# PREFERRED SPECIALTY MANAGEMENT (PSM) POLICY

**POLICY:** Multiple Sclerosis (MS) Preferred Specialty Management

**DATE REVIEWED:** 07/17/2019; selected revision 03/25/2020

**DRUGS AFFECTED:**

- Avonex® (interferon beta-1a injection [intramuscular] – Biogen Idec)
- Betaseron® (interferon beta-1b injection [subcutaneous] – Bayer)
- Copaxone® (glatiramer acetate injection [20 mg/mL and 40 mg/mL] – Teva, generics)
- Extavia® (interferon beta-1b injection [subcutaneous] – Novartis)
- Glatopa™ (glatiramer acetate injection 20 mg/mL and 40 mg/mL – Sandoz, generic)
- Plegridy™ (peginterferon beta-1a injection – Biogen Idec)
- Rebif® (interferon beta-1a injection, subcutaneous – Serono)
- Aubagio® (teriflunomide tablets – Genzyme/Sanofi)
- Gilenya™ (fingolimod capsules – Novartis)
- Mavenclad (cladribine tablets – EMD Serono)
- Mayzent® (siponimid tablets – Novartis)
- Tecfidera® (dimethyl fumarate delayed-release capsules – Biogen Idec)
- Vumerity® (diroximel fumarate delayed-release capsules – Biogen/Alkermes)

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## OVERVIEW

Several self-administered disease-modifying injectable products are available for use in multiple sclerosis (MS). This Preferred Specialty Management (PSM) policy involves the use of the following self-administered injectable products used for MS: Avonex, Betaseron, Copaxone (20 mg/mL and 40 mg/mL, generics), Glatopa (20 mg/mL and 40 mg/mL), Extavia, Rebif, and Plegridy.[1-9] The oral disease-modifying agents used for relapsing forms of MS, Vumerity, Tecfidera, Gilenya, Mayzent, Mavenclad, and Aubagio, are also included.[10-15] All products are indicated for use in adults. Of note, Gilenya is the only agent specifically indicated for children ≥ 10 to < 18 years of age for the treatment of relapsing forms of MS.[10] Mayzent has an indication for use in active secondary progressive MS and its pivotal data involved this patient population.[13] Copaxone has very limited data in this patient subset. A practice guideline recommendation regarding disease-modifying agents for adults with MS from the American Academy of Neurology (2018) states Gilenya as one of the agents to consider for patients with MS who have highly active disease. For more information on criteria within a Prior Authorization Policy, refer to the respective policies.[16-26]

## POLICY STATEMENT

This PSM program requires the patient to meet *ESI Standard PA Policy* criteria for Avonex, Betaseron/Extavia, Copaxone/Glatopa, Rebif, Plegridy, Aubagio, Gilenya, Mayzent, Mavenclad, and Tecfidera. Patients are directed to try one Preferred Product (generic glatiramer 20 mg/mL, generic glatiramer 40 mg/mL) prior to approval of a Non-Preferred Product. Some exceptions apply. All approvals are provided for 1 year in duration.

**Automation:** None

**Documentation:** In the *Multiple Sclerosis – Preferred Specialty Management (PSM) Policy*, documentation is required where noted in the criteria as **[documentation required]**. Documentation may include, but is not limited to, chart notes and magnetic resonance imaging (MRI) reports.

**Preferred Product:** generic glatiramer 20 mg/mL, generic glatiramer 40 mg/mL
**Non-Preferred Products:** Copaxone 20 mg/mL, Copaxone 40 mg/mL, Glatopa 20 mg/mL, Glatopa 40 mg/mL, Avonex, Betaseron, Extavia, Rebif, Plegridy, Aubagio, Gilenya, Mayzent, Mavenclad, Tecfidera, **Vumerity.**

