BlueCross BlueShield
Federal Employee Program

KESIMPTA
(ofatumumab)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

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

Regulatory Status

FDA-approved indication: Kesimpta 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).

Kesimpta is contraindicated in patients with active hepatitis B virus (HBV) infection. Complete HBV screening prior to the initiation of Kesimpta. There are no reports of HBV reactivation in MS patients treated with Kesimpta. However, HBV reactivation has occurred in other anti-CD20 antibodies which resulted in fulminant hepatitis, hepatic failure, and death (1).

The administration of Kesimpta should be delayed in patients with active infections until the infection has resolved (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 Kesimpta for inactivated vaccines. Live or live-attenuated vaccines are generally not recommended during treatment and after discontinuation until B-cell repletion (1).

As expected with any B-cell depleting therapy, decreased immunoglobulin levels were observed. Monitor the levels of immunoglobulins at the beginning, during, and after discontinuation of treatment with Kesimpta until B-cell repletion (1).

According to the algorithm defined by Pharmacotherapy: A Pathophysiologic Approach for the management of clinically definite multiple sclerosis, it may be reasonable for patients with severe

disease to use a monoclonal antibody without having tried other MS therapies (2).

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

Summary

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

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

References

1. Kesimpta [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; April 2024.
2. Bainbridge, Jacquelyn L., et al. "Multiple Sclerosis." Pharmacotherapy: A Pathophysiologic Approach, 11e, 2020. Available at: https://accesspharmacy.mhmedical.com/content.aspx?bookid=2577&sectionid=231921409.