; AND **b)** Patient has experienced inadequate efficacy or significant intolerance, according to the prescriber; OR Note: Prior use of Tecfidera, Bafiertam, or Vumerity with inadequate efficacy or significant intolerance (according to the prescriber) also counts. **iii.** Patient meets both of the following (a and b): **a)** Patient has tried generic glatiramer injection; AND **b)** Patient has experienced inadequate efficacy or significant intolerance, according to the prescriber; OR Note: Prior use of Copaxone or Glatopa with inadequate efficacy or significant intolerance (according to the prescriber) also counts. **iv.** Patient meets both of the following (a and b): **a)** Patient has tried generic fingolimod capsules; AND **b)** Patient has experienced inadequate efficacy or significant intolerance, according to the prescriber; OR Note: Prior use of Gilenya or Tascenso ODT with inadequate efficacy or significant intolerance (according to the prescriber) also counts. **v.** Patient meets both of the following (a and b): **a)** Patient has tried generic teriflunomide tablets; AND **b)** Patient has experienced inadequate efficacy or significant intolerance, according to the prescriber. Note: Prior use of Aubagio with inadequate efficacy or significant intolerance (according to the prescriber) also counts. **2.** If the patient meets the standard *Multiple Sclerosis – Plegridy Prior Authorization Policy* criteria, but does not meet criterion 1B, offer to review for the Preferred Product(s).

Non-Preferred Product	Exception Criteria
Ponvory	**1.** Approve for 1 year if the patient meets the following (A and B): **A)** Patient meets the standard Multiple Sclerosis – *Ponvory Prior Authorization Policy* criteria; AND **B)** Patient meets one of the following (i, ii, iii, iv, or v): **i.** Patient has been established on Ponvory for ≥ 120 days; OR **ii.** Patient meets both of the following (a and b): **a)** Patient has tried generic dimethyl fumarate delayed-release capsules; AND **b)** Patient has experienced inadequate efficacy or significant intolerance, according to the prescriber; OR Note: Prior use of Tecfidera, Bafiertam, or Vumerity with inadequate efficacy or significant intolerance (according to the prescriber) also counts. **iii.** Patient meets both of the following (a and b): **a)** Patient has tried generic glatiramer injection; AND **b)** Patient has experienced inadequate efficacy or significant intolerance, according to the prescriber; OR Note: Prior use of Copaxone or Glatopa with inadequate efficacy or significant intolerance (according to the prescriber) also counts. **iv.** Patient meets both of the following (a and b): **a)** Patient has tried generic fingolimod capsules; AND **b)** Patient has experienced inadequate efficacy or significant intolerance, according to the prescriber; OR Note: Prior use of Gilenya or Tascenso ODT with inadequate efficacy or significant intolerance (according to the prescriber) also counts. **v.** Patient meets both of the following (a and b): **a)** Patient has tried generic teriflunomide tablets; AND **b)** Patient has experienced inadequate efficacy or significant intolerance, according to the prescriber. Note: Prior use of Aubagio with inadequate efficacy or significant intolerance (according to the prescriber) also counts. **2.** If the patient meets the standard *Multiple Sclerosis – Ponvory Prior Authorization Policy* criteria, but does not meet criterion 1B, offer to review for the Preferred Product.

Non-Preferred Product	Exception Criteria
Rebif	**1.** Approve for 1 year if the patient meets the following (A and B): **A)** Patient meets the standard *Multiple Sclerosis – Rebif Prior Authorization Policy* criteria; AND **B)** Patient meets one of the following (i, ii, iii, iv, or v): **i.** Patient has been established on Rebif for ≥ 120 days; OR **ii.** Patient meets both of the following (a and b): **a)** Patient has tried generic dimethyl fumarate delayed-release tablets; AND **b)** Patient has experienced inadequate efficacy or significant intolerance, according to the prescriber; OR Note: Prior use of Tecfidera, Bafiertam, or Vumerity with inadequate efficacy or significant intolerance (according to the prescriber) also counts. **iii.** Patient meets both of the following (a and b): **a)** Patient has tried generic glatiramer injection; AND **b)** Patient has experienced inadequate efficacy or significant intolerance, according to the prescriber; OR Note: Prior use of Copaxone or Glatopa with inadequate efficacy or significant intolerance (according to the prescriber) also counts. **iv.** Patient meets both of the following (a and b): **a)** Patient has tried generic fingolimod capsules; AND **b)** Patient has experienced inadequate efficacy or significant intolerance, according to the prescriber; OR Note: Prior use of Gilenya or Tascenso ODT with inadequate efficacy or significant intolerance (according to the prescriber) also counts. **v.** Patient meets both of the following (a and b): **a)** Patient has tried generic teriflunomide tablets; AND **b)** Patient has experienced inadequate efficacy or significant intolerance, according to the prescriber. Note: Prior use of Aubagio with inadequate efficacy or significant intolerance (according to the prescriber) also counts. **2.** If the patient meets the standard *Multiple Sclerosis – Rebif Prior Authorization Policy* criteria, but does not meet criterion 1B, offer to review for the Preferred Product(s).

Non-Preferred Product	Exception Criteria
Vumerity	**1.** Approve for 1 year if the patient meets the following (A and B): **A)** Patient meets the standard *Multiple Sclerosis – Vumerity Prior Authorization Policy* criteria; AND **B)** Patient meets one of the following (i, ii, iii, or iv): **i.** Patient meets both of the following (a and b): **a)** Patient has tried generic dimethyl fumarate delayed-release capsules; AND **b)** Patient has experienced inadequate efficacy or significant intolerance, according to the prescriber; OR Note: Prior use of Tecfidera with inadequate efficacy or significant intolerance (according to the prescriber) also counts. **ii.** Patient meets both of the following (a and b): **a)** Patient has tried generic glatiramer injection; AND **b)** Patient has experienced inadequate efficacy or significant intolerance, according to the prescriber; OR Note: Prior use of Copaxone or Glatopa with inadequate efficacy or significant intolerance (according to the prescriber) also counts. **iii.** Patient meets both of the following (a and b): **a)** Patient has tried generic fingolimod capsules; AND **b)** Patient has experienced inadequate efficacy or significant intolerance, according to the prescriber; OR Note: Prior use of Gilenya or Tascenso ODT with inadequate efficacy or significant intolerance (according to the prescriber) also counts. **iv.** Patient meets both of the following (a and b): **a)** Patient has tried generic teriflunomide tablets; AND **b)** Patient has experienced inadequate efficacy or significant intolerance, according to the prescriber. Note: Prior use of Aubagio with inadequate efficacy or significant intolerance (according to the prescriber) also counts. **2.** If the patient meets the standard *Multiple Sclerosis – Vumerity Prior Authorization Policy* criteria, but does not meet criterion 1B, offer to review for the Preferred Product(s).
Zeposia	Refer to the *Multiple Sclerosis and Ulcerative Colitis – Zeposia Preferred Specialty Management Policy* criteria.

II. Tecfidera (Brand) Preferred Specialty Management Program

Non-Preferred Product	Exception Criteria
Tecfidera (brand)	**1.** Approve for 1 year if the patient meets the following (A and B): **A)** Patient meets the standard *Multiple Sclerosis – Dimethyl Fumarate Prior Authorization Policy* criteria; AND **B)** Patient meets both of the following (i and ii): **i.** Patient has tried generic dimethyl fumarate delayed-release capsules **[documentation required]**; AND **ii.** Patient cannot continue to use generic dimethyl fumarate delayed-release capsules due to a formulation difference in the inactive ingredient(s) [e.g., differences in dyes, fillers, preservatives] between the Brand and the bioequivalent generic which, per the prescriber, would result in a significant allergy or serious adverse reaction **[documentation required]**. **2.** If the patient meets the standard *Multiple Sclerosis – Dimethyl Fumarate Prior Authorization Policy* criteria, but does not meet criterion 1B, offer to review for the Preferred Product.

III. Fingolimod Preferred Specialty Management Program

Non-Preferred Product	Exception Criteria
Gilenya (brand)	**1.** Approve for 1 year if the patient meets the following (A and B): **A)** Patient meets the standard *Multiple Sclerosis – Fingolimod Prior Authorization Policy* criteria; AND **B)** Patient meets both of the following (i and ii): **i.** Patient meets one of the following (a, b, c, or d): **a)** Patient has been established on Gilenya (brand or generic) for ≥ 120 days; OR **b)** According to the prescriber, the patient has highly active or aggressive multiple sclerosis by meeting one of the following [(1), (2), (3), or (4)]: **(1)** Patient has demonstrated rapidly advancing deterioration(s) in physical functioning **[documentation required]**; OR Note: Examples include loss of mobility, lower levels of ambulation, and/or severe changes in strength or coordination. **(2)** Disabling relapse(s) with suboptimal response to systemic corticosteroids **[documentation required]**; OR **(3)** Magnetic resonance imaging (MRI) suggests highly active or aggressive multiple sclerosis **[documentation required]**; OR Note: Examples include new, enlarging, or a high burden of T2 lesions or gadolinium enhancing lesions. **(4)** Manifestations of multiple sclerosis-related cognitive impairment **[documentation required]**; OR **c)** Patient is ≥ 10 to < 18 years of age; OR **d)** Patient meets both of the following [(1) and (2)]: **(1)** Patient has tried generic dimethyl fumarate delayed-release capsules **[documentation required]**; AND **(2)** Patient has experience inadequate efficacy or significant intolerance according to the prescriber **[documentation required]**; AND Note: Prior use of Tecfidera, Bafiertam, or Vumerity with inadequate efficacy or significant intolerance (according to the prescriber) also counts **[documentation required]**. Prior use of glatiramer injection (brand or generic) with inadequate efficacy or significant intolerance

Non-Preferred Product	Exception Criteria
	(according to the prescriber) also counts **[documentation required]**. **ii.** Patient meets both of the following (a and b): **a)** Patient has tried generic fingolimod capsules **[documentation required]**; AND **b)** Patient cannot continue to use generic fingolimod capsules due to a formulation difference in the inactive ingredient(s) [e.g., differences in dyes, fillers, preservatives] between the Brand and the bioequivalent generic which, per the prescriber, would result in a significant allergy or serious adverse reaction **[documentation required]**. **2.** If the patient meets the standard *Multiple Sclerosis – Fingolimod Prior Authorization Policy* criteria, but does not meet criterion 1B, offer to review for the Preferred Product(s).

Non-Preferred Product	Exception Criteria
Tascenso ODT	**1.** Approve for 1 year if the patient meets the following (A and B): **A)** Patient meets the standard *Multiple Sclerosis – Tascenso ODT Prior Authorization Policy* criteria; AND **B)** Patient meets both of the following (i and ii): **i.** Patient meets one of the following (a, b, c, d, or e): **a)** Patient cannot swallow or has difficulty swallowing tablets or capsules; OR **b)** Patient has been established on Tascenso ODT for ≥ 120 days; OR **c)** According to the prescriber, the patient has highly active or aggressive multiple sclerosis by meeting one of the following [(1), (2), (3), or (4)]: **(1)** Patient has demonstrated rapidly advancing deterioration(s) in physical functioning **[documentation required]**; OR Note: Examples include loss of mobility, lower levels of ambulation, and/or severe changes in strength or coordination. **(2)** Disabling relapse(s) with suboptimal response to systemic corticosteroids **[documentation required]**; OR **(3)** Magnetic resonance imaging (MRI) suggests highly active or aggressive multiple sclerosis **[documentation required]**; OR Note: Examples include new, enlarging, or a high burden of T2 lesions or gadolinium enhancing lesions. **(4)** Manifestations of multiple sclerosis-related cognitive impairment **[documentation required]**; OR **d)** Patient is ≥ 10 to < 18 years of age; OR **e)** Patient meets both of the following [(1) and (2)]: **(1)** Patient has tried generic dimethyl fumarate delayed-release capsules **[documentation required]**; AND **(2)** Patient has experience inadequate efficacy or significant intolerance according to the prescriber **[documentation required]**; AND Note: Prior use of Tecfidera, Bafiertam, or Vumerity with inadequate efficacy or significant intolerance (according to the prescriber) also counts **[documentation required]**. Prior use of glatiramer injection (brand or generic) with inadequate efficacy or significant intolerance

