

Briumvi® (ublituximab-xiyy) (Intravenous)

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I. Length of Authorization

- Initial: Prior authorization validity will be provided initially for 12 months (365 days).
- Renewal: Prior authorization validity may be renewed every 12 months thereafter (365 days).

II. Dosing Limits

Max Units (per dose and over time) [HCPCS Unit]:

Initial dose:

- 150 billable units (150 mg) on day 1 and 450 billable units (450 mg) on day 15 and 168

Subsequent doses:

- 450 billable units (450 mg) every 168 days thereafter

III. Initial Approval Criteria ¹

Prior authorization validity is provided in the following conditions:

- Patient must have had an inadequate response to an adequate trial of one of the following drugs: dimethyl fumarate, fingolimod, teriflunomide, glatiramer acetate (generic, Glatopa), or cladribine, unless contraindicated or not tolerated; **AND**
- Member is at least 18 years of age; **AND**
- Member has been screened for the presence of Hepatitis B virus (HBV) prior to initiating treatment AND does not have active disease (i.e., positive results for Hepatitis B surface antigen [HBsAg] and anti-HBV tests); **AND**
- Member has had baseline serum immunoglobulins assessed; **AND**

Universal Criteria ¹

- Provider will confirm that member will not receive live or live-attenuated vaccines while on therapy or within 4 weeks prior to initiation of treatment; **AND**
- Member does not have an active infection; **AND**
- Member will have serum aminotransferases (alanine aminotransferase [ALT] and aspartate aminotransferase [AST]), alkaline phosphatase, and bilirubin levels measured at baseline and periodically throughout therapy; **AND**
- Used as single agent therapy; **AND**

- Member has not received a dose of ocrelizumab or ublituximab within the past 5 months; **AND**

Multiple Sclerosis †^{1,6,10,15}

- Member must have a confirmed diagnosis of multiple sclerosis (MS) as documented by laboratory report (i.e., MRI); **AND**
- Member has a diagnosis of a relapsing form of MS [i.e., relapsing-remitting MS (RRMS), active secondary progressive disease (SPMS), or clinically isolated syndrome (CIS)]

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

IV. Renewal Criteria^{1,9,13}

Prior authorization validity may be renewed based on the following criteria:

- Member continues to meet the universal and other indication-specific relevant criteria identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe infusion reactions, severe bacterial and viral infections, progressive multifocal leukoencephalopathy, hypogammaglobulinemia, clinically significant liver injury, etc.; **AND**
- Continuous monitoring of response to therapy indicates a beneficial response* [manifestations of MS disease activity include, but are not limited to, an increase in annualized relapse rate (ARR), development of new/worsening T2 hyperintensities or enhancing lesions on MRI, and progression of sustained impairment as evidenced by expanded disability status scale (EDSS), timed 25-foot walk (T25-FW), 9-hole peg test (9-HPT)]

***Note:**

- Inadequate response, in those who have been adherent and receiving therapy for sufficient time to realize the full treatment effect, is defined as ≥ 1 relapse, ≥ 2 unequivocally new MRI-detected lesions, or increased disability on examination over a one-year period.

V. Dosage/Administration ¹

Indication	Dose
Multiple Sclerosis	<u>Initial dosing:</u>
	- First Infusion: 150 mg intravenous infusion - Second Infusion: 450 mg intravenous infusion administered two weeks after the first infusion.
	<u>Subsequent doses:</u>
	450 mg intravenous infusion administered 24 weeks after the first infusion and every 24 weeks thereafter

VI. Billing Code/Availability Information

HCPCS Code:

- J2329 – Injection, ublituximab-xiiy, 1mg; 1 billable unit = 1 mg

NDC:

- Briumvi 150 mg/6 mL single-dose vial: 73150-0150-xx

VII. References

1. Briumvi [package Insert]. Morrisville, NC; TG Therapeutics, Inc.; January 2026. Accessed April 2026.
2. Steinman L, Fox E, Hartung HP, et al; ULTIMATE I and ULTIMATE II Investigators. Ublituximab versus Teriflunomide in Relapsing Multiple Sclerosis. N Engl J Med. 2022 Aug 25;387(8):704-714. doi: 10.1056/NEJMoa2201904.
3. Gawronski KM, Rainka MM, Patel MJ, Gengo FM. Treatment Options for Multiple Sclerosis: Current and Emerging Therapies. Pharmacotherapy. 2010; 30(9):916-927.
4. Goodin DS, Frohman EM, Garmany GP Jr, et al. Disease modifying therapies in multiple sclerosis: report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology and the MS Council for Clinical Practice Guidelines. Neurology. 2002 Jan 22; 58(2):169-78.
5. Freedman MS, Selchen D, Arnold DL, et al. Treatment optimization in MS: Canadian MS Working Group updated recommendations. Can J Neurol Sci. 2013 May;40(3):307-23.
6. Polman CH, Reingold SC, Banwell B, et al. Diagnostic criteria for multiple sclerosis: 2010 Revisions to the McDonald criteria. Ann Neurol. 2011 Feb; 69(2): 292–302. doi: 10.1002/ana.22366.
7. Lublin FD, Reingold SC, Cohen JA, et al. Defining the clinical course of multiple sclerosis: the 2013 revisions. Neurology. 2014 Jul 15;83(3):278-86.

8. Multiple Sclerosis Coalition. The use of disease-modifying therapies in multiple sclerosis: principles and current evidence. <https://ms-coalition.org/the-use-of-disease-modifying-therapies-in-multiple-sclerosis-updated/>. Accessed November 2025.
9. 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. Reaffirmed: 2025 Oct 19.
10. Thompson AJ, Banwell BL, Barkhof F, et al. Diagnosis of multiple sclerosis: 2017 revisions of the McDonald criteria. *Lancet Neurol*. 2018 Feb;17(2):162-173. doi: 10.1016/S1474-4422(17)30470-2.
11. Kappos L, Bar-Or A, Cree BAC, et al. Siponimod versus placebo in secondary progressive multiple sclerosis (EXPAND): a double-blind, randomised, phase 3 study. *Lancet*. 2018;391(10127):1263. Epub 2018 Mar 23.
12. Lorscheider J, Buzzard K, Jokubaitis V, et al, on behalf of the MSBase Study Group. Defining secondary progressive multiple sclerosis. *Brain*, Volume 139, Issue 9, September 2016, Pages 2395–2405, <https://doi.org/10.1093/brain/aww173>.
13. Freedman MS, Devonshire V, Duquette P, et al; Canadian MS Working Group. Treatment Optimization in Multiple Sclerosis: Canadian MS Working Group Recommendations. *Can J Neurol Sci*. 2020 Jul;47(4):437-455. doi: 10.1017/cjn.2020.66.
14. Cree BAC, Arnold DL, Chataway J, et al. Secondary Progressive Multiple Sclerosis: New Insights. *Neurology*. 2021 Aug 24;97(8):378-388. doi: 10.1212/WNL.0000000000012323. Epub 2021 Jun 4.
15. Montalban X, Lebrun-Fréney C, Oh J, et al. Diagnosis of multiple sclerosis: 2024 revisions of the McDonald criteria. *Lancet Neurol*. 2025 Oct;24(10):850-865. doi: 10.1016/S1474-4422(25)00270-4.

Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

Factor	Conclusion
Indication	Yes: Consider for PA

Safety and efficacy	No: PA not a priority
Potential for misuse/abuse	No: PA not a priority
Cost of drug	Yes: Consider for PA

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
G35.A	Relapsing-remitting multiple sclerosis
G35.B0	Primary progressive multiple sclerosis, unspecified
G35.B1	Active primary progressive multiple sclerosis
G35.B2	Non-active primary progressive multiple sclerosis
G35.C0	Secondary progressive multiple sclerosis, unspecified
G35.C1	Active secondary progressive multiple sclerosis
G35.C2	Non-active secondary progressive multiple sclerosis
G35.D	Multiple sclerosis, unspecified

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: <https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC