

Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	September 17, 2021 April 5, 2023

ZEPOSIA® (ozanimod)

LENGTH OF AUTHORIZATION: Up to one year

INITIAL REVIEW CRITERIA:

- Patient must be ≥ 18 years of age.
- Prior to initiating therapy, patient must have baseline assessments including complete blood count (CBC), cardiac evaluation, liver function tests (LFTs), and test for antibodies to varicella zoster virus (VZV).
- Ophthalmic evaluation if there are any vision changes. Patients with a history of diabetes mellitus and uveitis should have an ophthalmic evaluation prior to initiation.

For the treatment of Multiple Sclerosis:

- Patient must have a diagnosis of a relapsing form of Multiple Sclerosis [e.g., relapsing remitting disease (RRMS), active secondary progressive disease (SPMS), or clinically isolated syndrome (CIS); verified by progress notes, discharge notes, or "health conditions"].
- Drug must be used as single agent therapy.
- Previous trial with insufficient response, adverse reaction or contraindication to preferred disease modifying agent(s).

For the treatment of Ulcerative Colitis:

- o Patient must have a documented diagnosis of moderately to severely active ulcerative colitis.
- Patient has demonstrated corticosteroid dependence; **OR**
- Patient has had an inadequate response (clinical documentation must be submitted demonstrating response to previous therapies) or failed to tolerate oral mesalamine, oral corticosteroids (e.g. prednisone, dexamethasone, or methylprednisolone), cyclosporine, azathioprine or 6-mecaptopurine (6-MTP); AND
- Patient has had a trial of at least one preferred biological with an FDA approved indication, and experienced inadequate response or intolerance. If a preferred agent(s) is contraindicated, trial of an alternative preferred agent is required, if appropriate.

CONTINUATION OF THERAPY:

- Patient met initial review criteria.
- Documentation of improved clinical response.
- Dosing is appropriate as per labeling or is supported by compendia

DOSING and ADMINISTRATION:

- Refer to product labeling at <u>https://www.accessdata.fda.gov/scripts/cder/daf/</u>
- Available as 0.23 mg, 0.46 mg, and 0.92 mg capsules.