VENTURA COUNTY
HEALTH CARE PLAN

CARE VALUE POLICY

POLICY: Multiple Sclerosis Care Value 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)
- 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; effective 01/01/2023

OVERVIEW

This Care Value policy involves the use of self-administered injectable products and oral disease-modifying agents used in **multiple sclerosis**.[1-18] All products are indicated for use in adults. Of note, fingolimod is the only agent specifically indicated for children ≥ 10 to < 18 years of age for the treatment of relapsing forms of multiple sclerosis.[9] 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.[19]

POLICY STATEMENT

The Multiple Sclerosis Care Value 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 Non-Preferred Products the patient is required to meet the respective standard *Prior Authorization Policy* criteria. Requests for the Preferred Products do not have to meet standard *Prior Authorization Policy* criteria. The Program also directs the patient to try <u>one</u> Preferred Product (generic glatiramer injection or 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.

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 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.

The Gilenya (Brand) 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 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.

Automation: None.

Documentation: Documentation is required for use of 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 Care Value 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) Care Value Program

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

Gilenya (Brand) Care Value Program

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

RECOMMENDED EXCEPTION CRITERIA

I. Multiple Sclerosis Care Value 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 with inadequate efficacy or significant intolerance (according to the prescriber) also counts.

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 **iv.** Patient meets both of the following (a and b): **a)** Patient has tried generic generic fingolimod capsules; AND **b)** Patient has experienced inadequate efficacy or significant intolerance, according to the prescriber. Note: Prior use of Gilenya with inadequate efficacy or significant intolerance (according to the prescriber) also counts.
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 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 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 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 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 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 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 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 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 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 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 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 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), or Lemtrada (alemtuzumab intravenous infusion).

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, or iv): **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. 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 with inadequate efficacy or significant intolerance (according to the prescriber) also counts.

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 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 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 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 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 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 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 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 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 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 with inadequate efficacy or significant intolerance (according to the prescriber) also counts.
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 with inadequate efficacy or significant intolerance (according to the prescriber) also counts.

Non-Preferred Product	Exception Criteria
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 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]**.

III. Gilenya (Brand) Care Value 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. Prior use of glatiramer acetate injection (brand or generic) 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 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]**.

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 acetate 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; September 2022.
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. 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
Selected Revision	For Zeposia, removed the criteria and directed the patient to following the *Multiple Sclerosis and Ulcerative Colitis – Zeposia Care Value Policy*. Criteria added for Ponvory which was placed as a Non-Preferred Product in the Multiple Sclerosis Care Value Program.	06/02/2021
Selected Revision	In the Policy Statement, the statement that **r**equests for the Preferred Products do not have to meet standard *Prior Authorization Policy* criteria was removed. Other changes made are documented below. **Tecfidera:** Documentation requirements were added to support a trial of generic dimethyl fumarate delayed release capsules and generic glatiramer injection, as well as the requirement that the patient cannot take the respective generic due to a formulation differences in the inactive ingredient(s) that would result in a serious allergy or serious adverse reaction. Documentation was also added to the requirement in the Note regarding generic glatiramer injection that prior use of Copaxone or Glatopa with inadequate efficacy or significant intolerance also counts. Also, the wording of "Brand Tecfidera is being requested" was changed to "Patient cannot continue to use the generic dimethyl fumarate delayed-release capsules". **Copaxone:** Wording was revised from "Brand Copaxone is being requested" to "Patient cannot continue to use generic glatiramer injection". **Glatopa:** Wording was revised from "Brand Glatopa is being requested" to "Patient cannot continue to use generic glatiramer injection".	10/13/2021
Annual Revision	No criteria changes.	12/01/2021
Selected Revision	Documentation requirements removed from 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

HISTORY (CONTINUED)

Type of Revision	Summary of Changes	Review Date

Selected Revision	The Tecfidera (Brand) Care Value 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
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