Highmark Wholecare
Pharmacy Division
Phone 800-392-1147 Fax 888-245-2049

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[1]
         b) Moderate to severe UC

      ii. **One** of the following:
         a) Failed to achieve remission with or has a contraindication or an intolerance

[1] 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

☐New request ☐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)*:	☐Zeposia 7-Day Starter Pack [(4) 0.23 mg capsules and (3) 0.46 mg capsules] --- Quantity: 1 pack for 7 days ☐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 ☐Zeposia capsule Strength: _____ mg Quantity: _____ Refills: _____ ☐Zeposia _____ Quantity: _____ Refills: _____
Directions:	☐0.23 mg QD days 1 through 4, then 0.46 mg QD days 5 through 7, then 0.92 mg QD thereafter ☐0.92 mg QD ☐other: _____

Diagnosis *(submit documentation)*:	Dx code *(required)*:
Is the beneficiary currently being treated with Zeposia?	☐Yes ☐No *Submit documentation.*
Is Zeposia being prescribed by or in consultation with a neurologist or gastroenterologist?	☐Yes ☐No *Submit documentation of consultation if applicable.*

Check all of the following that apply to the beneficiary and SUBMIT DOCUMENTATION for each item.

☐Has severe untreated sleep apnea
☐Will be taking a monoamine oxidase inhibitor while taking Zeposia (e.g., selegiline, phenelzine)
☐Has a comorbid heart condition – describe: _____
☐Experienced any of the following in the past 6 months:
- ☐Myocardial infarction
- ☐Unstable angina
- ☐Stroke
- ☐Transient ischemic attack
- ☐Decompensated heart failure
- ☐Class III/IV heart failure

INITIAL requests

Check all of the following that apply to the beneficiary and this request and SUBMIT DOCUMENTATION for each item.

☐Is being treated for MULTIPLE SCLEROSIS (MS):
- ☐Has a relapsing form of MS
- ☐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 https://papdl.com/preferred-drug-list for a list of preferred Multiple Sclerosis Agents.*

☐Is being treated for ULCERATIVE COLITIS (UC):
- ☐Has moderate-to-severe disease
- ☐Has disease that is associated with high-risk or poor prognostic features
- ☐Failed to achieve remission with an induction course of corticosteroids
- ☐Has a contraindication or intolerance to an induction course of corticosteroids
- ☐Failed to maintain remission with an immunomodulator (e.g., AZA, cyclosporine, 6-MP, MTX)
- ☐Has a contraindication or intolerance to immunomodulators (e.g., AZA, cyclosporine, 6-MP, MTX)
- ☐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 https://papdl.com/preferred-drug-list for a list of preferred Cytokine and CAM Antagonists.*

RENEWAL requests

Check all of the following that apply to the beneficiary and this request and SUBMIT DOCUMENTATION for each item.

☐For a diagnosis of MULTIPLE SCLEROSIS, experienced improvement or stabilization of the MS disease course since starting Zeposia
☐For a diagnosis of ULCERATIVE COLITIS, experienced improvement in disease activity or level of functioning since starting Zeposia

PLEASE FAX COMPLETED FORM TO HIGHMARK WHOLECARE – PHARMACY DIVISION

Prescriber Signature:	Date: