

Briumvi™ (ublituximab-xiiy) Intravenous Injection

When requesting Briumvi™ (ublituximab-xiiy intravenous injection), 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 the following criteria for authorization:

- Is 18 years of age or older;
- Has a relapsing form of multiple sclerosis (i.e., clinically isolated syndrome, relapsing remitting disease, or active secondary progressive disease);
- Briumvi is prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of multiple sclerosis;
- For re-authorization, has been receiving Briumvi for at least 12 months and meets one of the following:
 - o Has experienced a beneficial clinical response when assessed 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
 - o Has experienced stabilization, slowed progression, or improvement in at least one symptom (e.g., motor function, fatigue, vision, bowel/bladder function, spasticity, walking/gait, or pain/numbness/tingling sensation).

Approval duration (initial and renewal): 12 months

Dosing Recommendations

- 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.
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.