VENTURA COUNTY
HEALTH CARE PLAN

CARE VALUE POLICY

POLICY: Multiple Sclerosis Care Value Policy

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® (siponimod tablets – Novartis)
- Tecfidera® (dimethyl fumarate delayed-release capsules – Biogen)
- Vumerity® (diroximel fumarate delayed-release capsules – Biogen/Alkermes)

OVERVIEW

Several self-administered disease-modifying injectable products are available for use in multiple sclerosis (MS). This Care policy involves the use of the following self-administered injectable products indicated for MS: Avonex, Betaseron, Copaxone (20 mg/mL and 40 mg/mL, generics), Extavia, Glatopa (20 mg/mL and 40 mg/mL), Plegridy and Rebif.[1-9] The oral disease-modifying agents used for relapsing forms of MS, Aubagio, Gilenya, Mavenclad, Mayzent, Tecfidera, and Vumerity are also included.[10-14] 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 (PA) Policy refer to the respective policies.[16-26]

POLICY STATEMENT

This Care Value program requires the patient to meet the respective *ESI Standard Prior Authorization Policy* criteria. Patients are directed to try one Preferred Product (generic glatiramer 20 mg/mL or generic glatiramer 40 mg/mL) prior to approval of a Non-Preferred Product. All approvals for are provided for 1 year in duration. Of note, only Non-Preferred Drugs are required to undergo prior authorization.

Automation: None.

Documentation: In the *Multiple Sclerosis – Care Value Policy*, documentation is required for initiation of therapy 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: Avonex, Betaseron, Copaxone 20 mg/mL, Copaxone 40 mg/mL, Extavia, Glatopa 20 mg/mL, Glatopa 40 mg/mL, Plegridy, Rebif, Aubagio, Gilenya, Mayzent, Mavenclad, Tecfidera, Vumerity.

RECOMMENDED EXCEPTION CRITERIA

Trade Name	Exception
Avonex	**1.** The patient must meet the following criteria (A and B): **A)** The patient meets the *ESI Standard Multiple Sclerosis – Avonex Prior Authorization Policy* criteria; AND **B)** The patient meets one of the following (i or ii): **i.** The patient has been established on Avonex for ≥ 120 days; OR **ii.** The patient meets both of the following (a and b): **a)** The patient has tried one Preferred Product (generic glatiramer 20 mg/mL or generic glatiramer 40 mg/mL); AND **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). **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).
Aubagio	**1.** The patient must meet the following criteria (A and B): **A)** The patient meets the *ESI Standard Multiple Sclerosis – Aubagio Prior Authorization Policy* criteria; AND **B)** The patient meets one of the following (i or ii) **i.** The patient has been established on Aubagio for ≥ 120 days; OR **ii.** The patient meets both of the following (a and b): **a)** The patient has tried one Preferred Product (generic glatiramer 20 mg/mL or generic glatiramer 40 mg/mL); AND **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). **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).

Trade Name	Exception
Betaseron	**1.** The patient must meet the following criteria (A and B): **A)** The patient meets the *ESI Standard Multiple Sclerosis – Betaseron/Extavia Prior Authorization Policy* criteria; AND **B)** The patient meets one of the following (i or ii): **i.** The patient has been established on Betaseron for ≥ 120 days; OR **ii.** The patient meets both of the criteria (a and b): **a)** The patient has tried one Preferred Product (generic glatiramer 20 mg/mL or generic glatiramer 40 mg/mL); AND **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). **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).
Copaxone 20 mg/mL	**1.** The patient must meet the following criteria (A and B): **A)** The patient meets the *ESI Standard Multiple Sclerosis – Copaxone/Glatopa PA Policy* criteria; AND **B)** The patient meets both of the following (i and ii): **i.** The patient has tried one Preferred Product (generic glatiramer 20 mg/mL or generic glatiramer 40 mg/mL); AND **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 prescribing physician, has or would result in a significant allergy or serious adverse reaction. **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): **A)** The patient meets the *ESI Standard Multiple Sclerosis – Copaxone/Glatopa PA Policy* criteria; AND **B)** The patient meets both of the following (i and ii): **i.** The patient has tried one Preferred Product (generic glatiramer 20 mg/mL or generic glatiramer 40 mg/mL); AND **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. **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).

