

Briumvi™ (ublituximab-xiij intravenous infusion)

When requesting Briumvi™ (ublituximab-xiij intravenous infusion), the individual requiring treatment must be diagnosed with the following FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-approved indication

Briumvi 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.

Coverage Guidelines

Multiple Sclerosis (MS)

The individual must meet **all** of the following criteria for initial authorization:

- Is ≥ 18 years of age;
- Has a relapsing form of multiple sclerosis (examples of relapsing forms of multiple sclerosis include clinically isolated syndrome, relapsing remitting disease, and active secondary progressive disease);
- Has experienced inadequate efficacy or significant intolerance to at least one disease-modifying agent used for multiple sclerosis (e.g., Aubagio, Avonex, Bafiertam, Betaseron, Copaxone, Extavia, Gilenya, Glatopa, Kesimpta, Lemtrada, Mavenclad, Mayzent, Ocrevus, Plegridy, Ponvory, Rebif, Tascenso ODT, Tecfidera, Tysabri, Vumerity, Zeposia);
- Briumvi is prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of multiple sclerosis.

The individual must meet **all** of the following criteria for reauthorization:

- Is ≥ 18 years of age;
- Has a relapsing form of multiple sclerosis (examples of relapsing forms of multiple sclerosis include clinically isolated syndrome, relapsing remitting disease, and active secondary progressive multiple sclerosis);
- Briumvi is prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of multiple sclerosis;
- If the individual has received Briumvi for 1 year or more, he/she must meet one of the following:
 - Experienced a beneficial clinical response by at least one objective measure (e.g., stabilization or reduced worsening in disease activity as evaluated by magnetic resonance imaging (MRI), 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); OR
- 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.

Approval duration (initial and renewal): 12 months

Recommended Dosing

- First Infusion: 150 mg intravenous infusion;
- Second Infusion: 450 mg intravenous infusion two weeks after the first infusion;
- Subsequent Infusions: 450 mg intravenous infusion 24 weeks after the first infusion and every 24 weeks thereafter

References

1. Briumvi™ intravenous infusion [prescribing information]. Morrisville, NC: TG Therapeutics; December 2022.
2. A Consensus Paper by the Multiple Sclerosis Coalition. The use of disease-modifying therapies in multiple sclerosis. Updated September 2019. Available at: https://www.nationalmssociety.org/NationalMSSociety/media/MSNationalFiles/Brochures/DMT_Consensus_MS_Coalition.pdf. Accessed on December 30, 2022.
3. McGinley MP, Goldschmidt C, Rae-Grant AD. Diagnosis and treatment of multiple sclerosis. A review. *JAMA*. 2021;325(8):765-779.
4. The Medical Letter on Drugs and Therapeutics. Drugs for multiple sclerosis. *Med Lett Drugs Ther*. 2021;63(1620):42-48.
5. Lublin FD, Reingold SC, Cohen JA, et al. Defining the clinical course of multiple sclerosis: the 2013 revisions. *Neurology*. 2014;83:278-286.
6. Thompson AJ, Banwell BL, Barkhof F, et al. Diagnosis of multiple sclerosis: 2017 revisions of the McDonald criteria. *Lancet Neurol*. 2018;17(2):162-173.