Medical Policy

Briumvi® (ublituximab-xiiy)	
MEDICAL POLICY NUMBER	MED_Clin_Ops_140
CURRENT VERSION EFFECTIVE DATE	January 1, 2024
APPLICABLE PRODUCT AND MARKET	*Individual Family Plan:* All Plans *Small Group*: All Plans *Medicare Advantage:* All Plans

*Policy applies to all markets where IFP, SG, or MA plans are offered.

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PURPOSE

The purpose of this policy is to establish the clinical review criteria that support the determination of medical necessity for Briumvi, ublituximab-xiiy therapy.

POLICY

Prior Authorization and Medical Review is required.

Coverage for Briumvi will be provided for 6 months and may be renewed unless otherwise specified.

- Max Units (per dose and over time):
  - Initial Dose: 300mg on day 1 and 450mg on day 15 and 168
  - Subsequent doses: 450 mg every 6 months thereafter

Initial

A. Patient is 18 years of age or older; **AND**
B. Patient has been screened for the presence of Hepatitis B virus (HBV) prior to initiating treatment and does not have active disease (i.e., positive HBsAg and anti-HBV tests); **AND**

Multiple Sclerosis, Relapsing Forms

A. Used as single agent therapy; **AND**
B. Patient has confirmed diagnosis of multiple sclerosis (MS) as documented by laboratory report (i.e., MRI); **AND**
C. Patient 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); **AND**
D. Patient has experienced inadequate efficacy or significant intolerance to one disease-modifying agent used for multiple Sclerosis.

Renewal

Coverage can be renewed based upon the following criteria:

A. Patient continues to meet universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in initial criteria; **AND**
B. Patient has not received a dose of ocrelizumab or ublituximab within the past 5 months; **AND**
C. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe infusion reactions, severe infections, progressive multifocal leukoencephalopathy, hypogammaglobulinemia, etc.; **AND**
D. 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 brain/spinal 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)]
    a. 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.

LIMITATIONS/EXCLUSIONS

1. Any indication other than those listed above due to insufficient evidence of therapeutic value.

DEFINITIONS

A. BRIUMVI (ublituximab-xiiy) injection, for intravenous use. Initial U.S. Approval: 2022
    a. BRIUMVI (ublituximab-xiiy) for injection is a clear to opalescent, colorless to slightly yellow solution for intravenous infusion after dilution in 0.9% Sodium Chloride Injection. It is supplied as an individually packaged, single-dose vial.

CODING

Applicable NDC Codes	
73150-0150-06	Briumvi 25mg/ml-6ml solution in a single dose vial

Applicable Procedure Code	
J3590	Unclassified biologic drug

Applicable ICD-10 Codes	
G35	Multiple Sclerosis

EVIDENCE BASED REFERENCES

1. Briumvi [package insert]. Morrisville, NC; TG Therapeutics, Inc; December 2022. Accessed February, 2023.
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.

POLICY HISTORY

Original Effective Date	2/28/2023
Revised Date	
P&T Committee Endorsement	02/28/2023
Updated to Brand New Day/Central Health Medicare Plan/Central Health Medicare Plan	01/01/2024