PREFERRED SPECIALTY MANAGEMENT POLICY

POLICY: Multiple Sclerosis Preferred Specialty Management Policy

- Aubagio® (teriflunomide tablets – Genzyme/Sanofi)
- Avonex® (interferon beta-1a intramuscular injection– Biogen)
- Bafiertam® (monomethyl fumarate delayed-release capsules – Banner Life Sciences)
- Betaseron® (interferon beta-1b subcutaneous injection – Bayer)
- Copaxone® (glatiramer acetate subcutaneous injection – Teva, generic)
- Extavia® (interferon beta-1b subcutaneous injection – Novartis)
- Gilenya® (fingolimod capsules – Novartis, generic)
- Glatopa® (glatiramer acetate subcutaneous injection – Sandoz, generic)
- Kesimpta® (ofatumumab subcutaneous injection – Novartis)
- Mavenclad® (cladribine tablets – EMD Serono)
- Mayzent® (siponimod tablets – Novartis)
- Plegridy® (peginterferon beta-1a subcutaneous injection – Biogen)
- Ponvory® (ponesimod tablets – Janssen)
- Rebif® (interferon beta-1a subcutaneous injection – Serono)
- Tascenso ODT™ (fingolimod orally disintegrating tablets – Handa/Cycle)
- Tecfidera® (dimethyl fumarate delayed-release capsules – Biogen, generic)
- Vumerity® (diroximel fumarate delayed-release capsules – Biogen)
- Zeposia® (ozanimod capsules – Celgene/Bristol Myers Squibb)

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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 (generic glatiramer injection, 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. The Program also directs the patient to try <u>one</u> Preferred Product (generic glatiramer injection, generic dimethyl fumarate delayed-release capsules, or generic fingolimod capsules) 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

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delayed-release capsules, or generic fingolimod capsules), 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.

Automation: None.

Documentation: Documentation is required for Tecfidera (brand) and Gilenya (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
Non-Preferred Products:	Aubagio, Avonex, Bafiertam, Betaseron, Copaxone, Extavia, Glatopa, Kesimpta, Mavenclad, Mayzent, Plegridy, Ponvory, Rebif, Vumerity, Zeposia

Tecfidera (Brand) Preferred Specialty Management Program

Preferred Products:	generic dimethyl fumarate delayed-release capsules
Non-Preferred Product:	Tecfidera (brand)

Fingolimod Preferred Specialty Management Program

Preferred Products:	generic dimethyl fumarate delayed-release capsules AND generic fingolimod capsules
Non-Preferred Product:	Gilenya (brand), Tascenso ODT

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RECOMMENDED EXCEPTION CRITERIA

I. Multiple Sclerosis Preferred Specialty Management Program

Non-Preferred Product	Exception Criteria
Aubagio	**1.** Approve for 1 year if the patient meets the following criteria (A and B): **A)** Patient meets the standard *Multiple Sclerosis – Aubagio Prior Authorization Policy* criteria; AND **B)** Patient meets one of the following (i, ii, iii, or iv): **i.** Patient has been established on Aubagio 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. Note: Prior use of Gilenya or Tascenso ODT with inadequate efficacy or significant intolerance (according to the prescriber) also counts. **2.** If the patient meets the standard *Multiple Sclerosis – Aubagio Prior Authorization Policy* criteria, but does not meet criterion 1B, offer to review for the Preferred Product(s).

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Non-Preferred Product	Exception Criteria
Avonex	**1.** Approve for 1 year if the patient meets the following criteria (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, or iv): **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. Note: Prior use of Gilenya or Tascenso ODT 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).

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Non-Preferred Product	Exception Criteria
Bafiertam	**1.** Approve for 1 year if the patient meets the following criteria (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, or iii): **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. Note: Prior use of Gilenya or Tascenso ODT 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).

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Non-Preferred Product	Exception Criteria
Betaseron	**1.** Approve for 1 year if the patient meets the following criteria (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, or iv): **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. Note: Prior use of Gilenya or Tascenso ODT 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).

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Non-Preferred Product	Exception Criteria
Copaxone 20 mg/mL and 40 mg/mL	**1.** Approve for 1 year if the patient meets the following criteria (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, or iii): **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. Note: Prior use of Gilenya or Tascenso ODT 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).

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Non-Preferred Product	Exception Criteria
Extavia	**1.** Approve for 1 year if the patient meets the following criteria (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, or iv): **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. Note: Prior use of Gilenya or Tascenso ODT 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).

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Non-Preferred Product	Exception Criteria
Glatopa 20 mg/mL and 40 mg/mL	**1.** Approve for 1 year if the patient meets the following criteria (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, or iii): **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. Note: Prior use of Gilenya or Tascenso ODT 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).

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Non-Preferred Product	Exception Criteria
Kesimpta	**1.** Approve for 1 year if the patient meets the following criteria (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, or v): **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 has previously received one of Tysabri (natalizumab intravenous infusion), Ocrevus (ocrelizumab intravenous infusion), Briumvi (ublituximab-xiiy intravenous infusion), Mavenclad (cladribine tablets), or Lemtrada (alemtuzumab intravenous infusion). **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).

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Non-Preferred Product	Exception Criteria
Mavenclad	**1.** Approve for 1 year if the patient meets the following criteria (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, or v): **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 has previously received one of Tysabri (natalizumab intravenous infusion), Ocrevus (ocrelizumab intravenous infusion), Kesimpta (ofatumumab subcutaneous injection), Briumvi (ublituximab-xiiy intravenous infusion), or Lemtrada (alemtuzumab intravenous infusion). **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).

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Non-Preferred Product	Exception Criteria
Mayzent	**1.** Approve for 1 year if the patient meets the following criteria (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, or v): **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. Note: Prior use of Gilenya or Tascenso ODT 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).

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Non-Preferred Product	Exception Criteria
Plegridy	**1.** Approve for 1 year if the patient meets the following criteria (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, or iv): **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. Note: Prior use of Gilenya or Tascenso ODT 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).

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Non-Preferred Product	Exception Criteria
Ponvory	**1.** Approve for 1 year if the patient meets the following criteria (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, or iv): **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 Glatopra 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. Note: Prior use of Gilenya or Tascenso ODT 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.

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Non-Preferred Product	Exception Criteria
Rebif	**1.** Approve for 1 year if the patient meets the following criteria (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, or iv): **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. Note: Prior use of Gilenya or Tascenso ODT 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).

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Non-Preferred Product	Exception Criteria
Vumerity	**1.** Approve for 1 year if the patient meets the following criteria (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, or iii): **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. Note: Prior use of Gilenya or Tascenso ODT 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.

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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 criteria (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(s).

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III. Fingolimod Preferred Specialty Management Program

Non-Preferred Product	Exception Criteria
Gilenya (brand)	**1.** Approve for 1 year if the patient meets the following criteria (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 capsules **[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 acetate injection (brand or generic) with inadequate efficacy or significant intolerance (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).

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Non-Preferred Product	Exception Criteria
Tascenso ODT	**1.** Approve for 1 year if the patient meets the following criteria (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 acetate injection (brand or generic) with inadequate efficacy or significant intolerance (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).

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Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	12/01/2021
Selected Revision	Documentation requirement removed for Gilenya.	03/09/2022
Selected Revision	**Aubagio, Avonex, Betaseron, Copaxone, Extavia, Gilenya, Glatopa, Kesimpta, Mavenclad, Mayzent, Plegridy, Ponvory, and Rebif:** For the requirement that the patient has tried generic dimethyl fumarate delayed-release capsules, it was added in a Note that prior use of Bafiertam or Vumerity also counts. Previously only prior to use Tecfidera fulfilled this requirement. **Bafiertam and Vumerity:** Continuation of therapy for patients established on Bafiertam or Vumerity for ≥ 120 days was removed.	06/08/2022
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 Ocrevus, Tysabri, or Lemtrada.	07/20/2022
Selected Revision	The Tecfidera (Brand) Preferred Specialty Management Program was revised to remove generic glatiramer injection as a Preferred Product. The related exception criteria for Tecfidera were revised as the requirement to try generic glatiramer injection for the patient population that has not received Tecfidera (brand) or has received Tecfidera (brand) for < 120 days were removed. Now, the criteria are the same for the previously defined population, as well as for patients who have been established on Tecfidera (brand) for ≥ 120 days such that the patient has tried generic dimethyl fumarate delayed-release capsules and that the 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.	09/21/2022

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