**RECOMMENDED EXCEPTION CRITERIA**

| Trade Name | Exception |
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| Avonex | **1.** The patient must meet the following criteria (A and B):<br>**A)** The patient meets the *ESI Standard Multiple Sclerosis – Avonex Prior Authorization Policy* criteria; AND<br>**B)** The patient meets one of the following (i or ii):<br>**i.** The patient has been established on Avonex for ≥ 120 days; OR<br>**ii.** The patient meets both of the criteria below (a and b):<br>**a)** The patient has tried one Preferred Product (generic glatiramer 20 mg/mL or generic glatiramer 40 mg/mL); AND<br>**b)** The patient has had unacceptable toxicity and/or suboptimal efficacy according to the prescriber. (Note: Prior use of Brand Name Copaxone 20 mg/mL, Copaxone 40 mg/mL, Glatopa 20 mg/mL, or Glatopa 40 mg/mL with unacceptable toxicity and/or suboptimal efficacy [according to the prescriber] also counts).<br>**2.** If the patient meets the ESI Standard *Multiple Sclerosis – Avonex Prior Authorization Policy* criteria but does not meet criteria 1.B.i or 1.B.ii, approve the Preferred Product(s). |
| Betaseron | **1.** The patient must meet the following criteria (A and B):<br>**A)** The patient meets the *ESI Standard Multiple Sclerosis – Betaseron/Extavia Prior Authorization Policy* criteria; AND<br>**B)** The patient meets one of the following (i or ii):<br>**i.** The patient has been established on Betaseron for ≥ 120 days; OR<br>**ii.** The patient meets both of the criteria below (a and b):<br>**a)** The patient has tried one Preferred Product (generic glatiramer 20 mg/mL or generic glatiramer 40 mg/mL); AND<br>**b)** The patient has an unacceptable toxicity and/or suboptimal efficacy according to the prescriber. (Note: Prior use of Brand Name Copaxone 20 mg/mL, Copaxone 40 mg/mL, Glatopa 20 mg/mL or Glatopa 40 mg/mL with unacceptable toxicity and/or suboptimal efficacy [according to the prescriber] also counts).<br>**2.** If the patient meets the ESI Standard *Multiple Sclerosis – Betaseron/Extavia Prior Authorization Policy* criteria but does not meet criteria 1.B.i or 1.B.ii, approve the Preferred Product(s). |

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| Trade Name | Exception |
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| Copaxone 20 mg/mL | **1.** The patient must meet the following criteria (A and B):<br>**A)** The patient meets the *ESI Standard Multiple Sclerosis – Copaxone/Glatopa Prior Authorization Policy* criteria; AND<br>**B)** The patient meets both of the following (i and ii):<br>**i.** The patient has tried one Preferred Product (generic glatiramer 20 mg/mL or generic glatiramer 40 mg/mL); AND<br>**ii.** Brand Copaxone 20 mg/mL is being requested 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, has or would result in a significant allergy or serious adverse reaction.<br>**2.** If the patient meets the ESI Standard *Multiple Sclerosis – Glatiramer Prior Authorization Policy* criteria but does not meet criteria 1.B.i or 1.B.ii, approve the Preferred Product(s). |
| Copaxone 40 mg/mL | **1.** The patient must meet the following criteria (A and B):<br>**A)** The patient meets the *ESI Standard Multiple Sclerosis – Copaxone/Glatopa Prior Authorization Policy* criteria; AND<br>**B)** The patient meets both of the following (i and ii):<br>**i.** The patient has tried one Preferred Product (generic glatiramer 20 mg/mL or generic glatiramer 40 mg/mL); AND<br>**ii.** Brand Copaxone 40 mg/mL is being requested 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, has or would result in a significant allergy or serious adverse reaction.<br>**2.** If the patient meets the ESI Standard *Multiple Sclerosis – Glatiramer Prior Authorization Policy* criteria but does not meet criteria 1.B.i or 1.B.ii, approve the Preferred Product(s). |
| Glatopa 20 mg/mL | **1.** The patient must meet the following criteria (A and B):<br>**A)** The patient meets the *ESI Standard Multiple Sclerosis – Copaxone/Glatopa Prior Authorization Policy* criteria; AND<br>**B)** The patient meets both of the following (i and ii):<br>**i.** The patient has tried one Preferred Product (generic glatiramer 20 mg/mL or generic glatiramer 40 mg/mL); AND<br>**ii.** Brand Glatopa 20 mg/mL is being requested 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, has or would result in a significant allergy or serious adverse reaction.<br>**2.** If the patient meets the ESI Standard *Multiple Sclerosis – Glatiramer Prior Authorization Policy* criteria but does not meet criteria 1.B.i or 1.B.ii, approve the Preferred Product(s). |