Trade Name	Exception
Extavia	**1.** The patient must meet the following criteria (A and B): **A)** The patient meets the *ESI Standard Multiple Sclerosis – Betaseron/Extavia Prior Authorization Policy* criteria; AND **B)** The patient meets one of the following (i or ii) **i.** The patient has been established on Extavia for ≥ 120 days; OR **ii.** The patient meets both of the following (a and b): **a)** The patient has tried one Preferred Product (generic glatiramer 20 mg/mL or generic glatiramer 40 mg/mL); AND **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). **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).
Gilenya	**1.** The patient must meet the following criteria (A and B): **A)** The patient meets the *ESI Standard Multiple Sclerosis – Gilenya Care Value Policy* criteria; AND **B)** The patient meets one of the following (i, ii, iii or iv): **i.** The patient has been established on Gilenya for ≥ 120 days; OR **ii.** The patient is a child ≥ 10 to < 18 years of age; OR **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): **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 **b)** Disabling relapse(s) with suboptimal response to systemic corticosteroids **[documentation required]**; OR **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 **d)** Manifestations of multiple sclerosis-related cognitive impairment **[documentation required]**; OR **iv.** The patient meets both of the following (a and b): **a)** The patient has tried one Preferred Product (generic glatiramer 20 mg/mL or generic glatiramer 40 mg/mL); AND **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). **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 I.B.iv, approve the Preferred Product(s).

Trade Name	Exception
Glatopa 20 mg/mL	**1.** The patient must meet the following criteria (A and B): **A)** The patient meets the *ESI Standard Multiple Sclerosis – Copaxone/Glatopa PA Policy* criteria; AND **B)** The patient meets both of the following (i and ii): **i.** The patient has tried one Preferred Product (generic glatiramer 20 mg/mL or generic glatiramer 40 mg/mL); AND **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. **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 40 mg/mL	**1.** The patient must meet the following criteria (A and B): **A)** The patient meets the *ESI Standard Multiple Sclerosis – Copaxone/Glatopa PA Policy* criteria; AND **B)** The patient meets both of the following (i and ii): **i.** The patient has tried one Preferred Product (generic glatiramer 20 mg/mL or generic glatiramer 40 mg/mL); AND **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. **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).
Mayzent	**1.** The patient must meet the following criteria (A and B): **A)** The patient meets the *ESI Standard Multiple Sclerosis – Mayzent Prior Authorization Policy* criteria; AND **B)** The patient meets one of the following (i or ii): **i.** The patient has been established on Mayzent for ≥ 120 days; OR **ii.** The patient meets one of the following (a or b): **a)** The patient has active secondary progressive multiple sclerosis; OR **b)** The patient meet both of the following criteria (1 and 2): **1.** The patient has tried one Preferred Product product (generic glatiramer 20 mg/mL or generic glatiramer 40 mg/mL); AND **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). **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).

Trade Name	Exception
Mavenclad	**1.** The patient must meet the following criteria (A and B): **A)** The patient meets the *ESI Standard Multiple Sclerosis – Mavenclad Prior Authorization Policy* criteria; AND **B)** The patient meets one of the following (i or ii): **i.** The patient has been established on Mavenclad for ≥ 120 days; OR **ii.** The patient meets both of the following (a and b): **a)** The patient has tried one Preferred Product (generic glatiramer 20 mg/mL or generic glatiramer 40 mg/mL); AND **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). **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).
Plegridy	**1.** The patient must meet the following criteria (A and B): **A)** The patient meets the *ESI Standard Multiple Sclerosis – Plegridy Prior Authorization Policy* criteria; AND **B)** The patient meets one of the following (i or ii): **i.** The patient has been established on Plegridy for ≥ 120 days; OR **ii.** The patient meets both of the criteria below (a and b): **a)** The patient has tried one Preferred Product (generic glatiramer 20 mg/mL or generic glatiramer 40 mg/mL); AND **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 physician] also counts). **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).
Rebif	**1.** The patient must meet the following criteria (A and B): **A)** The patient meets the *ESI Standard Multiple Sclerosis – Rebif Prior Authorization Policy* criteria; AND **B)** The patient meets one of the following (i or ii): **i.** The patient has been established on Rebif for ≥ 120 days; OR **ii.** The patient meets both of the criteria below (a and b): **a)** The patient has tried one Preferred Product (generic glatiramer 20 mg/mL or generic glatiramer 40 mg/mL); AND **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). **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).

