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POLICY Document for BRIUMVI

The overall objective of this policy is to support the appropriate and cost-effective use of the medication, specific to use of preferred medication options, lower cost site of care and overall, clinically appropriate use. This document provides specific information to each of the three sections of the overall policy.

Section 1: Site of Care

- Policy information specific to site of care (outpatient, hospital outpatient, home infusion)

Section 2: Clinical Criteria

- Policy information specific to the clinical appropriateness for the medication

Section 1: Site of Care

Site of Care Criteria
Briumvi

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated.

Brand Name	Generic Name	Dosage Form
Briumvi	ublituximab-xiiy	intravenous

Criteria For Approval For Administration In Outpatient Hospital Setting

This policy provides coverage for administration of Briumvi in an outpatient hospital setting for up to 45 days when a member is new to therapy or is reinitiating therapy after not being on therapy for at least 7 months.

This policy provides coverage for administration of Briumvi in an outpatient hospital setting for a longer course of treatment when ANY of the following criteria are met:

- The member has experienced an adverse reaction that did not respond to conventional interventions (e.g., acetaminophen, steroids, diphenhydramine, fluids, other pre-

medications medications or slowing of infusion rate) or a severe adverse event (anaphylaxis, anaphylactoid reactions, myocardial infarction, thromboembolism, or seizures) during or immediately after an infusion.

- The member is medically unstable (e.g. respiratory, cardiovascular, or renal conditions).
- The member has severe venous access issues that require the use of a special interventions only available in the outpatient hospital setting.
- The member has significant behavioral issues and/or physical or cognitive impairment that would impact the safety of the infusion therapy AND the patient does not have access to a caregiver.
- Alternative infusion sites (pharmacy, physician office, ambulatory care, etc.) are greater than 30 miles from the member's home
- The member is less than 14 years of age.

For situations where administration of the Briumvi does not meet the criteria for outpatient hospital infusion, coverage for the Briumvi is provided when administered in alternative sites such as; physician office, home infusion or ambulatory care.

Required Documentation

The following information is necessary to initiate the site of care prior authorization review (where applicable):

- Medical records supporting the member has experienced an adverse reaction that did not respond to conventional interventions or a severe adverse event during or immediately after an infusion
- Medical records supporting the member is medically unstable
- Medical records supporting the member has severe venous access issues that require specialized interventions only available in the outpatient hospital setting
- Medical records supporting the member has behavioral issues and/or physical or cognitive impairment and no access to a caregive
- Records supporting alternative infusion sites are greater than 30 miles from the member's home
- Medical records supporting the member is new to therapy

Section 2: Clinical Criteria

Specialty Guideline Management Multiple Sclerosis Products

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Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Aubagio	teriflunomide
Avonex	interferon beta-1a
Bafiertam	monomethyl fumarate
Betaseron	interferon beta-1a
Briumvi	ublituximab-xiiy
Copaxone	glatiramer acetate
Extavia	interferon beta-1b
Gilenya	fingolimod hydrochloride
Glatopa	glatiramer acetate
Kesimpta	ofatumumab
Mayzent	siponimod
Ocrevus	ocrelizumab
Ocrevus Zunovo	ocrelizumab and hyaluronidase-ocsq
Plegridy	peginterferon beta-1a
Ponvory	ponesimod
Rebif	interferon beta-1a
Tascenso ODT	fingolimod lauryl sulfate
Tecfidera	dimethyl fumarate
Vumerity	diroximel fumarate

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications[1-24]

Aubagio, Avonex, Bafiertam, Betaseron, Briumvi, Copaxone, dimethyl fumarate, Extavia, glatiramer, Glatopa, Kesimpta, Mayzent, Plegridy, Ponvory, Rebif, Tecfidera, teriflunomide, and Vumerity are

indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

Gilenya, Tascenso ODT, and fingolimod are indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in patients 10 years of age and older.