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| Trade Name | Exception |
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| Glatopa 40 mg/mL | **1.** The patient must meet the following criteria (A and B):<br>**A)** The patient meets the *ESI Standard Multiple Sclerosis – Copaxone/Glatopa Prior Authorization Policy* criteria; AND<br>**B)** The patient meets both of the following (i and ii):<br>**i.** The patient has tried one Preferred Product (generic glatiramer 20 mg/mL or generic glatiramer 40 mg/mL); AND<br>**ii.** Brand Glatopa 40 mg/mL is being requested 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, has or would result in a significant allergy or serious adverse reaction.<br>**2.** If the patient meets the ESI Standard *Multiple Sclerosis – Glatiramer Prior Authorization Policy* criteria but does not meet criteria 1.B.i or 1.B.ii, approve the Preferred Product(s). |
| Extavia | **1.** The patient must meet the following criteria (A and B):<br>**A)** The patient meets the *ESI Standard Multiple Sclerosis – Betaseron/Extavia Prior Authorization Policy* criteria; AND<br>**B)** The patient meets one of the following (i or ii):<br>**i.** The patient has been established on Extavia for ≥ 120 days; OR<br>**ii.** The patient meets both of the criteria below (a and b):<br>**a)** The patient has tried one Preferred Product (generic glatiramer 20 mg/mL or generic glatiramer 40 mg/mL); AND<br>**b)** The patient has had unacceptable toxicity and/or suboptimal efficacy according to the prescribing physician. (Note: Prior use of Brand Name Copaxone 20 mg/mL, Copaxone 40 mg/mL, Glatopa 20 mg/mL, or Glatopa 40 mg/mL with unacceptable toxicity and/or suboptimal efficacy [according to the prescriber] also counts).<br>**2.** If the patient meets the ESI Standard *Multiple Sclerosis – Betaseron/Extavia Prior Authorization Policy* criteria but does not meet criteria 1.B.i or 1.B.ii, approve the Preferred Product(s). |
| Rebif | **1.** The patient must meet the following criteria (A and B):<br>**A)** The patient meets the *ESI Standard Multiple Sclerosis – Rebif PA Policy* criteria; AND<br>**B)** The patient meets one of the following (i or ii):<br>**i.** The patient has been established on Rebif for ≥ 120 days; OR<br>**ii.** The patient meets both of the criteria below (a and b):<br>**a)** The patient has tried one Step 1 product (generic glatiramer 20 mg/mL or generic glatiramer 40 mg/mL); AND<br>**b)** The patient has had unacceptable toxicity and/or suboptimal efficacy according to the prescriber. (Note: Prior use of Brand Name Copaxone 20 mg/mL, Copaxone 40 mg/mL, Glatopa 20 mg/mL, or Glatopa 40 mg/mL with unacceptable toxicity and/or suboptimal efficacy [according to the prescriber] also counts).<br>**2.** If the patient meets the ESI Standard *Multiple Sclerosis – Rebif Prior Authorization Policy* criteria but does not meet criteria 1.B.i or 1.B.ii, approve the Preferred Product(s). |

