BlueCross BlueShield
Federal Employee Program

BRIUMVI
(ublituximab-xiiy)

RATIONALE FOR INCLUSION IN PA PROGRAM

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).

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

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.; October 2024.
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.