MEDICAL MUTUAL®

# Drug Policy

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| **Policy:** | **Multiple Sclerosis Care Value Program** | **Annual Review Date:** **02/20/2025** |
| **Impacted Drugs:** | • Avonex® (interferon beta-1a injection [intramuscular] – Biogen Idec)<br>• Betaseron® (interferon beta-1b injection [subcutaneous] – Bayer)<br>• Extavia® (interferon beta-1b injection [subcutaneous] – Novartis)<br>• Kesimpta (ofatumumab injection [subcutaneous] – Novartis)<br>• Mayzent® (siponimod tablets – Novartis)<br>• Plegridy® (peginterferon beta-1a injection [subcutaneous] – Biogen Idec)<br>• Ponvory® (ponesimod tablets – Janssen)<br>• Rebif® (interferon beta-1a injection, subcutaneous – Serono)<br>• Vumerity® (diroximel fumarate delayed-release capsules – Biogen/Alkermes)<br>• Zeposia® (ozanimod capsules – Celgene) | **Last Revised Date:** **02/20/2025** |

## 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.

## 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 the listed Preferred Product(s) (generic glatiramer injection, generic dimethyl fumarate delayed-release capsules or generic fingolimod capsules) prior to the approval of a Non-Preferred Product. Requests for Non-Preferred Products will also be reviewed using the exception criteria (below). All approvals are provided for 1 year.

The Fumaric Acid Derivatives 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.

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The Sphingosine 1-Phosphate (S1P) Receptor Modulators Care Value Program has been developed to encourage the use of 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.

The Oral Multiple Sclerosis Care Value Program has been developed to encourage the use of the Preferred Products (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 *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 injectable Multiple Sclerosis Care Value Program has been developed to encourage the use of generic glatiramer injection. 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.

**Fumaric Acid Derivatives Care Value Program**

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| **Preferred Product:** | generic dimethyl fumarate delayed-release capsules |
| **Non-Preferred Product:** | Vumerity |

**Sphingosine 1-Phosphate (S1P) Receptor Modulators Care Value Program**

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| **Preferred Products:** | generic fingolimod capsules |
| **Non-Preferred Products Step 2:** | Mayzent, Zeposia |
| **Non-Preferred Products Step 3:** | Ponvory |

**Injectable Multiple Sclerosis Care Value Program**

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| **Preferred Products:** | generic glatiramer injection |
| **Non-Preferred Product:** | Avonex, Betaseron, Extavia, Kesimpta, Plegridy, Rebif |

## RECOMMENDED EXCEPTION CRITERIA

I. **Fumaric Acid Derivatives Care Value Program**

| Non-Preferred Product | Exception Criteria |
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| Vumerity | **1.** Approve for 1 year if the patient meets the following (A and B):<br>**A)** Patient meets the standard *Multiple Sclerosis – Vumerity Prior Authorization Policy* criteria; AND<br>**B)** Patient meets both of the following (a and b):<br>**a)** Patient has tried generic dimethyl fumarate delayed-release capsules; AND<br>**b)** Patient has experienced intolerable gastrointestinal adverse events.<br>Note: Prior use of Tecfidera with intolerable gastrointestinal adverse events also counts. |

## II. Sphingosine 1-Phosphate (S1P) Receptor Modulators Care Value Program

| Non-Preferred Product | Exception Criteria |
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| Mayzent | **1.** Approve for 1 year if the patient meets the following (A and B):<br>**A)** Patient meets the standard *Multiple Sclerosis – Mayzent Prior Authorization Policy* criteria; AND<br>**B)** Patient meets one of the following (i or ii):<br>**i.** Patient has been established on Mayzent for ≥ 120 days; OR<br>**ii.** Patient meets both of the following (a and b):<br>**a)** Patient has tried generic fingolimod capsules; AND<br>**b)** Patient has experienced inadequate efficacy or significant intolerance, according to the prescriber.<br>Note: Prior use of Gilenya with inadequate efficacy or significant intolerance (according to the prescriber) also counts. |
| Ponvory | **1.** Approve for 1 year if the patient meets the following (A and B):<br>**A)** Patient meets the standard Multiple Sclerosis – *Ponvory Prior Authorization Policy* criteria; AND<br>**B)** Patient meets one of the following (i, ii, or iii):<br>**i.** Patient has been established on Ponvory for ≥ 120 days; OR<br>**ii.** Patient meets both of the following (a and b):<br>**a)** Patient has tried generic fingolimod capsules; AND<br>**b)** Patient has experienced inadequate efficacy or significant intolerance, according to the prescriber; OR<br>Note: Prior use of Gilenya with inadequate efficacy or significant intolerance (according to the prescriber) also counts.<br>**iii.** Patient meets both of the following (a and b):<br>**a)** Patient has tried Mayzent or Zeposia; AND<br>**b)** Patient has experienced inadequate efficacy or significant intolerance, according to the prescriber. |

| Non-Preferred Product | Exception Criteria |
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| Zeposia | Refer to the *Multiple Sclerosis and Ulcerative Colitis – Zeposia Care Value Policy* criteria. |

