ZEPOSIA® (ozanimod) Resources for Healthcare Providers

INDICATION: ZEPOSIA is indicated for the treatment of moderately to severely active ulcerative colitis (UC) in adults.

SELECT IMPORTANT SAFETY INFORMATION

Contraindications:

- Patients who in the last 6 months, experienced myocardial infarction, unstable angina, stroke, transient ischemic attack (TIA), decompensated heart failure requiring hospitalization, or Class III/IV heart failure or have a presence of Mobitz type II second-degree or third-degree atrioventricular (AV) block, sick sinus syndrome, or sino-atrial block, unless the patient has a functioning pacemaker
- Patients with severe untreated sleep apnea
- Patients taking a monoamine oxidase (MAO) inhibitor

Please see Important Safety Information on pages 5–7 and full Prescribing Information and Medication Guide at http://www.zeposiahcp.com/ulcerative-colitis/.

Bristol Myers Squibb™

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ZEPOSIA 360 Support™ Program Overview

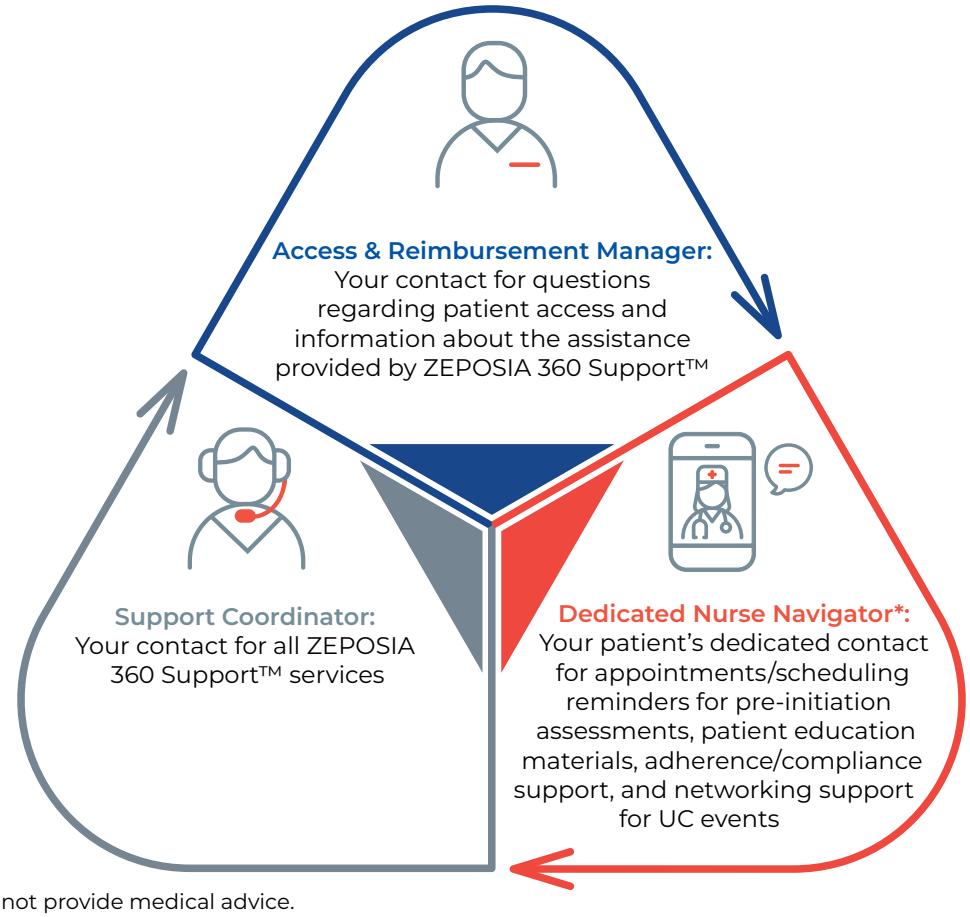
Patient Pre-Initiation Support

Patient Financial Support

Patient Access Support

Ongoing Support

Your ZEPOSIA 360 Support™ Team



UC – ulcerative colitis.
*Nurse Navigators do not provide medical advice.