Trade Name	Exception
Tecfidera	**1.** The patient must meet the following criteria (A and B): **A)** The patient meets the *ESI Standard Multiple Sclerosis – Tecfidera Prior Authorization Policy* criteria; AND **B)** The patient meets one of the following (i or ii): **i.** The patient has been established on Tecfidera for ≥ 120 days; OR **ii.** The patient meet both of the following (a and b): **a)** The patient has tried one Preferred Product (generic glatiramer 20 mg/mL or generic glatiramer 40 mg/mL); AND **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). **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).
Vumerity	**1.** The patient must meet the following criteria (A and B): **A)** The patient meets the *ESI Standard Multiple Sclerosis – Vumerity Prior Authorization Policy* criteria; AND **B)** The patient meets one of the following (i or ii): **i.** The patient has been established on Vumerity for ≥ 120 days; OR **ii.** The patient meets both of the following (a and b): **a)** The patient has tried one Preferred Product (generic glatiramer 20 mg/mL or generic glatiramer 40 mg/mL); AND **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). **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

1. Avonex® intramuscular injection [prescribing information]. Cambridge, MA: Biogen, Inc.; July 2019.
2. Betaseron® injection for subcutaneous use [prescribing information]. Whippany, NJ: Bayer HealthCare Pharmaceuticals; August 2018.
3. Copaxone® injection for subcutaneous use [prescribing information]. Overland Park, KS and North Wales, PA Teva Neuroscience/Pharmaceuticals, Inc.; September 2018.
4. Extavia® injection for subcutaneous use [prescribing information]. East Hanover, NJ: Novartis; December 2018.
5. Glatiramer acetate injection 20 mg/mL [prescribing information]. Morgantown, WV: Mylan Pharmaceuticals; November 2018.
6. Glatiramer acetate injection 40 mg/mL [prescribing information]. Morgantown, WV: Mylan Pharmaceuticals; November 2018.
7. Glatopa™ injection for subcutaneous use [prescribing information]. Princeton, NJ: Sandoz; October 2018.
8. Rebif® subcutaneous injection [prescribing information]. Rockland, MA: EMD Serono, Inc; July 2019.
9. Plegridy™ subcutaneous injection [prescribing information]. Cambridge, MA: Biogen Idec, Inc.; July 2019.
10. Gilenya™ capsules [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; January 2019.
11. Aubagio® tablets [prescribing information]. Cambridge, MA: Genzyme Corporation (a Sanofi company); March 2019.
12. Mavenclad® tablets [prescribing information]. Rockland, MA: END Serono; March 2019.