Non-Preferred Product	Exception Criteria
	(according to the prescriber) also counts **[documentation required]**. **ii.** Patient meets one of the following (a or b): **a)** Patient meets both of the following (i and ii): **i.** Patient has tried generic fingolimod capsules **[documentation required]**; AND **ii.** Patient cannot continue to use generic fingolimod capsules due to a formulation difference in the inactive ingredient(s) [e.g., differences in dyes, fillers, preservatives] between the Brand and the bioequivalent generic which, per the prescriber, would result in a significant allergy or serious adverse reaction **[documentation required]**. **b)** Patient cannot swallow or has difficulty swallowing tablets or capsules. **2.** If the patient meets the standard *Multiple Sclerosis – Fingolimod Prior Authorization Policy* criteria, but does not meet criterion 1B, offer to review for the Preferred Product(s).

IV. Aubagio Preferred Specialty Management Program

Non-Preferred Product	Exception Criteria
Aubagio (brand)	**1.** Approve for 1 year if the patient meets the following (A and B): **A)** Patient meets the standard *Multiple Sclerosis – Teriflunomide Prior Authorization Policy* criteria; AND **B)** Patient meets one the following (i or ii): **i.** Patient meets both of the following (a and b): **a)** Patient has been established on Aubagio (brand or generic) for ≥ 120 days; AND **b)** Patient meets both of the following [(1) and (2)]: **(1)** Patient has tried generic teriflunomide tablets **[documentation required]**; AND **(2)** Patient cannot continue to use generic teriflunomide tablets due to a formulation difference in the inactive ingredient(s) [e.g., differences in dyes, fillers, preservatives] between the Brand and the bioequivalent generic which, per the prescriber, would result in a significant allergy or serious adverse reaction **[documentation required]**; OR **ii.** Patient meets ALL of the following (a, b, c, and d): **a)** Patient meets both of the following [(1) and (2)]: **(1)** Patient has tried generic dimethyl fumarate delayed-release capsules **[documentation required]**; AND **(2)** Patient has experienced inadequate efficacy or significant intolerance, according to the prescriber **[documentation required]**; AND Note: Prior use of Tecfidera, Bafiertam, or Vumerity with inadequate efficacy or significant intolerance (according to the prescriber) also counts. **b)** Patient meets both of the following [(1) and (2)]: **(1)** Patient has tried generic glatiramer injection **[documentation required]**; AND **(2)** Patient has experienced inadequate efficacy or significant intolerance, according to the prescriber **[documentation required]**; AND Note: Prior use of Copaxone or Glatopa with inadequate efficacy or significant intolerance (according to the prescriber) also counts. **c)** Patient meets both of the following [(1) and (2)]: **(1)** Patient has tried generic fingolimod capsules **[documentation required]**; AND

Non-Preferred Product	Exception Criteria
	(2) Patient has experienced inadequate efficacy or significant intolerance, according to the prescriber; AND **d)** Patient meets both of the following [(1) and (2)] **(1)** Patient has tried generic teriflunomide tablets **[documentation required]**; AND **(2)** Patient cannot continue to use generic teriflunomide tablets due to a formulation difference in the inactive ingredient(s) [e.g., differences in dyes, fillers, preservatives] between the Brand and the bioequivalent generic which, per the prescriber, would result in a significant allergy or serious adverse reaction **[documentation required]**. **2.** If the patient meets the standard *Multiple Sclerosis – Teriflunomide Prior Authorization Policy* criteria, but does not meet criterion 1B, offer to review for the Preferred Product(s).

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6. Glatopa® subcutaneous injection [prescribing information]. Princeton, NJ: Sandoz; March 2023.
7. Rebif® subcutaneous injection [prescribing information]. Rockland, MA: EMD Serono; July 2023.
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12. Mayzent® tablets [prescribing information]. East Hanover, NJ: Novartis; June 2022.
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20. Rae-Grant A, Day GS, Marrie RA, et al. Practice guideline recommendations summary: disease-modifying therapies for adults with multiple sclerosis. Report of the guideline development, dissemination, and implementation subcommittee of the American Academy of Neurology. *Neurology*. 2018;90:777-788.

