OCREVUS
(ocrelizumab)

RATIONALE FOR INCLUSION IN PA PROGRAM

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

Regulatory Status
FDA-approved indication: Ocrevus is a CD20-directed cytolytic antibody indicated for the treatment of patients with relapsing or primary progressive forms of multiple sclerosis (1).

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

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

Administer all immunizations 6 weeks prior to drug initiation or after the repletion of B cells following drug discontinuation. Live, attenuated vaccines are generally not recommended (1).

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

Summary
Ocrevus is indicated for the treatment of patients with relapsing or primary progressive forms of multiple sclerosis. Ocrevus is a monoclonal antibody 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 in pediatric patients have not been established (1).
Prior authorization is required to ensure the safe, clinically appropriate and cost effective use of the Ocrevus while maintaining optimal therapeutic outcomes.

References