

## Mandell Center Medication Protocol: Zeposia(Ozanimod)

### Indications and Usage:

- 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.

### Prior to initiating ZEPOSIA, the following are required:

*Labwork:* within 6 months or after discontinuation of previous MS therapy

- CBC with differential
- Liver Profile
- VZV Antibody (IgG) unless confirmed case of vaccination or history of chicken pox

### *Cardiologic Assessment:*

- ECG to determine whether pre-existing conduction abnormalities are present.
- Patients with the following need cardiology clearance:
  - With significant QT prolongation (QTcF > 450 msec in males, > 470 msec in females).
  - With arrhythmias requiring treatment with Class 1a or Class III anti-arrhythmic drugs.
  - With ischemic heart disease, heart failure, history of cardiac arrest or myocardial infarction, cerebrovascular disease, and uncontrolled hypertension.
  - With a history of with second-degree Mobitz type II or higher AV block, sick-sinus syndrome, or sinoatrial heart block.

### *Current or prior medications:*

- If patients are taking anti-neoplastic, immunosuppressive, immune-modulating therapies, or if there is a history of prior use of these drugs, consider possible unintended additive immunosuppressive.
- Determine if patients are taking drugs that could slow heart rate or atrioventricular conduction. MAO inhibitors contraindicated.

### *Ophthalmic Assessment:*

- In patients with a history of uveitis, macular edema, or diabetes obtain an evaluation of the fundus, including the macula.

### *Respiratory effects:*

- Spirometric evaluation of respiratory function should be performed during therapy if clinically indicated (history of COPD, severe asthma).

*Imaging:*

- Baseline MRI Brain (with or without contrast per provider) within 3 months prior to first treatment course (may also be performed at provider discretion).
- \*For patients transitioning from Tysabri, MRI brain with and without contrast to be performed for JCV positive patients upon discontinuing Tysabri and at 6 months after discontinuing Tysabri.
- MRI Brain (with or without contrast) to be performed at provider discretion for patients with progressive forms of MS.

**Vaccinations:**

- If live attenuated vaccine immunizations are required, administer at least 1 month prior to initiation. Avoid the use of live attenuated vaccines during and for 3 months after treatment with ZEPOSIA.

**Contraception:**

- Women of childbearing potential should be counseled on the potential for a serious risk to the fetus and the need for contraception during treatment and for 3 months after stopping ZEPOSIA.

**Dosing and Administration:**

*Initiate ZEPOSIA with a 7-day titration, as shown below:*

- Days 1-4 0.23 mg once daily
- Days 5-7 0.46 mg once daily
- Day 8 and thereafter 0.92 mg once daily

**Delayed or Missed Dosing:**

- Delay initiation of ZEPOSIA in patients with an active infection until the infection is resolved.
- Do not skip a dose.

*Reinitiating ZEPOSIA After Treatment Interruption:*

- If a dose of ZEPOSIA is missed during the first 2 weeks of treatment, reinitiate treatment using the titration regimen.
- If a dose of ZEPOSIA is missed after the first 2 weeks of treatment, continue with the treatment as planned.

**Management of Medication Reaction:**

- Call your healthcare provider if you feel you are experiencing any medication related side effects.



**Patient Counseling Information:**

*Diet:*

- Avoid certain foods that are high (over 150 mg) in tyramine such as aged, fermented, cured, smoked and pickled foods. Eating these foods while taking ZEPOSIA may increase blood pressure.

*Infection:*

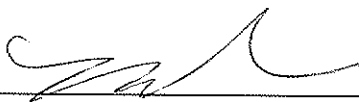
- Consider interruption of treatment with ZEPOSIA if a patient develops a serious infection.
- Because the elimination of ZEPOSIA after discontinuation may take up to 3 months, continue monitoring for infections throughout this period.

*Disease Rebound:*

- Severe exacerbation of disease, including disease rebound, has been rarely reported after discontinuation of a S1P receptor modulator. The possibility of severe exacerbation of disease should be considered after stopping ZEPOSIA treatment

**Follow up monitoring:**

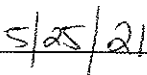
- Initial follow-up with provider every 3 months for the first year, then every 6 months.
- Labwork: every 3 months year one, then every 6 months thereafter if stable
  - CBC with differential
  - Liver Profile
- ALC  $\leq$  0.3 and or WBC  $\leq$  2.0 change to QOD dosing and repeat CBC w diff in 1 month
- Prompt Ophthalmic evaluation with vision change.
- Imaging:
  - MRI Brain with and without contrast 6 months after initiation of Zeposia.
  - Annual MRI Brain and C-Spine without contrast (or per provider discretion).



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Mandell Multiple Sclerosis Center



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Date

Reference: Zeposia PI revision 9/2020