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| Trade Name | Exception |
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| Plegridy | **1.** The patient must meet the following criteria (A and B):<br>**A)** The patient meets the *ESI Standard Multiple Sclerosis – Plegridy Prior Authorization Policy* criteria; AND<br>**B)** The patient meets one of the following (i or ii):<br>**i.** The patient has been established on Plegridy for ≥ 120 days; OR<br>**ii.** The patient meets both of the criteria below (a and b):<br>**a)** The patient has tried one Preferred Product (generic glatiramer 20 mg/mL or generic glatiramer 40 mg/mL); AND<br>**b)** The patient has had unacceptable toxicity and/or suboptimal efficacy according to the prescriber. (Note: Prior use of Brand Name Copaxone 20 mg/mL, Copaxone 40 mg/mL, Glatopa 20 mg/mL, or Glatopa 40 mg/mL with unacceptable toxicity and/or suboptimal efficacy [according to the prescriber] also counts).<br>**2.** If the patient meets the ESI Standard *Multiple Sclerosis – Plegridy Prior Authorization Policy* criteria but does not meet criteria 1.B.i or 1.B.ii, approve the Preferred Product(s). |
| Aubagio | **1.** The patient must meet the following criteria (A and B):<br>**A)** The patient meets the *ESI Standard Multiple Sclerosis – Aubagio Prior Authorization Policy* criteria; AND<br>**B)** The patient meets one of the following (i or ii):<br>**i.** The patient has been established on Aubagio for ≥ 120 days; OR<br>**ii.** The patient meets both of the following (a and b):<br>**a)** The patient has tried one Preferred Product (generic glatiramer 20 mg/mL or generic glatiramer 40 mg/mL); AND<br>**b)** The patient has had unacceptable toxicity and/or suboptimal efficacy according to the prescriber. (Note: Prior use of Brand Name Copaxone 20 mg/mL, Copaxone 40 mg/mL, Glatopa 20 mg/mL, or Glatopa 40 mg/mL with unacceptable toxicity and/or suboptimal efficacy [according to the prescriber] also counts).<br>**2.** If the patient meets the ESI Standard *Multiple Sclerosis – Aubagio Prior Authorization Policy* criteria but does not meet criteria 1.B.i or 1.B.ii, approve the Preferred Product(s). |

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| Trade Name | Exception |
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| Gilenya | **1.** The patient must meet the following criteria (A and B):<br>**A)** The patient meets the *ESI Standard Multiple Sclerosis – Gilenya Prior AuthorizationPolicy* criteria; AND<br>**B)** The patient meets one of the following (i, ii, iii, or iv):<br>**i.** The patient has been established on Gilenya for ≥ 120 days; OR<br>**ii.** The patient is a child ≥ 10 to < 18 years of age; OR<br>**iii.** According to the prescriber the patient has highly-active or aggressive multiple sclerosis by meeting one of the following (a, b, c, or d):<br>**a)** The patient has demonstrated rapidly-advancing deterioration(s) in physical functioning (e.g., loss of mobility/or lower levels of ambulation, severe changes in strength or coordination) **[documentation required]**; OR<br>**b)** Disabling relapse(s) with suboptimal response to systemic corticosteroids **[documentation required]**; OR<br>**c)** Magnetic resonance imaging [MRI] findings suggest highly-active or aggressive multiple sclerosis (e.g., new, enlarging, or a high burden of T2 lesions or gadolinium-enhancing lesions) **[documentation required]**; OR<br>**d)** Manifestations of multiple sclerosis-related cognitive impairment **[documentation required]**; OR<br>**iv.** The patient meets both of the following (a and b):<br>**a)** The patient has tried one Preferred Product (generic glatiramer 20 mg/mL or generic glatiramer 40 mg/mL); AND<br>**b)** The patient has had unacceptable toxicity and/or suboptimal efficacy according to the prescriber. (Note: Prior use of Brand Name Copaxone 20 mg/mL, Copaxone 40 mg/mL, Glatopa 20 mg/mL, or Glatopa 40 mg/mL with unacceptable toxicity and/or suboptimal efficacy [according to the prescriber] also counts).<br>**2.** If the patient meets the ESI Standard *Multiple Sclerosis – Gilenya Prior Authorization Policy* criteria but does not meet criteria 1.B.i, 1.B.ii, 1.B.iii, or 1.B.iv, approve the Preferred Product(s). |
| Mavenclad | **1.** The patient must meet the following criteria (A and B):<br>**A)** The patient meets the *ESI Standard Multiple Sclerosis – Mavenclad Prior Authorization Policy* criteria; AND<br>**B)** The patient meets one of the following (i or ii):<br>**i.** The patient has been established on Mavenclad for ≥ 120 days; OR<br>**ii.** The patient meets both of the following (a and b):<br>**a)** The patient has tried one Preferred Product (generic glatiramer 20 mg/mL or generic glatiramer 40 mg/mL); AND<br>**b)** The patient has had unacceptable toxicity and/or suboptimal efficacy according to the prescriber. (Note: Prior use of Brand Name Copaxone 20 mg/mL, Copaxone 40 mg/mL, Glatopa 20 mg/mL, or Glatopa 40 mg/mL with unacceptable toxicity and/or suboptimal efficacy [according to the prescriber] also counts).<br>**2.** If the patient meets the ESI Standard *Multiple Sclerosis – Mavenclad Prior Authorization Policy* criteria but does not meet criteria 1.B.i or 1.B.ii, approve the Preferred Product(s). |