13. Mayzent™ tablets [prescribing information]. East Hanover, NJ: Novartis; March 2019.
14. Tecfidera® delayed-release capsules [prescribing information]. Cambridge, MA: Biogen Idec, Inc; July 2019.
15. Vumerity® delayed-release capsules [prescribing information]. Cambridge, MA and Waltham, MA: Biogen and Alkermes; October 2019.
16. *Avonex Prior Authorization Policy*. Express Scripts Holding Company. Updated 07/17/2019.
17. *Betaseron/Extavia Prior Authorization Policy*. Express Scripts Holding Company. Updated 07/17/2019.
18. *Glatiramer Products Prior Authorization Policy*. Express Scripts Holding Company. Updated 07/17/2019.
19. *Plegridy Prior Authorization Policy*. Express Scripts Holding Company. Updated 07/17/2019.
20. *Rebif Prior Authorization Policy*. Express Scripts Holding Company. Updated 07/17/2019.
21. *Aubagio Prior Authorization Policy*. Express Scripts Holding Company. Updated 07/17/2019.
22. *Gilenya Prior Authorization Policy*. Express Scripts Holding Company. Updated 07/17/2019.
23. *Mayzent Prior Authorization Policy*. Express Scripts Holding Company. Updated 07/17/2019.
24. *Mavenclad Prior Authorization Policy*. Express Scripts Holding Company. Updated 07/17/2019.
25. *Tecfidera Prior Authorization Policy*. Express Scripts Holding Company. Updated 07/17/2019.
26. *Vumerity Prior Authorization Policy*. Express Scripts Holding Company. Updated 11/06/2019.

HISTORY

Type of Revision	Summary of Changes	Date Reviewed
Selected revision	Added Glatopa 40 mg/mL to the criteria are appropriate.	02/21/2018
Selected revision.	Added criteria which permits exceptions for Gilenya for use if the patient is a child aged ≥ 10 to < 18 years of age.	05/23/2018
Annual revision	Exception criteria were added for Gilenya to approve Gilenya if, according to the prescribing physician, the patient has highly-active or aggressive MS and that one of the following conditions is net, along with corresponding documentation requirements: 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); disabling relapse(s) with suboptimal response to systemic corticosteroids; magnetic resonance imaging findings suggest highly-active or aggressive MS (e.g., new, enlarging, or a high burden of T2 lesions or gadolinium-enhancing lesions); OR manifestations of MS-related cognitive impairment.	10/31/2018
Annual revision	Extavia was added to the program (effective 1/1/2019) and placed in Step 2 with related criteria added.	10/31/2018
Selected revision	Mayzent and Mavenclad were added as Non-Preferred products. As such, exception criteria were added for Mayzent and Mavenclad that are similar to those for the other oral multiple sclerosis medications (e.g., Tecfidera, Aubagio). For Mayzent, an additional exception was added for patients with secondary progressive multiple sclerosis. There were no other changes to the criteria.	06/12/2019
Early annual revision	The following medications were added to the rule as Non-Preferred Products. Copaxone 20 mg/mL, Copaxone 40 mg/mL, Glatopa 20 mg/mL, Avonex, Betaseron, Rebif, and Plegridy. New criteria were developed. Also, Step 1 and Step 2 agents are now referred to as "Preferred Products" and "Non-Preferred Products", respectively. It was clarified that only Non-Preferred Products are required to undergo prior authorization. The following criteria changes were made: **1. Mayzent:** The descriptor "active" was added to the diagnosis of secondary progressive MS. **2. All Non-Preferred Products:** Criteria that had the wording "according to the prescribing prescribing physician" were changed to state "according to the prescriber". For Mayzent, the criteria that allows exceptions if the patient has secondary progressive multiple sclerosis had "active" added as a descriptor.	07/17/2019 (Effective 8/9/2019)
Selected revision	The following changes were made: **1.** Criteria were added to allow auto-approvals if the patient has met the Prior Authorization Policy criteria for the respective requested Non-Preferred Product. **2.** Vumerity was added as a Non-Preferred Product. Patients must meet the following criteria (A and B): **A)** The patient meets the *ESI Standard Multiple Sclerosis – Vumerity Prior Authorization Policy* criteria; AND **B)** The patient meets one of the following (i or ii): **i.** The patient has been established on Vumerity for ≥ 120 days; OR **ii.** The patient meets both of the following (a and b): **a)** The patient has tried one Preferred Product (generic glatiramer 20 mg/mL or generic glatiramer 40 mg/mL); AND **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).	03/25/2020

MS – Multiple sclerosis.