Enroll in ZEPOSIA 360 Support™

Enroll online at **www.ZEPOSIAportal.com**

Fax us at **1-833-727-7701**

Call us at **1-833-ZEPOSIA (1-833-937-6742)**
(translation services available)
Monday – Friday, 8 AM – 8 PM ET

Visit **https://www.zeposiahcp.com/ulcerative-colitis/**

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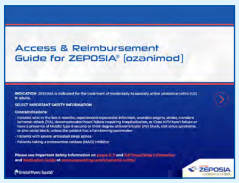
ZEPOSIA® (ozanimod) Resources



Access and Reimbursement Guide

Provides an overview of the ZEPOSIA 360 Support™ Program, assistance available from initiation to delivery, the step-by-step process for getting started with ZEPOSIA, potential payer coverage scenarios, a prior authorization checklist, considerations for navigating formulary exceptions and appeals, and example letters of medical necessity, appeal, and formulary exception

Specialty Pharmacy Resource

Provides a quick overview of the benefits of using specialty pharmacies (SPs) and a list of SPs ready to handle ZEPOSIA prescriptions

Portal Assist

Provides an outline of how to enroll and manage patients using the ZEPOSIA Portal

Baseline Testing Clearance Form

Form that is submitted by the prescriber to ZEPOSIA 360 Support™ to verify that a patient's baseline tests have been reviewed and that they are able to start therapy. This form is only needed for patients who have their baseline tests done through ZEPOSIA 360 Support™ at home

Baseline Assessment Assistance Brochure

Brochure detailing baseline assessments overview and assistance options for ZEPOSIA initiation assessments

Dosing, Initiation, and Patient Support Guide

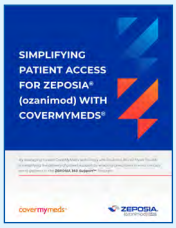
Provides important information on how to get patients started on ZEPOSIA and an overview of assistance available through the ZEPOSIA 360 Support™ Program

Template Letters

Template letters of medical necessity, appeals, and formulary exception

In-Home Support Overview

Provides brief overview of in-home support available to patients



CoverMyMeds Overview

Overview of support available through CoverMyMeds® to enroll patients in the ZEPOSIA 360 Support™ Program and assist with access

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Indication and Important Safety Information for ZEPOSIA® (ozanimod)

Indication

ZEPOSIA® (ozanimod) is indicated for the treatment of moderately to severely active ulcerative colitis (UC) in adults.

IMPORTANT SAFETY INFORMATION

Contraindications:

- Patients who in the last 6 months, experienced myocardial infarction, unstable angina, stroke, transient ischemic attack (TIA), decompensated heart failure requiring hospitalization, or Class III/IV heart failure or have a presence of Mobitz type II second-degree or third-degree atrioventricular (AV) block, sick sinus syndrome, or sino-atrial block, unless the patient has a functioning pacemaker
- Patients with severe untreated sleep apnea
- Patients taking a monoamine oxidase (MAO) inhibitor

Infections: ZEPOSIA may increase the susceptibility to infections. Life-threatening and rare fatal infections have occurred in patients receiving ZEPOSIA. Obtain a recent (i.e., within 6 months or after discontinuation of prior UC therapy) complete blood count (CBC) including lymphocyte count before initiation of ZEPOSIA. Delay initiation of ZEPOSIA in patients with an active infection until the infection is resolved. Consider interruption of treatment with ZEPOSIA if a patient develops a serious infection. Continue monitoring for infections up to 3 months after discontinuing ZEPOSIA.

- Herpes zoster was reported as an adverse reaction in ZEPOSIA-treated patients. Herpes simplex encephalitis and varicella zoster meningitis have been reported with sphingosine 1-phosphate (S1P) receptor modulators. Patients without a healthcare professional-confirmed history of varicella (chickenpox), or without documentation of a full course of vaccination against varicella zoster virus (VZV), should be tested for antibodies to VZV before initiating ZEPOSIA. A full course of vaccination for antibody-negative patients with varicella vaccine is recommended prior to commencing treatment with ZEPOSIA.
- Cases of fatal cryptococcal meningitis (CM) were reported in patients treated with another S1P receptor modulator. If CM is suspected, ZEPOSIA should be suspended until cryptococcal infection has been excluded. If CM is diagnosed, appropriate treatment should be initiated.
- In the UC clinical studies, patients who received ZEPOSIA were not to receive concomitant treatment with antineoplastic, non-corticosteroid immunosuppressive, or immune-modulating therapies used for treatment of UC. Concomitant use of ZEPOSIA with any of these therapies would be expected to increase the risk of immunosuppression. When switching to ZEPOSIA from immunosuppressive medications, consider the duration of their effects and their mode of action to avoid unintended additive immunosuppressive effects.
- Use of live attenuated vaccines should be avoided during and for 3 months after treatment with ZEPOSIA. If live attenuated vaccine immunizations are required, administer at least 1 month prior to initiation of ZEPOSIA.

