Medical Policy:

Briumvi™ (ublituximab-xiij) Intravenous

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.372	March 25, 2024	February 9, 2023

The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as "EmblemHealth"), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Definitions

Briumvi, a CD20-directed cytolytic antibody, is indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing remitting disease, and active secondary progressive disease, in adults.

Length of Authorization

Coverage will be provided for 12 months and may be renewed.

Dosing Limits [Medical Benefit]

150 mg by intravenous infusion, followed 2 weeks later by a second 450 mg intravenous infusion; **OR**
450 by intravenous infusion once every 24 weeks.

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

Initial dose: 300 mg on day 1 and 450 mg on day 15 and 168
Subsequent doses: 450 mg every 6 months thereafter

Guideline

I. INITIAL CRITERIA

1. **Multiple Sclerosis, Relapsing Forms**.
   A. Patient is ≥ 18 years of age; **AND**
   B. Patient has a relapsing form of multiple sclerosis; **AND**
   Note: Examples of relapsing forms of multiple sclerosis include clinically isolated syndrome, relapsing remitting disease, and active secondary progressive disease.
   C. Medication will not be used concomitantly with other Disease Modifying Agents for MS; **AND**
   D. Medication is prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of multiple sclerosis

II. RENEWAL CRITERIA

Multiple Sclerosis, Relapsing Forms: *Patient has been receiving Briumvi for 1 year or more*:

A. Patient is ≥ 18 years of age; **AND**
B. Patient has a relapsing form of multiple sclerosis; **AND**
Note: Examples of relapsing forms of multiple sclerosis include clinically isolated syndrome, relapsing remitting disease, and active secondary progressive multiple sclerosis.
C. Patient meets one of the following (i **OR** ii):
   i. Patient experienced a beneficial clinical response when assessed by at least one objective measure; **OR**
   Note: Examples include stabilization or reduced worsening in disease activity as evaluated by magnetic resonance imaging (MRI) [absence or a decrease in gadolinium enhancing lesions, decrease in the number of new or enlarging T2 lesions]; stabilization or reduced worsening on the Expanded Disability Status Scale (EDSS) score; achievement in criteria for No Evidence of Disease Activity-3 (NEDA-3) or NEDA-4; improvement on the fatigue symptom and impact questionnaire-relapsing multiple sclerosis (FSIQ-RMS) scale; reduction or absence of relapses; improvement or maintenance on the six-minute walk test or 12-Item Multiple Sclerosis Walking Scale; improvement on the Multiple Sclerosis Functional Composite (MSFC) score; and/or attenuation of brain volume loss.
   ii. Patient experienced stabilization, slowed progression, or improvement in at least one symptom such as motor function, fatigue, vision, bowel/bladder function, spasticity, walking/gait, or pain/numbness/tingling sensation; **AND**
D. Medication is prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of multiple sclerosis.

Applicable Procedure Codes

Code	Description
J2329	Injection, ublituximab-xiiy, 1mg

Applicable NDCs

Code	Description
73150-0150-06	Briumvi 150 mg/6 mL, single dose vial

ICD-10 Diagnoses

Code	Description
G35	Multiple Sclerosis

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	3/25/2024	Annual Review: updated dosing limits, removed J3590, added J2329 Initial Criteria: removed: "According to the prescriber, the patient has experienced inadequate efficacy or significant intolerance to one disease modifying agent used for multiple sclerosis; **AND"** Renewal criteria- removed section with less than 1 year therapy with Briumvi
EmblemHealth & ConnectiCare	02/09/2023	New Policy

References

1. Briumvi™ intravenous infusion [prescribing information]. Morrisville, NC: TG Therapeutics; December 2022.