VENTURA COUNTY
HEALTH CARE PLAN

CARE VALUE POLICY

POLICY: Multiple Sclerosis Care Value Policy

Beta Interferon Products (Self-Injectable)
• Extavia® (interferon beta-1b subcutaneous injection – Novartis)
Fumarate Products (Oral)
• Tecfidera® (dimethyl fumarate delayed-release capsules – Biogen, generic)
Glatiramer Products (Self-Injectable)
• Copaxone® (glatiramer subcutaneous injection – Teva, generic)
Pyrimidine Synthesis Inhibitor (Oral)
• Aubagio® (teriflunomide tablets – Genzyme/Sanofi, generic)
Sphingosine 1-Phosphate Receptor Modulator
• Gilenya® (fingolimod capsules – Novartis, generic) • Tascenso ODT® (fingolimod orally disintegrating tablets – Handa/Cycle)

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OVERVIEW

This Care Value policy involves the use of selected self-administered injectable products and selected oral disease-modifying agents used in **multiple sclerosis**.[1-6] 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.[3,6] 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.[7]

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 *Care Value Policy* criteria. The Program also directs the patient to try both Preferred Products (generic glatiramer injection and generic dimethyl fumarate delayed-release 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 standard *Care Value 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 *Care Value 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 *Care Value 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 certain products as noted in the criteria as **[documentation required]**. Documentation may include, but is not limited to, chart notes, prescription claims records, prescription receipts, magnetic resonance imaging reports, and/or other information.

Automation: None.

Multiple Sclerosis Care Value Program

Preferred Products:	generic glatiramer injection and generic dimethyl fumarate delayed-release capsules
Non-Preferred Products:	Copaxone, Extavia

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
Copaxone 20 mg/mL and 40 mg/mL	**1.** Approve for 1 year if the patient meets BOTH of the following (A and B): **A)** Patient meets the standard *Multiple Sclerosis – Glatiramer Products Care Value Policy* criteria; AND **B)** Patient meets BOTH of the following (i and ii): **i.** Patient meets ONE of the following (a or b): **a)** Patient has been established on a glatiramer product for ≥ 120 days; OR **b)** 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. **ii.** Patient meets BOTH of the following (a and b): **a)** Patient has tried generic glatiramer injection **[documentation required]**; 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 **[documentation required]**.

Non-Preferred Product	Exception Criteria
Extavia	**1.** Approve for 1 year if the patient meets BOTH of the following (A and B): **A)** Patient meets the standard *Multiple Sclerosis – Betaseron/Extavia Care Value Policy* criteria; AND **B)** Patient meets ONE of the following (i or ii): **i.** Patient has been established on Extavia for ≥ 120 days; OR **ii.** Patient meets BOTH of the following (a and b): **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]**. Note: Prior use of Copaxone or Glatopa with inadequate efficacy or significant intolerance (according to the prescriber) also counts.

II. Tecfidera (Brand) Care Value Program

Non-Preferred Product	Exception Criteria
Tecfidera (brand)	**1.** Approve for 1 year if the patient meets BOTH of the following (A and B): **A)** Patient meets the standard *Multiple Sclerosis – Dimethyl Fumarate Care Value 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 BOTH of the following (A and B): **A)** Patient meets the standard *Multiple Sclerosis – Fingolimod Care Value 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 BOTH of the following (A and B): **A)** Patient meets the standard *Multiple Sclerosis – Tascenso ODT Care Value 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 BOTH of the following (A and B): **A)** Patient meets the standard *Multiple Sclerosis – Teriflunomide Care Value 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. **b)** 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 **c)** 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. Copaxone® subcutaneous injection [prescribing information]. Parsippany, NJ: Teva; February 2023.
2. Extavia® subcutaneous injection [prescribing information]. East Hanover, NJ: Novartis; July 2023.
3. Gilenya® capsules [prescribing information]. East Hanover, NJ: Novartis; September 2023.
4. Aubagio® tablets [prescribing information]. Cambridge, MA: Genzyme/Sanofi; December 2022.
5. Tecfidera® delayed-release capsules [prescribing information]. Cambridge, MA: Biogen; February 2023.
6. Tascenso ODT™ [prescribing information]. Cambridge, UK and San Jose, CA: Cycle/Handa; August 2023.
7. 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.