HISTORY

Type of Revision	Summary of Changes	Review Date
Early Annual Revision	Effective 01/01/2023 **Multiple Sclerosis Preferred Specialty Management Program:** Generic fingolimod capsules were added as a Preferred Product. For **Multiple Sclerosis**, generic fingolimod capsules were added to the list of products that may have been tried with inadequate efficacy or significant intolerance prior to a Non-Preferred Product. Also a Note was added that prior use of Gilenya (brand) with inadequate efficacy or significant intolerance (according to the prescriber) also counts. **Gilenya (Brand) Preferred Specialty Management Program:** This was added as a new step in which the Preferred Products are generic dimethyl fumarate delayed-release capsules and generic fingolimod capsules. To receive Gilenya (brand), a patient must have experienced inadequate efficacy or significant intolerance to generic dimethyl fumarate delayed-release capsules (documentation required) AND meet the standard multisource brand criteria after a trial of generic fingolimod capsules (documentation required). Additional exception criteria for Gilenya (brand) were developed (see policy). Previously, inadequate efficacy or significant intolerance to one of generic glatiramer injection or generic dimethyl fumarate delayed-release capsules was required.	10/26/2022

HISTORY (CONTINUED)

Type of Revision	Summary of Changes	Review Date
Selected Revision	Effective 01/01/2023 **Gilenya (Brand) Preferred Specialty Management Program:** Documentation requirements were added regarding prior use of Tecfidera, Bafiertam, Vumerity and generic glatiramer injection (brand or generic), which also applies to the criteria related to inadequate efficacy or significant intolerance.	12/14/2022
Selected Revision	**Kesimpta:** Added an exception to the requirement that the patient has tried one of the Preferred Products if the patient has previously received one of Briumvi or Mavenclad. Tascenso ODT was added to the Note related to the requirement of a trial of generic fingolimod capsules that prior use of Tascensco ODT, with inadequate efficacy or significant intolerance (according to the prescriber), also counts. **Mavenclad:** Added an exception to the requirement that the patient has tried one of the Preferred Products if the patient has previously received one of Tysabri, Lemtrada, Ocrevus, Briumvi, or Kesimpta. Tascenso ODT was added to the Note related to the requirement of a trial of generic fingolimod capsules that prior use of Tascenso ODT, with inadequate efficacy or significant intolerance (according to the prescriber), also counts. **Aubagio, Avonex, Bafiertam, Betaseron, Copaxone, Extavia, Glatopa, Mayzent, Plegridy, Ponvory, Rebif, and Vumerity:** Tascenso ODT was added to the Note related to the requirement of a trial of generic fingolimod capsules that prior use of Tascenso ODT, with inadequate efficacy or significant intolerance (according to the prescriber), also counts. **Tascenso ODT:** This was added as Non-Preferred Product to the **Fingolimod** Preferred Specialty Management Program, which was previous named the Gilenya (Brand) Preferred Specialty Management Program. Criteria were developed.	03/01/2023

Selected Revision	It was noted that Aubagio is now available as a generic in the listing of the medications. **Multiple Sclerosis Preferred Specialty Management:** The criteria for Aubagio (brand) was removed. For Mavenclad and Kesimpta, regarding the criterion that addresses highly effective therapies, it was added to approve if the patient has tried the requested product (i.e., Mavenclad or Kesimpta). **Aubagio (Brand) Preferred Specialty Management Program:** This was added as a new program. Preferred Products are generic glatiramer injection, AND generic dimethyl fumarate delayed-release capsules, AND generic fingolimod capsules, AND generic teriflunomide; the Non-Preferred Product is Aubagio (brand). Criteria were developed (refer to the policy).	04/12/2023 (effective 07/01/2023 regarding Aubagio)
Selected Revision	**Multiple Sclerosis Preferred Specialty Management:** Generic teriflunomide was added as a Preferred Product. If a patient has tried generic teriflunomide tablets and has experienced inadequate efficacy or significant intolerance, according to the prescriber, this would count toward the requirement to receive a Non-Preferred Product. A Note was added that prior use of Aubagio with inadequate efficacy or significant intolerance (according to the prescriber) also counts.	07/26/2023
Annual Revision	No criteria changes.	11/08/2023