

## PHARMACY POLICY STATEMENT

### Ohio Medicaid

<b>DRUG NAME</b>	<b>Briumvi (ublituximab-xiiy)</b>
<b>BENEFIT TYPE</b>	Medical
<b>STATUS</b>	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-xiyy) 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.
10/31/2024	Annual review; no updates. Approved by ODM 2/13/2025.

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](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

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Revised date: 10/31/2024