PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Briumvi (ublituximab-xiiy)
BENEFIT TYPE	Medical
STATUS	Prior Authorization Required

Briumvi, approved by the FDA in 2022, is a CD20-directed cytolytic antibody 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. Maintenance doses are infused over one hour by the healthcare provider every 24 weeks.

Briumvi (ublituximab-xiiy) will be considered for coverage when the following criteria are met:

Relapsing forms of Multiple Sclerosis (MS)

For **initial** authorization:

1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with a neurologist; AND
3. Member has a confirmed diagnosis of relapsing multiple sclerosis, including clinically isolated syndrome (CIS), relapsing-remitting disease (RRMS), or active secondary progressive disease (SPMS); AND
4. Member has documentation of at least one of the following:
   a) Inadequate response to at least one preferred disease-modifying MS drug
   b) Highly active disease (aggressive or rapidly evolving) in the expert opinion of the prescriber; AND
5. Member has tested negative for active hepatitis B, or a hepatologist has been consulted; AND
6. Briumvi will not be used concurrently with another disease-modifying agent for MS.
7. **Dosage allowed/Quantity limit:**
   First dose: 150 mg IV infusion
   Second dose: 450 mg IV infusion 2 weeks after first infusion
   Maintenance: 450 mg IV infusion 24 weeks after first infusion, and every 24 weeks thereafter.
   QL: 7 vials for the first 24 weeks, then 3 vials every 24 weeks going forward

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:

1. Chart notes must show a positive clinical response to treatment (e.g., fewer relapses, reduced number or volume of brain lesions on MRI, slowed disability progression)

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Briumvi (ublituximab-xiiy) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
01/04/2023	New policy for Briumvi created.

References:

1. Briumvi [prescribing information]. TG Therapeutics; 2022.
2. Steinman L, Fox E, Hartung HP, et al. Ublituximab versus Teriflunomide in Relapsing Multiple Sclerosis. *N Engl J Med*. 2022;387(8):704-714. doi:10.1056/NEJMoa2201904
3. Rae-Grant A, Day GS, Marrie RA, et al. Practice guideline recommendations summary: Disease-modifying therapies for adults with multiple sclerosis: Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology [published correction appears in Neurology. 2019 Jan 8;92(2):112]. *Neurology*. 2018;90(17):777-788
4. National Multiple Sclerosis Society. The Use of Disease-Modifying Therapies in Multiple Sclerosis: Principles and Current Evidence. A Consensus Paper by the Multiple Sclerosis Coalition; 2019. Available from: https://www.nationalmssociety.org/NationalMSSociety/media/MSNationalFiles/Brochures/DMT_Consensus_MS_Coalition.pdf. Accessed January 4, 2023.
5. McGinley MP, Goldschmidt CH, Rae-Grant AD. Diagnosis and Treatment of Multiple Sclerosis: A Review [published correction appears in JAMA. 2021 Jun 1;325(21):2211]. *JAMA*. 2021;325(8):765-779. doi:10.1001/jama.2020.26858
6. Hauser SL, Cree BAC. Treatment of Multiple Sclerosis: A Review. *Am J Med*. 2020;133(12):1380-1390.e2. doi:10.1016/j.amjmed.2020.05.049

Effective date: 07/01/2023
Revised date: 01/04/2023