

# 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 <sup>1</sup>

Prior authorization validity is provided in the following conditions:

- Patient must have a contraindication, intolerance, or failure to ONE generic disease-modifying agent prior to the consideration of Briumvi®; **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 <sup>1</sup>

- 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 †<sup>1,6,10,15</sup>

- 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); Ⓞ Orphan Drug

## IV. Renewal Criteria<sup>1,9,13</sup>

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  $\geq 1$  relapse,  $\geq 2$  unequivocally new MRI-detected lesions, or increased disability on examination over a one-year period.

## V. Dosage/Administration<sup>1</sup>

Indication	Dose
Multiple Sclerosis	<u>Initial dosing:</u> <ul style="list-style-type: none"><li>• First Infusion: 150 mg intravenous infusion</li><li>• Second Infusion: 450 mg intravenous infusion administered two weeks after the first infusion.</li></ul>
	<u>Subsequent doses:</u> <ul style="list-style-type: none"><li>• 450 mg intravenous infusion administered 24 weeks after the <b>first</b> infusion and every 24 weeks thereafter</li></ul>

## VI. Billing Code/Availability Information

HCPCS Code:

- J2329 – Injection, ublituximab-xiyy, 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.
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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>.

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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 (NQL) Factor Checklist**

Non-quantitative treatment limitations (NQLs) 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 NQL 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

<b>Medicare Part B Administrative Contractor (MAC) Jurisdictions</b>		
<b>Jurisdiction</b>	<b>Applicable State/US Territory</b>	<b>Contractor</b>
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.
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