EXPRESS SCRIPTS®

CARE VALUE POLICY

POLICY: Multiple Sclerosis Care Value Policy

Cladribine Products (Oral)
• Mavenclad® (cladribine tablets – EMD Serono, generic)
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) • Ponvory® (ponesimod tablets – Vanda) • Tascenso ODT® (fingolimod orally disintegrating tablets – Handa/Cycle)

REVIEW DATE: 07/22/2026

OVERVIEW

This Care Value policy involves the use of selected self-administered injectable products and selected oral disease-modifying agents used for **multiple sclerosis**.[1-10] All products are indicated for use in adults. Of note, fingolimod and Tascenso ODT are indicated for children ≥ 10 years of age for the treatment of relapsing forms of multiple sclerosis.[5,8]

POLICY STATEMENT

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

The Tecfidera (Brand) Care Value Program has been developed to encourage the use of generic dimethyl fumarate delayed-release capsules. For all medications (Preferred and Non-Preferred), the patient is required to meet 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. If a patient requesting the Non-Preferred Product (Tecfidera [brand]) meets the standard *Care Value Policy* criteria but has not tried the Preferred Product, approval for the Preferred Product will be authorized.

The S1P 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 *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. If a patient requesting a Non-Preferred Product meets the standard *Care Value Policy* criteria but has not tried the Preferred Products, an offer to review for the Preferred Products will be made.

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 all medications (Preferred and Non-Preferred), the patient is required to meet the respective 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. If a patient requesting a Non-Preferred Product meets the standard *Care Value Policy* criteria but has not tried the Preferred Products, an offer to review for the Preferred Products will be made.

The Mavenclad (Brand) Care Value Program has been developed to encourage the use of generic cladribine tablets. For all medications (Preferred and Non-Preferred), 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. If a patient requesting the Non-Preferred Product (Mavenclad [brand]) meets the standard *Care Value Policy* criteria but has not tried the Preferred Product, approval for the Preferred Product will be authorized.

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. All documentation must include patient-specific identifying information.

Automation: None.

Multiple Sclerosis Care Value Program

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

Tecfidera (Brand) Care Value Program

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

S1P Care Value Program

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

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)

Mavenclad (Brand) Care Value Program
Preferred Product: generic cladribine tablets
Non-Preferred Product: Mavenclad (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 (Injectable) – 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 **[documentation required]**. **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]**. **2.** If the patient meets the standard *Multiple Sclerosis (Injectable) – Glatiramer Products Care Value Policy* criteria, but does not meet criterion 1B, offer to review for the Preferred Product(s).

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 (Oral – Fumarate) – 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]**. **2.** If the patient meets the standard *Multiple Sclerosis (Oral – Fumarate) – Dimethyl Fumarate Care Value Policy* criteria, but does not meet criterion 1B, approve generic dimethyl fumarate delayed-release capsules.

III. S1P Care Value Program

Non-Preferred Product	Exception Criteria
Ponvory	**1.** Approve for 1 year if the patient meets BOTH of the following (A and B): **A)** Patient meets the standard *Multiple Sclerosis (Oral – Sphingosine 1-Receptor Modulator) – Ponvory Care Value Policy* criteria; AND **B)** Patient meets ONE of the following (i or ii): **i.** Patient has been established on Ponvory 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 **[documentation required].** **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 **[documentation required]**. Note: Prior use of Gilenya (brand) or Tascenso ODT with inadequate efficacy or significant intolerance (according to the prescriber) also counts **[documentation required]**. **2.** If the patient meets the standard *Multiple Sclerosis (Oral – Sphingosine 1-Receptor Modulator) – Ponvory Care Value Policy* criteria, but does not meet criterion 1B, offer to review for the Preferred Product(s).

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 (Oral – Sphingosine 1-Receptor Modulator) – 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, or c): **a)** Patient has been established on Gilenya (brand or generic) for ≥ 120 days; OR **b)** Patient is ≥ 10 to < 18 years of age; OR **c)** 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 **[documentation required]**. **ii.** Patient meets BOTH of the following (a and b): **a)** Patient has tried generic fingolimod capsules **[documentation required]**; AND **b)** Patient cannot continue to use generic fingolimod capsules due to a formulation difference in the inactive ingredient(s) [e.g., differences in dyes, fillers, preservatives] between the Brand and the bioequivalent generic which, per the prescriber, would result in a significant allergy or serious adverse reaction **[documentation required]**. **2.** If the patient meets the standard *Multiple Sclerosis (Oral – Sphingosine 1-Receptor Modulator) – Fingolimod Care Value Policy* criteria, but does not meet criterion 1B, offer to review for the Preferred Product(s).

Non-Preferred Product	Exception Criteria
Tascenso ODT	**1.** Approve for 1 year if the patient meets BOTH of the following (A and B): **A)** Patient meets the standard *Multiple Sclerosis (Oral – Sphingosine 1-Receptor Modulator) – 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, or d): **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)** 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 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 **[documentation required]**. **ii.** Patient meets ONE of the following (a or b): **a)** Patient meets BOTH of the following (i and ii): **i.** Patient has tried generic fingolimod capsules **[documentation required]**; AND **ii.** Patient cannot continue to use generic fingolimod capsules due to a formulation difference in the inactive ingredient(s) [e.g., differences in dyes, fillers, preservatives] between the Brand and the bioequivalent generic which, per the prescriber, would result in a significant allergy or serious adverse reaction **[documentation required]**. **b)** Patient cannot swallow or has difficulty swallowing tablets or capsules. **2.** If the patient meets the standard *Multiple Sclerosis (Oral – Sphingosine 1-Receptor Modulator) – Tascenso ODT Care Value Policy* criteria, but does not meet criterion 1B, offer to review for the Preferred Product(s).

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 (Oral – Other) – 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 **[documentation required]**. **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 **[documentation required]**. **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 Note: Prior use of Gilenya or Tascenso ODT with inadequate efficacy or significant intolerance (according to the prescriber) also counts **[documentation required]**. **d)** Patient meets BOTH of the following [(1) and (2)]:

	(1) Patient has tried generic teriflunomide tablets **[documentation required]**; AND **(2)** Patient cannot continue to use generic teriflunomide tablets due to a formulation difference in the inactive ingredient(s) [e.g., differences in dyes, fillers, preservatives] between the Brand and the bioequivalent generic which, per the prescriber, would result in a significant allergy or serious adverse reaction **[documentation required]**. **2.** If the patient meets the standard *Multiple Sclerosis (Oral – Other) – Teriflunomide Care Value Policy* criteria, but does not meet criterion 1B, offer to review for the Preferred Product(s).

V. Mavenclad (Brand) Care Value Program

Non-Preferred Product	Exception Criteria
Mavenclad (brand)	**1.** Approve for 1 year if the patient meets BOTH of the following (A and B): **A)** Patient meets the standard *Multiple Sclerosis (Oral – Other) – Cladribine Care Value Policy* criteria; AND **B)** Patient meets BOTH of the following (i and ii): **i.** Patient has tried generic cladribine tablets **[documentation required]**; AND **ii.** Patient cannot continue to use generic cladribine tablets due to a formulation difference in the inactive ingredient(s) [e.g., differences in dyes, fillers, preservatives] between the Brand and the bioequivalent generic which, per the prescriber, would result in a significant allergy or serious adverse reaction **[documentation required]**. **2.** If the patient meets the standard *Multiple Sclerosis (Oral – Other) – Cladribine Care Value Policy* criteria, but does not meet criterion 1B, approve generic cladribine tablets.

REFERENCES

1. Copaxone® subcutaneous injection [prescribing information]. Parsippany, NJ: Teva; June 2026.
2. Glatopa® subcutaneous injection [prescribing information]. Princeton, NJ: Sandoz; February 2025.
3. Glatiramer acetate subcutaneous injection (20 mg/mL) [prescribing information]. Morgantown, WV: Mylan; February 2025.
4. Glatiramer acetate subcutaneous injection (40 mg/mL) [prescribing information]. Morgantown, WV: Mylan; February 2025.
5. Gilenya® capsules [prescribing information]. East Hanover, NJ: Novartis; August 2025.
6. Aubagio® tablets [prescribing information]. Cambridge, MA: Genzyme/Sanofi; February 2026.
7. Tecfidera® delayed-release capsules [prescribing information]. Cambridge, MA: Biogen; March 2024.
8. Tascenso ODT™ [prescribing information]. Cambridge, UK and San Jose, CA: Cycle/Handa; June 2026.
9. Ponvory® tablets [prescribing information]. Washington, DC: Vanda; October 2024.
10. Mavenclad® tablets [prescribing information]. Rockland, MA: EMD Serono; May 2026.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	10/09/2024
Selected Revision	The name of the Fingolimod Care Value Program was changed to S1P Care Value Program. In addition, the following changes were made: **Ponvory:** Ponvory was added as a Non-Preferred Product to the S1P Care Value Program. Exception criteria were added. **Gilenya (brand):** Regarding the trial of dimethyl fumarate delayed-release tablets, the exception was removed that prior use of glatiramer injection (brand or generic) with inadequate efficacy or significant intolerance (according to the prescriber) also counts [documentation required]. **Tascenso ODT:** Regarding the trial of dimethyl fumarate delayed-release tablets, the exception was removed that prior use of glatiramer injection (brand or generic) with inadequate efficacy or significant intolerance (according to the prescriber) also counts [documentation required].	01/08/2025
Selected Revision	In the S1P Care Value Program, criteria for Ponvory were clarified that a trial of generic dimethyl fumarate delayed-release capsules AND generic fingolimod capsules are required (along with inadequate efficacy or significant intolerance, according to the prescriber). Patients established on Ponvory for ≥ 120 days do not have to meet this requirement. There is not an offer to review for the Preferred Products if criteria are not met.	01/22/2025
Early Annual Revision	**Extavia:** This agent was removed from the policy, as well as the appendix. It is no longer listed as a Non-Preferred Product in the Multiple Sclerosis Care Value Program; the related criteria were also deleted. **Gilenya:** The criteria that allowed exceptions for a patient who has, according to the prescriber, highly active or aggressive multiple sclerosis were deleted. This was defined by meeting one of the following: 1) Patient has demonstrated rapidly advancing deterioration(s) in physical functioning [documentation required] with a Note that examples include loss of mobility, lower levels of ambulation, and/or severe changes in strength or coordination; OR 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] with a note that examples include new, enlarging, or a high burden of T2 lesions or gadolinium enhancing lesions; OR 4) Manifestations of multiple sclerosis related cognitive impairment [documentation required]. **Tascenso ODT:** The criteria that allowed exceptions for a patient who has, according to the prescriber, highly active or aggressive multiple sclerosis were deleted. This was defined by meeting one of the following: 1) Patient has demonstrated rapidly advancing deterioration(s) in physical functioning [documentation required] with a Note that examples include loss of mobility, lower levels of ambulation, and/or severe changes in strength or coordination; OR 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] with a note that examples include new, enlarging, or a high burden of T2 lesions or gadolinium enhancing lesions; OR 4) Manifestations of multiple sclerosis related cognitive impairment [documentation required].	07/23/2025

HISTORY (CONTINUED)

Type of Revision	Summary of Changes	Review Date
Selected Revision	**Policy Statement:** The Policy Statement was updated to reflect the addition of the Mavenclad (Brand) Care Value Program. **Mavenclad (Brand) Care Value Program:** A new Care Value Program was added which directs requests for brand Mavenclad to generic cladribine tablets. Patients are required to meet the standard *Multiple Sclerosis (Oral – Other) – Cladribine Care Value Policy* criteria for brand Mavenclad requests. Additionally, documentation is required that the patient has tried generic cladribine tablets and cannot continue to use generic cladribine 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.	02/25/2026 (effective 05/11/2026)
Selected Revision	**Policy Statement:** The Policy Statement was updated to reflect that throughout all components of the policy, both Preferred and Non-Preferred Products will require that the respective standard *Care Value Policy* criteria be met; previously, only Non-Preferred Products were required to meet the criteria. This change is effective 05/11/2026. **Criteria:** References to standard *Care Value Policies* were updated throughout to reflect the current names of the policies; the requirements of the respective *Care Value Policies* are unchanged. **Mavenclad:** A correction was made to note that the respective *Care Value* policy requirements must be met; previously, this was listed as *Prior Authorization* policy requirements.	04/22/2026 (effective 05/11/2026)
Annual Revision	**Copaxone:** In the existing Note that a trial of Bafiertam, Tecfidera (brand), or Vumerity satisfies the requirement for the trial of generic dimethyl fumarate, it was clarified that documentation is required. **Aubagio:** In the existing Note that a trial of Bafiertam, Tecfidera (brand), or Vumerity satisfies the requirement for the trial of generic dimethyl fumarate, it was clarified that documentation is required. In the existing Note that a trial of Copaxone or Glatopa satisfies the requirement for the trial of generic glatiramer acetate, it was clarified that documentation is required. For the requirement to try generic fingolimod, a Note was added that Gilenya or Tascenso ODT also satisfy the requirement [documentation required].	07/22/2026