UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Multiple Sclerosis (Injectable – CD20-Directed Cytolytic Antibody) – Briumvi Utilization Management Medical Policy
- Briumvi® (ublituximab-xiiy intravenous infusion – TG Therapeutics)

REVIEW DATE: 07/22/2026

OVERVIEW

Briumvi, a CD20-directed cytolytic antibody, is 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.[1]

Guidelines

Briumvi is not addressed in guidelines. In September 2019, a consensus paper was updated by the MS Coalition that discusses the use of disease-modifying therapies in MS.[2] Many options from various disease classes, involving different mechanisms of action and modes of administration, have shown benefits in patients with MS. In addition, practice guidelines for disease-modifying therapies for adults with MS were published by the American Academy of Neurology in 2018.[3] It is noted that many disease-modifying therapies are available and have demonstrated efficacy for the prevention of clinical relapses and new magnetic resonance imaging (MRI)-detected lesions. A lack of response is difficult to define, as most patients with MS are not free of all disease activity. It is recommended that clinicians evaluate various factors, such as clinical relapses, new MRI-detected lesions, or increased disability on examination, over a 1-year period of using a disease-modifying therapy.

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Briumvi. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indication. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Briumvi as well as the monitoring required for adverse events and long-term efficacy, approval requires Briumvi to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Briumvi is recommended in those who meet the following criteria:

FDA-Approved Indication

---

1. **Multiple Sclerosis, Relapsing Forms.** Approve for 1 year if the patient meets ONE of the following (A or B):
   - **A)** Initial Therapy. Approve if the patient meets ALL of the following (i, ii, and iii):
     - **i.** Patient is ≥ 18 years of age; AND
     - **ii.** Patient has a relapsing form of multiple sclerosis; AND

© 2026. All Rights Reserved.
This document is confidential and proprietary. Unauthorized use and distribution are prohibited.

Note: Examples of relapsing forms of multiple sclerosis include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease.

iii. The medication is prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of multiple sclerosis; OR

B) Patient is Currently Receiving Briumvi for ≥ 1 Year. Approve if the patient meets ALL of the following (i, ii, iii, and iv):
Note: A patient who has received < 1 year of therapy or who is restarting therapy with Briumvi should be considered under criterion 1A (Multiple Sclerosis [Relapsing Forms], Initial Therapy).

i. Patient is ≥ 18 years of age; AND

ii. Patient has a relapsing form of multiple sclerosis; AND
Note: Examples of relapsing forms of multiple sclerosis include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease.

iii. Patient meets ONE of the following (a or b):

a) Patient experienced a beneficial clinical response when assessed by at least one objective measure; OR
Note: Examples include stabilization or reduced worsening in disease activity as evaluated by magnetic resonance imaging (MRI) [absence or a decrease in gadolinium enhancing lesions, decrease in the number of new or enlarging T2 lesions]; stabilization or reduced worsening on the Expanded Disability Status Scale (EDSS) score; achievement in criteria for No Evidence of Disease Activity-3 (NEDA-3) or NEDA-4; improvement on the fatigue symptom and impact questionnaire-relapsing multiple sclerosis (FSIQ-RMS) scale; reduction or absence of relapses; improvement or maintenance on the six-minute walk test or 12-Item Multiple Sclerosis Walking Scale; improvement on the Multiple Sclerosis Functional Composite (MSFC) score; and/or attenuation of brain volume loss.

b) Patient experienced stabilization, slowed progression, or improvement in at least one symptom such as motor function, fatigue, vision, bowel/bladder function, spasticity, walking/gait, or pain/numbness/tingling sensation; AND

iv. The medication is prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of multiple sclerosis.

Dosing. Approve the following dosing regimens (A and/or B):

A) 150 mg by intravenous infusion, followed 2 weeks later by a second 450 mg intravenous infusion; AND/OR

B) 450 mg by intravenous infusion once every 24 weeks.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Briumvi is not recommended in the following situations:

1. **Concurrent Use with Other Disease-Modifying Agents Used for Multiple Sclerosis.** These agents are not indicated for use in combination (See Appendix for examples). Additional data are required to determine if use of disease-modifying multiple sclerosis agents in combination is safe and provides added efficacy.

2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

© 2026. All Rights Reserved.
This document is confidential and proprietary. Unauthorized use and distribution are prohibited.

REFERENCES

1. Briumvi® intravenous infusion [prescribing information]. Morrisville, NC: TG Therapeutics; January 2026.
2. A Consensus Paper by the Multiple Sclerosis Coalition. The use of disease-modifying therapies in multiple sclerosis. Updated September 2019.
3. 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.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	Ocrevus Zunovo was added to the Appendix.	10/09/2024
Early Annual Revision	Extavia was removed from the Appendix. The name of the policy was changed to add "Injectable – CD20-Directed Cytolytic Antibody".	07/23/2025
Annual Revision	**Multiple Sclerosis, Relapsing Forms:** In Dosing, previously criteria approved regimen A "or" B; the "or" was updated to "and/or" such that the dosing now reads A) 150 mg by intravenous infusion, followed 2 weeks later by a second 450 mg intravenous infusion; AND/OR B) 450 mg by intravenous infusion once every 24 weeks. **Appendix:** It was noted that a generic for Mavenclad (cladribine tablets) is now available.	07/22/2026

APPENDIX

Medication	Mode of Administration
Aubagio® (teriflunomide tablets, generic)	Oral
Avonex® (interferon beta-1a intramuscular injection)	Injection (self-administered)
Bafiertam® (monomethyl fumarate delayed-release capsules)	Oral
Betaseron® (interferon beta-1b subcutaneous injection)	Injection (self-administered)
Briumvi® (ublituximab-xiiy intravenous infusion)	Intravenous infusion
Copaxone® (glatiramer acetate subcutaneous injection, generic)	Injection (self-administered)
Gilenya® (fingolimod capsules, generic)	Oral
Glatopa® (glatiramer acetate subcutaneous injection)	Injection (self-administered)
Kesimpta® (ofatumumab subcutaneous injection)	Injection (self-administered)
Lemtrada® (alemtuzumab intravenous infusion)	Intravenous infusion
Mavenclad® (cladribine tablets, generic)	Oral
Mayzent® (siponimod tablets)	Oral
Ocrevus® (ocrelizumab intravenous infusion)	Intravenous infusion
Ocrevus Zunovo® (ocrelizumab and hyaluronidase-ocsq subcutaneous injection)	Subcutaneous injection (not self-administered)
Plegridy® (peginterferon beta-1a subcutaneous or intramuscular injection)	Injection (self-administered)
Ponvory® (ponesimod tablets)	Oral
Rebif® (interferon beta-1a subcutaneous injection)	Injection (self-administered)
Tascenso ODT® (fingolimod orally disintegrating tablets)	Oral
Tecfidera® (dimethyl fumarate delayed-release capsules, generic)	Oral
Tyruko® (natalizumab-sztn intravenous infusion)	Intravenous infusion
Tysabri® (natalizumab intravenous infusion)	Intravenous infusion
Vumerity® (diroximel fumarate delayed-release capsules)	Oral
Zeposia® (ozanimod capsules)	Oral

© 2026. All Rights Reserved.
This document is confidential and proprietary. Unauthorized use and distribution are prohibited.