BlueCross BlueShield
Federal Employee Program

OCREVUS (ocrelizumab)
OCREVUS ZUNOVO (ocrelizumab and hyaluronidase-ocsq)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Ocrevus/Ocrevus Zunovo are multiple sclerosis (MS) disease-modifying agents. Ocrevus/Ocrevus Zunovo can potentially alter the course of disease by lessening the frequency of relapses and disease progression. Ocrevus/Ocrevus Zunovo is a recombinant humanized monoclonal antibody that targets CD20 proteins on premature and mature B cells. Ocrevus/Ocrevus Zunovo binds to CD20 on B cells which results in antibody-dependent cellular cytolysis and complement-mediated lysis. Ocrevus/Ocrevus Zunovo depletes circulating B cells after each treatment (1-2).

Regulatory Status

FDA-approved indication: Ocrevus/Ocrevus Zunovo are CD20-directed cytolytic antibodies indicated for the treatment of: (1-2)

- Relapsing forms of multiple sclerosis, to include clinically isolated syndrome, relapsing-remitting disease, and active-secondary progressive disease, in adults
- Primary progressive MS, in adults

Ocrevus/Ocrevus Zunovo are contraindicated in patients with active hepatitis B virus (HBV) infection. Complete HBV screening prior to the initiation of Ocrevus/Ocrevus Zunovo. HBV reactivation has been reported in the postmarketing setting with Ocrevus/Ocrevus Zunovo and other anti-CD20 antibodies which resulted in fulminant hepatitis, hepatic failure, and death (1-2).

The administration of Ocrevus/ Ocrevus Zunovo should be delayed in patients with active infections until the infection has resolved. Ocrevus/ Ocrevus Zunovo increases the risk for upper/lower respiratory tract, skin, and herpes-related infections (1-2).

Administer all immunizations according to immunization guidelines at least 4 weeks prior to initiation of Ocrevus/ Ocrevus Zunovo for live or live-attenuated vaccines and at least 2 weeks prior to initiation of Ocrevus/Ocrevus Zunovo for non-live vaccines, and after the repletion of B cells following drug discontinuation. Live, attenuated vaccines are generally not recommended (1-2).

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Cases of progressive multifocal leukoencephalopathy (PML), a potentially lethal opportunistic brain infection, have been reported in patients with MS treated with Ocrevus/Ocrevus Zunovo in the postmarketing setting. PML has occurred in patients who had not been treated previously wth natalizumab, were not taking any immunosuppressive or immunomodulatory medications associated with the risk of PML, and did not have any known ongoing systemic medical conditions resulting in compromised immune system function. Ocrevus/Ocrevus Zunovo should be withheld at the first sign or symptom of PML, and appropriate diagnostic evaluation performed. If PML is confirmed, treatment with Ocrevus/Ocrevus Zunovo should be discontinued (1-2).

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 Ocrevus/Ocrevus Zunovo until B-cell repletion (1-2).

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 (3).

Safety and effectiveness of Ocrevus/Ocrevus Zunovo in pediatric patients have not been established (1-2).

Summary

Ocrevus/Ocrevus Zunovo are indicated for the treatment of patients with relapsing or primary progressive forms of multiple sclerosis. Ocrevus/Ocrevus Zunovo are monoclonal antibodies that targets CD20, a protein prominent on premature and mature B cells, and decreases the amount of circulating B cells through antibody-dependent cellular cytolysis and compliment-mediated lysis. Safety and effectiveness of Ocrevus/Ocrevus Zunovo in pediatric patients have not been established (1-2).

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

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References

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