

**I. Requirements for Prior Authorization of Zeposia (ozanimod)****A. Prescriptions That Require Prior Authorization**

All prescriptions for Zeposia (ozanimod) must be prior authorized.

**B. Review of Documentation for Medical Necessity**

In evaluating a request for prior authorization of a prescription for Zeposia (ozanimod), the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed Zeposia (ozanimod) for the treatment of a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling or a medically accepted indication; **AND**
2. Is prescribed Zeposia (ozanimod) by or in consultation with an appropriate specialist (i.e., a neurologist for a diagnosis of multiple sclerosis or a gastroenterologist for a diagnosis of ulcerative colitis); **AND**
3. Does not have a contraindication to Zeposia (ozanimod); **AND**
4. Is prescribed a dose that is consistent with the FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
5. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed literature; **AND**
6. For treatment of multiple sclerosis, **one** of the following:
  - a. Has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Multiple Sclerosis Agents approved for the beneficiary's diagnosis
  - b. Has a current history (within the past 90 days) of being prescribed Zeposia (ozanimod) (does not apply to non-preferred brands when the therapeutically equivalent generic is preferred or to non-preferred generics when the therapeutically equivalent brand is preferred)

See the Preferred Drug List (PDL) for the list of preferred Multiple Sclerosis Agents at:  
<https://papdl.com/preferred-drug-list>;

**AND**

7. For treatment of ulcerative colitis (UC), **both** of the following:
  - a. **Both** of the following:
    - i. Has **one** of the following diagnoses:
      - a) Mild UC that is associated with multiple poor prognostic factors<sup>1</sup>
      - b) Moderate to severe UC
    - ii. **One** of the following:
      - a) Failed to achieve remission with or has a contraindication or an intolerance

<sup>1</sup> Poor prognostic factors include initial diagnosis or clinical evidence supports the onset of symptoms at <40 years of age, extensive colitis, severe endoscopic disease (presence of large and/or deep ulcers), hospitalization for colitis, elevated inflammatory markers, low serum albumin, extra-intestinal manifestations, early need for corticosteroids (ACG 2019; AGA 2019; AGA 2020).

to an induction course of corticosteroids,

b) **One** of the following:

- (i) Failed to maintain remission with an immunomodulator in accordance with current consensus guidelines (e.g., American College of Gastroenterology, American Gastroenterological Association, European Crohn's and Colitis Organization, etc.)
- (ii) Has a contraindication or an intolerance to immunomodulators in accordance with current consensus guidelines,

c) **Both** of the following:

- (i) Has achieved remission with Zeposia (ozanimod)
- (ii) Will be using Zeposia (ozanimod) as maintenance therapy to maintain remission

b. **One** of the following:

- i. Has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Cytokine and CAM Antagonists approved or medically accepted for treatment of ulcerative colitis
- ii. Has a current history (within the past 90 days) of being prescribed Zeposia (ozanimod) (does not apply to non-preferred brands when the therapeutically equivalent generic is preferred or to non-preferred generics when the therapeutically equivalent brand is preferred)

See the Preferred Drug List (PDL) for the list of preferred Cytokine and CAM Antagonists at: <https://papdl.com/preferred-drug-list>;

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

**FOR RENEWALS OF PRIOR AUTHORIZATION FOR ZEPOSIA (OZANIMOD):** The determination of medical necessity of a request for renewal of a prior authorization for Zeposia (ozanimod) that was previously approved will take into account whether the beneficiary:

1. Is prescribed Zeposia (ozanimod) by or in consultation with an appropriate specialist (i.e., a neurologist for a diagnosis of multiple sclerosis or a gastroenterologist for a diagnosis of ulcerative colitis); **AND**
2. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
3. Does not have a contraindication to Zeposia (ozanimod); **AND**
4. For treatment of multiple sclerosis, has documented improvement or stabilization of the multiple sclerosis disease course; **AND**
5. For treatment of ulcerative colitis, experienced improvement in disease activity and/or level of functioning since starting Zeposia (ozanimod).

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in



the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for Zeposia (ozanimod). If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

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**ZEPOSIA (ozanimod) PRIOR AUTHORIZATION FORM**

<input type="checkbox"/> New request	<input type="checkbox"/> Renewal request	total pages: _____	Prescriber name:	
Name of office contact:			Specialty:	
Contact's phone number:			NPI:	MA Provider ID#:
LTC facility contact/phone:			Street address:	
Beneficiary Name:			Suite #:	City/state/zip:
Beneficiary ID#:	DOB:	Phone:	Fax:	

**CLINICAL INFORMATION**

Drug requested (check all products being requested):	<input type="checkbox"/> Zeposia 7-Day Starter Pack [(4) 0.23 mg capsules and (3) 0.46 mg capsules] --- Quantity: 1 pack for 7 days <input type="checkbox"/> Zeposia Starter Kit [(4) 0.23 mg capsules, (3) 0.46 mg capsules, and (30) 0.92 mg capsules] --- Quantity: 1 pack for 37 days <input type="checkbox"/> Zeposia capsule Strength: _____ mg Quantity: _____ Refills: _____ <input type="checkbox"/> Zeposia _____ Quantity: _____ Refills: _____	
Directions:	<input type="checkbox"/> 0.23 mg QD days 1 through 4, then 0.46 mg QD days 5 through 7, then 0.92 mg QD thereafter <input type="checkbox"/> 0.92 mg QD <input type="checkbox"/> other: _____	
Diagnosis (submit documentation):		Dx code (required):
Is the beneficiary currently being treated with Zeposia?		<input type="checkbox"/> Yes <input type="checkbox"/> No Submit documentation.
Is Zeposia being prescribed by or in consultation with a neurologist or gastroenterologist?		<input type="checkbox"/> Yes Submit documentation of <input type="checkbox"/> No consultation if applicable.
<b>Check all of the following that apply to the beneficiary and <u>SUBMIT DOCUMENTATION</u> for each item.</b> <input type="checkbox"/> Has severe untreated sleep apnea <input type="checkbox"/> Will be taking a monoamine oxidase inhibitor while taking Zeposia (e.g., selegiline, phenelzine) <input type="checkbox"/> Has a comorbid heart condition – describe: _____ <input type="checkbox"/> Experienced any of the following in the past 6 months: <div style="display: flex; justify-content: space-between;"> <div> <input type="checkbox"/> Myocardial infarction  <input type="checkbox"/> Unstable angina  <input type="checkbox"/> Stroke </div> <div> <input type="checkbox"/> Transient ischemic attack  <input type="checkbox"/> Decompensated heart failure  <input type="checkbox"/> Class III/IV heart failure </div> </div>		

**INITIAL requests**

<b>Check all of the following that apply to the beneficiary and this request and <u>SUBMIT DOCUMENTATION</u> for each item.</b> <input type="checkbox"/> Is being treated for <b>MULTIPLE SCLEROSIS (MS)</b> : <input type="checkbox"/> Has a relapsing form of MS <input type="checkbox"/> Tried and failed or has a contraindication or an intolerance to the preferred Multiple Sclerosis Agents that are FDA-approved or medically accepted for the treatment of MS. Refer to <a href="https://papdl.com/preferred-drug-list">https://papdl.com/preferred-drug-list</a> for a list of preferred Multiple Sclerosis Agents. <input type="checkbox"/> Is being treated for <b>ULCERATIVE COLITIS (UC)</b> : <input type="checkbox"/> Has moderate-to-severe disease <input type="checkbox"/> Has disease that is associated with high-risk or poor prognostic features <input type="checkbox"/> Failed to achieve remission with an induction course of corticosteroids <input type="checkbox"/> Has a contraindication or intolerance to an induction course of corticosteroids <input type="checkbox"/> Failed to maintain remission with an immunomodulator (e.g., AZA, cyclosporine, 6-MP, MTX) <input type="checkbox"/> Has a contraindication or intolerance to immunomodulators (e.g., AZA, cyclosporine, 6-MP, MTX) <input type="checkbox"/> Tried and failed or has a contraindication or intolerance to the preferred Cytokine and CAM Antagonists that are FDA-approved or medically accepted for the treatment of UC. Refer to <a href="https://papdl.com/preferred-drug-list">https://papdl.com/preferred-drug-list</a> for a list of preferred Cytokine and CAM Antagonists.	
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**RENEWAL requests**

<b>Check all of the following that apply to the beneficiary and this request and <u>SUBMIT DOCUMENTATION</u> for each item.</b> <input type="checkbox"/> For a diagnosis of <b>MULTIPLE SCLEROSIS</b> , experienced improvement or stabilization of the MS disease course since starting Zeposia <input type="checkbox"/> For a diagnosis of <b>ULCERATIVE COLITIS</b> , experienced improvement in disease activity or level of functioning since starting Zeposia	
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**PLEASE FAX COMPLETED FORM TO GATEWAY – PHARMACY DIVISION**

Prescriber Signature:	Date:
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