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| Trade Name | Exception |
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| Mayzent | **1.** The patient must meet the following criteria (A and B):<br>**A)** The patient meets the *ESI Standard Multiple Sclerosis – Mayzent Prior Authorization Policy* criteria; AND<br>**B)** The patient meets one of the following (i or ii):<br>**i.** The patient has been established on Mayzent for ≥ 120 days; OR<br>**ii.** The patient meets one of the following (a or b):<br>**a)** The patient has active secondary progressive multiple sclerosis; OR<br>**b)** The patient meet both of the following criteria (1 and 2):<br>**1.** The patient has tried one Preferred Product (generic glatiramer 20 mg/mL or generic glatiramer 40 mg/mL); AND<br>**2.** The patient has had unacceptable toxicity and/or suboptimal efficacy according to the prescriber. (Note: Prior use of Brand Name Copaxone 20 mg/mL, Copaxone 40 mg/mL, Glatopa 20 mg/mL, or Glatopa 40 mg/mL with unacceptable toxicity and/or suboptimal efficacy [according to the prescriber] also counts).<br>**2.** If the patient meets the ESI Standard *Multiple Sclerosis – Mayzent Prior Authorization Policy* criteria but does not meet criteria 1.B.i or 1.B.ii, approve the Preferred Product(s). |
| Tecfidera | **1.** The patient must meet the following criteria (A and B):<br>**A)** The patient meets the *ESI Standard Multiple Sclerosis – Tecfidera Prior Authorization Policy* criteria; AND<br>**B)** The patient meets one of the following (i or ii):<br>**i.** The patient has been established on Tecfidera for ≥ 120 days; OR<br>**ii.** The patient meets both of the following (a and b):<br>**a)** The patient has tried one Preferred Product (generic glatiramer 20 mg/mL or generic glatiramer 40 mg/mL); AND<br>**b)** The patient has had unacceptable toxicity and/or suboptimal efficacy according to the prescriber. (Note: Prior use of Brand Name Copaxone 20 mg/mL, Copaxone 40 mg/mL, Glatopa 20 mg/mL, or Glatopa 40 mg/mL with unacceptable toxicity and/or suboptimal efficacy [according to the prescriber] also counts).<br>**2.** If the patient meets the ESI Standard *Multiple Sclerosis – Tecfidera Prior Authorization Policy* criteria but does not meet criteria 1.B.i or 1.B.ii, approve the Preferred Product(s). |

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| Trade Name | Exception |
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| Vumerity | **1.** The patient must meet the following criteria (A and B):<br>**A)** The patient meets the *ESI Standard Multiple Sclerosis – Vumerity Prior Authorization Policy* criteria; AND<br>**B)** The patient meets one of the following (i or ii):<br>**i.** The patient has been established on Vumerity for ≥ 120 days; OR<br>**ii.** The patient meets both of the following (a and b):<br>**a)** The patient has tried one Preferred Product (generic glatiramer 20 mg/mL or generic glatiramer 40 mg/mL); AND<br>**b)** The patient has had unacceptable toxicity and/or suboptimal efficacy according to the prescriber. (Note: Prior use of Brand Name Copaxone 20 mg/mL, Copaxone 40 mg/mL, Glatopa 20 mg/mL, or Glatopa 40 mg/mL with unacceptable toxicity and/or suboptimal efficacy [according to the prescriber] also counts).<br>**2.** If the patient meets the ESI Standard *Multiple Sclerosis – Vumerity Prior Authorization Policy* criteria but does not meet criteria 1.B.i or 1.B.ii, approve the Preferred Product(s). |

**REFERENCES**

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4. Extavia® injection for subcutaneous use [prescribing information]. East Hanover, NJ: Novartis; December 2018.
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24. *Mavenclad Prior Authorization Policy*. Express Scripts Holding Company. Updated 07/17/2019.
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