Briumvi®
(ublituximab-xiiy)

FDA INDICATIONS AND USAGE[1]

Briumvi® 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.

APPROVAL CRITERIA[1,2,3]

1. Patient is 18 years of age or older **AND**;
2. Patient has a diagnosis of relapsing form of multiple sclerosis, clinically isolated syndrome, relapsing-remitting disease, or active secondary progressive disease **AND**;
3. Prescribed by or in consultation with a neurologist or a prescriber that specializes in MS **AND**;
4. Patient has had an ineffective response due to continued clinical relapse, intolerance or contraindication to two or more MS drugs within the last 12 months **AND;**
5. For women of reproductive potential, provider attests the patient is not pregnant and will not become pregnant while treated with Briumvi.

DENIAL CRITERIA [1]

1. Failure to meet approval criteria **OR**;
2. Briumvi is being prescribed concurrently with other disease modifying therapies for MS **OR**;
3. Patient has an active hepatitis B infection.

CAUTIONS[1]

- Prior to initiating Briumvi, patients should be tested for quantitative serum immunoglobulins. Patients with low serum immunoglobulins should be evaluated by an immunologist prior to initiating treatment.
- Briumvi administration should be delayed in patients with an active infection until the infection is resolved or receiving live-attenuated vaccines.
- Patients should pre-medicate with methylprednisolone (or an equivalent corticosteroid) and an antihistamine (e.g., diphenhydramine) prior to each infusion.
- Briumvi may cause fetal harm.

DURATION OF APPROVAL

- Initial Approval: up to 6 months
- Reauthorization Approval: up to 12 months if the prescriber documents the patient has disease improvement or stabilization.

QUANTITY LIMIT

- Initial dose: 150 mg, followed by a 450 mg dose 2 weeks later
- Maintenance dose: 450 mg every 24 weeks.
- HCPCS: J3590

REFERENCES / FOOTNOTES:

1. Briumvi® [prescribing information]. Morrisville, NC: TG Therapeutics, Inc. December 2022. Accessed February 1, 2023.
2. 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. Neurology 2018;90:777-788.
3. Steinman L, Fox E, Hartung HP, et al. Ublituximab versus Teriflunomide in Relapsing Multiple Sclerosis. N Engl J Med 2022; 387:704-714