**III. Injectable Multiple Sclerosis Care Value Program**

| Non-Preferred Product | Exception Criteria |
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| Avonex | **1.** Approve for 1 year if the patient meets the following (A and B):<br>**A)** Patient meets the standard *Multiple Sclerosis – Avonex Prior Authorization Policy* criteria; AND<br>**B)** Patient meets one of the following (i or ii):<br>**i.** Patient has been established on Avonex for ≥ 120 days; OR<br>**ii.** Patient meets both of the following (a and b):<br>**a)** Patient has tried generic glatiramer injection; AND<br>**b)** Patient has experienced inadequate efficacy or significant intolerance, according to the prescriber.<br>Note: Prior use of Copaxone or Glatopa with inadequate efficacy or significant intolerance (according to the prescriber) also counts. |
| Betaseron | **1.** Approve for 1 year if the patient meets the following (A and B):<br>**A)** Patient meets the standard *Multiple Sclerosis – Betaseron/Extavia Prior Authorization Policy* criteria; AND<br>**B)** Patient meets one of the following (i or ii):<br>**i.** Patient has been established on Betaseron for ≥ 120 days; OR<br>**ii.** Patient meets both of the following (a and b):<br>1. Patient has tried generic glatiramer injection; AND<br>2. Patient has experienced inadequate efficacy or significant intolerance, according to the prescriber.<br>Note: Prior use of Copaxone or Glatopa with inadequate efficacy or significant intolerance (according to the prescriber) also counts. |
| Extavia | **1.** Approve for 1 year if the patient meets the following (A and B):<br>**A)** Patient meets the standard *Multiple Sclerosis – Betaseron/Extavia Prior Authorization Policy* criteria; AND<br>**B)** Patient meets one of the following (i or ii):<br>**i.** Patient has been established on Extavia for ≥ 120 days; OR<br>**ii.** Patient meets both of the following (a and b):<br>**a)** Patient has tried generic glatiramer injection; AND<br>**b)** Patient has experienced inadequate efficacy or significant intolerance, according to the prescriber.<br>Note: Prior use of Copaxone or Glatopa with inadequate efficacy or significant intolerance (according to the prescriber) also counts. |

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| Kesimpta | **1.** Approve for 1 year if the patient meets the following (A and B):<br>**A)** Patient meets the standard *Multiple Sclerosis – Kesimpta Prior Authorization Policy* criteria; AND<br>**B)** Patient meets one of the following (i or ii):<br>**i.** Patient has been established on Kesimpta for ≥ 120 days; OR<br>**ii.** Patient meets both of the following (a and b):<br>**a)** Patient has tried generic glatiramer injection; AND<br>**b)** Patient has experienced inadequate efficacy or significant intolerance,-according to the prescriber.<br>Note: Prior use of Copaxone or Glatopa with inadequate efficacy or significant intolerance (according to the prescriber) also counts. |
| Plegridy | **1.** Approve for 1 year if the patient meets the following (A and B):<br>**A)** Patient meets the standard *Multiple Sclerosis – Plegridy Prior Authorization Policy* criteria; AND<br>**B)** Patient meets one of the following (i or ii):<br>**i.** Patient has been established on Plegridy for ≥ 120 days; OR<br>**ii.** Patient meets both of the following (a and b):<br>**a)** Patient has tried generic glatiramer injection; AND<br>**b)** Patient has experienced inadequate efficacy or significant intolerance, according to the prescriber.<br>Note: Prior use of Copaxone or Glatopa with inadequate efficacy or significant intolerance (according to the prescriber) also counts. |
| Rebif | **1.** Approve for 1 year if the patient meets the following (A and B):<br>**A)** Patient meets the standard *Multiple Sclerosis – Rebif Prior Authorization Policy* criteria; AND<br>**B)** Patient meets one of the following (i or ii):<br>**i.** Patient has been established on Rebif for ≥ 120 days; OR<br>**ii.** Patient meets both of the following (a and b):<br>**a)** Patient has tried generic glatiramer injection; AND<br>**b)** Patient has experienced inadequate efficacy or significant intolerance, according to the prescriber.<br>Note: Prior use of Copaxone or Glatopa with inadequate efficacy or significant intolerance (according to the prescriber) also counts. |

**Initial Approval/ Extended Approval.**
**A)** *Initial Approval:* 1 year (365 days)
**B)** *Extended Approval:* 1 year (365 days)

## 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.