RAISONALE FOR INCLUSION IN PA PROGRAM

Background
Zeposia (ozanimod) is a sphingosine-1-phosphate (S1P) receptor modulator that binds with high affinity to S1P receptors 1 and 5. Zeposia blocks the capacity of lymphocytes to egress from lymph nodes, reducing the number of lymphocytes in peripheral blood. The mechanism by which Zeposia exerts therapeutic effects in multiple sclerosis is unknown but may involve the reduction of lymphocyte migration into the central nervous system (1).

Regulatory Status
FDA approved indication: Zeposia is a sphingosine 1-phosphate receptor modulator 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).

Before initiation of treatment with Zeposia, the following should be assessed: (1)

- Complete blood count (CBC) – Obtain a recent (i.e., within the last 6 months or after discontinuation of prior MS therapy) CBC including lymphocyte count
- Cardiac evaluation – Obtain an electrocardiogram (ECG) to determine whether preexisting conduction abnormalities are present
- Liver function tests – Obtain recent (i.e., within the last 6 months) transaminase and bilirubin levels
- Ophthalmic assessment – In patient with a history of uveitis or macular edema, obtain an evaluation of the fundus, including the macula
- Vaccination – Test patients for antibodies to varicella zoster virus (VZV) before initiating Zeposia; VZV vaccination of antibody-negative patients is recommended prior to commencing treatment with Zeposia. If live attenuated vaccine immunizations are required, administer at least 1 month prior to initiation of Zeposia.

Zeposia is contraindicated in patients who in the last 6 months experienced a myocardial infarction, unstable angina, stroke, transient ischemic attack (TIA), decompensated heart failure requiring hospitalization, or Class III/IV heart failure (1).
Zeposia is also contraindicated in patients with Mobitz type II second-degree or third degree atrioventricular (AV) block, sick sinus syndrome, or sino-atrial block, unless the patient has a functioning pacemaker (1).

The safety and effectiveness of Zeposia in pediatric patients less than 18 years of age have not been established (1).

Summary
Zeposia (ozanimod) is a sphingosine-1-phosphate (S1P) receptor modulator that binds with high affinity to S1P receptors 1 and 5. Zeposia blocks the capacity of lymphocytes to egress from lymph nodes, reducing the number of lymphocytes in peripheral blood. The mechanism by which Zeposia exerts therapeutic effects in multiple sclerosis is unknown but may involve the reduction of lymphocyte migration into the central nervous system. The safety and effectiveness of Zeposia in pediatric patients less than 18 years of age have not been established (1).

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

References