ublituximab-xiiy (Briumvi)

Commercial 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 Health and Safety Code section 1367.21 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.

For billing purposes, drugs must be submitted with the drug's assigned HCPCS code (as listed in the drug policy) and the corresponding NDC (national drug code). An unlisted, unspecified, or miscellaneous code should not be used if there is a specific code assigned to the drug.

Members with the following plans: **PPO, Direct Contract HMO, and when applicable, ASO, Shared Advantage, HMO (non-direct)** may be required to have their medication administered at a preferred site of service, including the home, a physician's office, or an independent infusion center not associated with a hospital.

For members that cannot receive infusions in the preferred home or ambulatory setting AND meet one of the following criteria points, drug administration may be performed at a hospital outpatient facility infusion center.

CRITERIA FOR HOSPITAL OUTPATIENT FACILITY ADMINISTRATION

MCG Care Guidelines, 19th edition, 2015

ADMINISTRATION OF THIS DRUG IN THE HOSPITAL OUTPATIENT FACILITY SITE OF CARE REQUIRES ONE OF THE FOLLOWING: (*Supporting Documentation must be submitted)*

1. Patient is initiating therapy with Briumvi (150 mg initial dose, 450 mg two weeks later, then one 400 mg 24 weeks after the first dose) or is being re-initiated on Briumvi after at least 6 months off therapy. *Subsequent doses will require medical necessity for continued use in the hospital outpatient facility site of care.*

OR

Additional clinical monitoring is required during administration as evidenced by one of the following:

2. Patient has experienced a previous severe adverse event on Briumvi based on documentation submitted.
3. Patient continues to experience moderate to severe adverse events on Briumvi based on documentation submitted, despite receiving premedication such as acetaminophen, steroids, diphenhydramine, fluids, etc.
4. Patient is clinically unstable based on documentation submitted.
5. Patient is physically or cognitively unstable based on documentation submitted.

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:

1. 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:

- Yearly if administered at a hospital outpatient facility
- Indefinite if administered in a preferred site of service

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