VENTURA COUNTY
HEALTH CARE PLAN

CARE VALUE POLICY

POLICY: Multiple Sclerosis Care Value Policy

- Aubagio® (teriflunomide tablets – Genzyme/Sanofi, generic)
- 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 subcutaneous injection – Teva, generic)
- Extavia® (interferon beta-1b subcutaneous injection – Novartis)
- Gilenya® (fingolimod capsules – Novartis, generic)
- Glatopa® (glatiramer 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)

REVIEW DATE: 10/26/2022; selected revision 12/14/2022, 03/01/2023, 04/12/2023, and 07/26/2023

OVERVIEW

This Care Value policy involves the use of self-administered injectable products and oral disease-modifying agents used in **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 Tecfidera 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 Care Value Program has been developed to encourage the use of the Preferred Products. For all Non-Preferred Products, the patient is required to meet the respective standard *Prior Authorization Policy* criteria. The Program also directs the patient to try the listed Preferred Product(s) 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.

The Tecfidera (Brand) Care Value Program has been developed to encourage the use of generic dimethyl fumarate delayed-release capsules. For the Non-Preferred Product, the patient is required to meet 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.

The Fingolimod Care Value Program has been developed to encourage the use of the Preferred Products (generic dimethyl fumarate delayed-release capsules and generic fingolimod capsules). For all Non-Preferred Products the patient is required to meet 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.

The Aubagio Care Value 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 the Non-Preferred Product, the patient is required to meet the 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.

Documentation: Documentation is required for use of 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.

Automation: None.

Multiple Sclerosis Care Value 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) Care Value Program

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

Fingolimod Care Value Program

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

Aubagio Care Value 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)

RECOMMENDED EXCEPTION CRITERIA

I. Multiple Sclerosis Care Value 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.

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.

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.

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 (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.

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.

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 (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.

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 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), Briumvi (ublituximab-xiiy intravenous infusion), Mavenclad (cladribine tablets), Lemtrada (alemtuzumab intravenous infusion), or Kesimpta.

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.

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.

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 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.

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.

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 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.

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.
Zeposia	Refer to the *Multiple Sclerosis and Ulcerative Colitis – Zeposia Care Value Policy* criteria.

II. Tecfidera (Brand) Care Value 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]**.

III. Fingolimod Care Value 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 (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]**.

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 (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.

IV. Aubagio Care Value 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 **(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]**.

REFERENCES

1. Avonex® intramuscular injection [prescribing information]. Cambridge, MA: Biogen; November 2021.
2. Betaseron® subcutaneous injection [prescribing information]. Whippany, NJ: Bayer; November 2021.
3. Copaxone® subcutaneous injection [prescribing information]. Parsippany, NJ: Teva; July 2020.
4. Extavia® subcutaneous injection [prescribing information]. East Hanover, NJ: Novartis; November 2021.
5. Glatiramer subcutaneous injection [prescribing information]. Morgantown, WV: Mylan; September 2020.
6. Glatopa® subcutaneous injection [prescribing information]. Princeton, NJ: Sandoz; July 2020.
7. Rebif® subcutaneous injection [prescribing information]. Rockland, MA: EMD Serono; July 2020.
8. Plegridy® subcutaneous injection [prescribing information]. Cambridge, MA: Biogen; March 2022.
9. Gilenya® capsules [prescribing information]. East Hanover, NJ: Novartis; July 2022.
10. Aubagio® tablets [prescribing information]. Cambridge, MA: Genzyme/Sanofi; April 2022.
11. Mavenclad® tablets [prescribing information]. Rockland, MA: EMD Serono; September 2022.
12. Mayzent® tablets [prescribing information]. East Hanover, NJ: Novartis; June 2022.
13. Tecfidera® delayed-release capsules [prescribing information]. Cambridge, MA: Biogen; September 2022.
14. Vumerity® delayed-release capsules [prescribing information]. Cambridge, MA: Biogen; September 2022.
15. Zeposia® capsules [prescribing information]. Summit, NJ: Celgene/Bristol Myers Squibb; April 2023.
16. Kesimpta® subcutaneous injection [prescribing information]. East Hanover, NJ: Novartis; September 2022.
17. Bafiertam® delayed-release capsules [prescribing information]. High Point, NC: Banner Life Sciences; May 2021.
18. Ponvory® tablets [prescribing information]. Titusville, NJ: Janssen; April 2021.
19. Tascenso ODT™ [prescribing information]. Cambridge, UK and San Jose, CA: Cycle/Handa; December 2022.
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.