

**ublituximab-xiiy (Briumvi)****Medical Benefit Drug Policy****Place of Service**

Home Infusion Administration

Infusion Center Administration

Office Administration

Outpatient Facility Infusion Administration

**Drug Details****USP Category:** CENTRAL NERVOUS SYSTEM AGENTS**Mechanism of Action:** CD20-directed cytolytic antibody recombinant chimeric monoclonal IgG1 antibody**HCPCS:**

J2329:Injection, ublituximab-xiiy, 1mg

**How Supplied:**

150 mg/6 mL (25 mg/mL) in a single-dose vial

**Condition(s) listed in policy** *(see coverage criteria for details)*

- Multiple Sclerosis, Relapsing forms to include Clinically Isolated Syndrome, Relapsing-Remitting Disease, and Active Secondary Progressive Disease

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the California Code of Regulations (CCR), Title 22, Section 51303 and 51313 must be met.

**Special Instructions and Pertinent Information**

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

**Coverage Criteria****The following condition(s) require Prior Authorization/Preservice.****Multiple Sclerosis, Relapsing forms to include Clinically Isolated Syndrome, Relapsing-Remitting Disease, and Active Secondary Progressive Disease****Meets medical necessity if all the following are met:**

- Not used in combination with other immunomodulators for multiple sclerosis

**Covered Doses:**

Up to 150 mg given intravenously for the first dose, then 450 mg two weeks later for the second dose, followed by 450 mg 24 weeks after the first infusion, then every 24 weeks thereafter

**Coverage Period:**

Initial: Yearly

Subsequent: Indefinite

**ICD-10:**

G35

**References**

1. AHFS. Available by subscription at <http://www.lexi.com>
2. Briumvi (ublituximab-xiiy) Prescribing Information. TG Therapeutics, Inc., Morrisville, NC: 10/2024.
3. DrugDex. Available by subscription at <http://www.micromedexsolutions.com/home/dispatch>

**Review History**

Date of Last Annual Review: 2Q2025

Changes from previous policy version:

- No clinical change to policy following annual review.

*Blue Shield of California Medication Policy to Determine Medical Necessity  
Reviewed by P&T Committee*