pa health & wellness

Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: 11/2021**
Policy Number: PHW.PDL.043.02	**Effective Date: 01/03/2022** **Revision Date: 10/2021**
Policy Name: Ozanimod (Zeposia)	

Type of Submission – Check all that apply:

- ✓ **New Policy**
- ☐ **Revised Policy***
- ☐ **Annual Review - No Revisions**
- ✓ **Statewide PDL -** *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

Name of Authorized Individual (Please type or print):	**Signature of Authorized Individual:**
Venkateswara R. Davuluri, MD	

Clinical Policy: Ozanimod (Zeposia)

Reference Number: PHW.PDL.043.02
Effective Date: 01/03/2022
Last Review Date: 10/2021

Revision Log

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with PA Health and Wellness® that Zeposia is **medically necessary** when the following criteria are met:

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 member:

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 member'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 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

[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).

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;

AND

8. If a prescription for Zeposia (ozanimod) is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in PA.CP.PMN.59 Quantity Limit Override.

   NOTE: If the member 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 member, 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 member:

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); **AND**

6. If a prescription for Zeposia (ozanimod) is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in PA.CP.PMN.59 Quantity Limit Override.

   NOTE: If the member 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 member, 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 member.

D. **Approval Duration: 6 months**

E. References

1. Zeposia Package Insert. Summit, NJ: Celgene Corporation; May 2021.
2. Olek MJ, Mowry E. Disease-modifying therapies for multiple sclerosis: Pharmacology, administration, and adverse effects. In: UpToDate [internet database]. Gonzalez-Scarano F, Dashe JF, eds. Waltham, MA: UpToDate Inc. Updated May 11, 2021. Accessed July 15, 2021.
3. Olek MJ, Mowry E. Initial disease-modifying therapy for relapsing-remitting multiple sclerosis in adults. In: UpToDate [internet database]. Gonzalez-Scarano F, Dashe JF, eds. Waltham, MA: UpToDate Inc. Updated June 4, 2021. Accessed July 15, 2021.
4. Rae-Grant A, Day GS, Marrie RA, et al. Practice guideline recommendations summary: Disease-modifying therapies for adults with multiple sclerosis: Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology. Neurology. 2018; 90:777.
5. Sandborn WJ, Feagan BG, Hanauer S, et al. Long-term efficacy and safety of ozanimod in moderately to severely active ulcerative colitis: results from the open-label extension of the randomized, phase 2 TOUCHSTONE study. J Crohns Colitis. 2021;15(7):1120-1129.
6. Cohen RD, Stein AC. Management of moderate to severe ulcerative colitis in adults. In: UpToDate [internet database]. Lamont JT, Robson KM, eds. Waltham, MA: UpToDate Inc. Updated August 23, 2021. Accessed August 26, 2021.
7. Harbord M, Eliakim R, Bettenworth D, et al. Third European evidence-based consensus on diagnosis and management of ulcerative colitis. Part 2: current management. J Crohns Colitis; 2017;11(7):769-784.
8. Rubin DT, Ananthakrishnan AN, Siegel CA, Sauer BG, Long MD. ACG clinical guideline: ulcerative colitis in adults. Am J Gastroenterol. 2019;114:384-413.
9. Ko CW, Singh S, Feuerstein JD, Falck-Ytter C, Falck-Ytter Y, Cross RK. AGA clinical practice guidelines on the management of mild-to-moderate ulcerative colitis. Gastroenterology. 2019;156:748-764.
10. Feuerstein JD, Isaacs KL, Schneider Y, Siddique SM, Falck-Ytter Y, Singh S. AGA

clinical practice guidelines on the management of moderate to severe ulcerative colitis. Gastroenterology. 2020;158:1450-1461.

Reviews, Revisions, and Approvals	Date
Policy created	10/2021