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Section:	Prescription Drugs	**Effective Date:**	January 1, 2024
Subsection:	Central Nervous System Drugs	**Original Policy Date:**	January 20, 2023
Subject:	Briumvi	**Page:**	1 of 5

Last Review Date: December 8, 2023

Briumvi

Description

Briumvi (ublituximab-xiiy)

Background
Briumvi (ublituximab-xiiy) is a multiple sclerosis (MS) disease-modifying agent. Briumvi can potentially alter the course of disease by lessening the frequency of relapses and disease progression. Briumvi is a recombinant chimeric monoclonal IgG1 antibody that targets CD20 proteins on premature and mature B cells. Briumvi binds to CD20 on B cells which results in antibody-dependent cellular cytolysis and complement-dependent cytolysis (1).

Regulatory Status
FDA-approved indication: 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 (1).

Briumvi is contraindicated in patients with active hepatitis B virus (HBV) infection. Complete HBV screening prior to the initiation of Briumvi. Fulminant hepatitis, hepatic failure, and death caused by HBV reactivation have occurred in patients treated with anti-CD20 antibodies (1).

The administration of Briumvi should be delayed in patients with active infections until the infection has resolved. Briumvi increases the risk for infections, including serious and fatal bacterial, fungal, and new or reactivated viral infections (1).

Administer all immunizations according to immunization guidelines at least 4 weeks prior to drug initiation for live or live-attenuated vaccines and, whenever possible, at least 2 weeks prior to initiation of Briumvi for non-live vaccines (1).

Decreased immunoglobulin levels may occur with Briumvi treatment. Monitor the levels of quantitative serum immunoglobulins during treatment, especially in patients with opportunistic or recurrent infections, and after discontinuation of therapy until B-cell repletion (1).

Briumvi may cause fetal harm when administered to a pregnant woman. Advise females of reproductive potential to use effective contraception during Briumvi treatment and for 6 months after the last dose (1).

Safety and effectiveness of Briumvi in pediatric patients have not been established (1).

Related policies
Acthar Gel, Ampyra, Aubagio, Gilenya, Kesimpta, Lemtrada, Mavenclad, Mayzent, MS Injectables, Ocrevus, Ponvory, Tecfidera, Tysabri, Zeposia

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Briumvi may be considered **medically necessary** if the conditions indicated below are met.

Briumvi may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age and older

Diagnosis

Patient must have the following:

1. Relapsing Multiple Sclerosis (RMS), including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease
    a. Ineffective response due to continued clinical relapse, intolerance or contraindication to two or more MS drugs

i. Does not apply if the patient has advanced, progressive, or severe disease

AND ALL of the following:

1. Patient is not at risk for HBV infection **OR** patient is at risk for HBV infection and HBV infection has been ruled out or treatment for HBV infection has been initiated
2. Absence of active infection
3. Prescriber agrees to monitor levels of quantitative serum immunoglobulins
4. Prescriber agrees to pre-medicate with a corticosteroid, antihistamine, and/or antipyretic, as clinically indicated
5. **NOT** used in combination with other immune-modulating or immunosuppressive therapies, including immunosuppressant doses of corticosteroids
6. **NOT** used in combination with another MS disease modifying agent
7. **NOT** given concurrently with live vaccines or live attenuated vaccines
8. Females of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Briumvi and for 6 months after the last dose

Prior – Approval *Renewal* Requirements

Age 18 years of age and older

Diagnosis

Patient must have the following:

1. Relapsing Multiple Sclerosis (RMS), including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease

AND ALL of the following:

1. Absence of active infection
2. Prescriber agrees to monitor levels of quantitative serum immunoglobulins
3. Prescriber agrees to pre-medicate with a corticosteroid, antihistamine, and/or antipyretic, as clinically indicated
4. **NOT** used in combination with other immune-modulating or immunosuppressive therapies, including immunosuppressant doses of corticosteroids

5. **NOT** used in combination with another MS disease modifying agent
6. **NOT** given concurrently with live vaccines or live attenuated vaccines
7. Females of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Briumvi and for 6 months after the last dose

Policy Guidelines

Pre - PA Allowance
None

Prior - Approval Limits
Duration 2 years

Prior – Approval *Renewal* Limits
Same as above

Rationale

Summary
Briumvi is a monoclonal antibody that targets CD20, a protein prominent on premature and mature B cells, and decreases the amount of circulating B cells that is used in the treatment of patients with relapsing forms of multiple sclerosis (MS). Briumvi can increase the risk for developing infections. Safety and effectiveness of Briumvi in pediatric patients have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of the Briumvi while maintaining optimal therapeutic outcomes.

References

1. Briumvi [package insert]. Morrisville, NC: TG Therapeutics, Inc.; December 2022.
2. Dorr J, Paul F. The transition from first-line to second-line therapy in multiple sclerosis. Curr Treat Options Neurol. 2015;17:25.
3. Goodin DS, Frohman EM, Garmany GP, et al. Disease modifying therapies in multiple sclerosis. Neurology. 2002;58:169-78.
4. Costello K, Halper J, Kalb R, el al. The use of disease-modifying therapies in multiple sclerosis: principles and current evidence. MS Coalition. 2016. Accessed on April 3, 2017.

5. Disease-modifying therapies for relapsing-remitting and primary-progressive multiple sclerosis: effectiveness and value. Institute for Clinical and Economic Review. Published March 6, 2017.
6. Cahill JF, Izzo A, Garg N. Immunization in patients with multiple sclerosis. Neurological Bulletin. 2010;2(1):17-21.

Policy History

Date	Action
January 2023	Addition to PA
March 2023	Annual review
June 2023	Annual review
December 2023	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 8, 2023 and is effective on January 1, 2024.