Ocrevus and Ocrevus Zunovo are indicated for:

- Treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.
- Treatment of primary progressive MS, in adults.

All other indications are considered experimental/investigational and not medically necessary.

Prescriber Specialties

This medication must be prescribed by or in consultation with a neurologist.

Coverage Criteria

Relapsing Forms of Multiple Sclerosis (MS)[1-25]

Authorization of 12 months may be granted to members who have been diagnosed with a relapsing form of multiple sclerosis (including relapsing-remitting and secondary progressive disease for those who continue to experience relapse).

Clinically Isolated Syndrome[1-25]

Authorization of 12 months may be granted to members for the treatment of clinically isolated syndrome of multiple sclerosis.

Primary Progressive MS (Ocrevus and Ocrevus Zunovo only)[16-17,25]

Authorization of 12 months may be granted to members for treatment of primary progressive multiple sclerosis.

Continuation of Therapy

For all indications: Authorization of 12 months may be granted for all members (including new members) who achieve or maintain a positive clinical response as evidenced by experiencing disease stability or improvement while receiving the requested medication.

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Other Criteria[26-28]

Members will not use the requested medication concomitantly with other disease modifying multiple sclerosis agents (Note: Ampyra and Nuedexta are not disease modifying).

For all products FDA-approved in adults only: Authorization may be granted for pediatric members less than 18 years of age when benefits outweigh risks.

REFERENCES

SECTION 1

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SECTION 2

1. Aubagio [package insert]. Cambridge, MA: Genzyme Corporation; June 2024.
2. Avonex [package insert]. Cambridge, MA: Biogen Inc.; July 2023.
3. Bafiertam [package insert]. High Point, NC: Banner Life Sciences LLC; June 2025.
4. Betaseron [package insert]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; September 2025.
5. Briumvi [package insert]. Morrisville, NC: TG Therapeutics, Inc.; August 2025.
6. Copaxone [package insert]. Parsippany, NJ: Teva Neuroscience, Inc.; January 2025.
7. Dalfampridine [package insert]. Raleigh, NC; Accord Healthcare, Inc.; October 2023.
8. Dimethyl fumarate [package insert]. Bridgewater, NJ; Amneal Pharmaceuticals LLC; May 2025.
9. Extavia [package insert]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; July 2023.
10. Fingolimod [package insert]. Weston, FL; Apotex Corp.; September 2025.
11. Gilenya [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; August 2025.
12. Glatiramer [package insert]. Cranbury, NJ; Sun Pharmaceutical Industries, Inc.; August 2025.
13. Glatopa [package insert]. Princeton, NJ: Sandoz Inc.; February 2025.
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16. Ocrevus [package insert]. South San Francisco, CA: Genentech, Inc.; August 2025.
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18. Plegridy [package insert]. Cambridge, MA: Biogen Inc.; July 2023.
19. Ponvory [package insert]. Washington, D.C.: Vanda Pharmaceuticals, Inc.; October 2024.
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21. Tascenso ODT [package insert]. Swindon, UK: Catalent Pharma Solutions; January 2025.
22. Tecfidera [package insert]. Cambridge, MA: Biogen Inc.; March 2024.
23. Teriflunomide [package insert]. East Windsor, NJ; Aurobindo Pharma USA, Inc.; October 2024.
24. Vumerity [package insert]. Cambridge, MA: Biogen Inc.; September 2024.
25. Rae-Grant A, Day G, Marrie R, et al. Practice guideline recommendations summary: Disease-modifying therapies for adults with multiple sclerosis. Neurology. 2018;90(17)777-788.
26. Walsh R, Chitnis T. Therapeutic Advances in Pediatric Multiple Sclerosis. Children. 2025;12(3):259.

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28. Pediatric MS. National Multiple Sclerosis Society. Updated March 2023. Accessed August 22, 2025. https://www.nationalmssociety.org/for-professionals/for-healthcare-professionals/managing-and-treating-ms/pediatric-ms.