Please see Important Safety Information continued on next page, and full Prescribing Information and Medication Guide at http://www.zeposiahcp.com/ulcerative-colitis/.

Important Safety Information for ZEPOSIA® (ozanimod) (cont.)

Progressive Multifocal Leukoencephalopathy (PML): PML is an opportunistic viral infection of the brain that typically occurs in patients who are immunocompromised, and that usually leads to death or severe disability.

PML has been reported in patients treated with S1P receptor modulators, including ZEPOSIA, and other UC therapies and has been associated with some risk factors. If PML is suspected, withhold ZEPOSIA and perform an appropriate diagnostic evaluation.

If confirmed, treatment with ZEPOSIA should be discontinued.

Bradyarrhythmia and Atrioventricular Conduction Delays: Since initiation of ZEPOSIA may result in a transient decrease in heart rate and atrioventricular conduction delays, dose titration is recommended to help reduce cardiac effects. Initiation of ZEPOSIA without dose escalation may result in greater decreases in heart rate. If treatment with ZEPOSIA is considered, advice from a cardiologist should be sought for those individuals:

- with significant QT prolongation
- with arrhythmias requiring treatment with Class 1a or 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 Mobitz type II second-degree or higher AV block, sick sinus syndrome, or sino-atrial heart block

Liver Injury: Elevations of aminotransferases may occur in patients receiving ZEPOSIA. Obtain liver function tests, if not recently available (i.e., within 6 months), before initiation of ZEPOSIA. Patients who develop symptoms suggestive of hepatic dysfunction should have hepatic enzymes checked and ZEPOSIA should be discontinued if significant liver injury is confirmed. Caution should be exercised when using ZEPOSIA in patients with history of significant liver disease.

Fetal Risk: There are no adequate and well-controlled studies in pregnant women. Based on animal studies, ZEPOSIA may cause fetal harm. Women of childbearing potential should use effective contraception to avoid pregnancy during treatment and for 3 months after stopping ZEPOSIA.

Increased Blood Pressure: Increase in systolic pressure was observed after about 3 months of treatment and persisted throughout treatment. Blood pressure should be monitored during treatment and managed appropriately. Certain foods that may contain very high amounts of tyramine could cause severe hypertension in patients taking ZEPOSIA. Patients should be advised to avoid foods containing a very large amount of tyramine while taking ZEPOSIA.

Respiratory Effects: ZEPOSIA may cause a decline in pulmonary function. Spirometric evaluation of respiratory function should be performed during therapy, if clinically indicated.

Please see Important Safety Information continued on next page, and full Prescribing Information and Medication Guide at http://www.zeposiahcp.com/ulcerative-colitis/.

Important Safety Information for ZEPOSIA® (ozanimod) (cont.)

Macular Edema: S1P modulators have been associated with an increased risk of macular edema. Patients with a history of uveitis or diabetes mellitus are at increased risk. Patients with a history of these conditions should have an ophthalmic evaluation of the fundus, including the macula, prior to treatment initiation and regular follow-up examinations. An ophthalmic evaluation is recommended in all patients at any time if there is a change in vision. Continued use of ZEPOSIA in patients with macular edema has not been evaluated; potential benefits and risks for the individual patient should be considered if deciding whether ZEPOSIA should be discontinued.

Posterior Reversible Encephalopathy Syndrome (PRES): Rare cases of PRES have been reported in patients receiving a S1P receptor modulator. If a ZEPOSIA-treated patient develops unexpected neurological or psychiatric symptoms or any symptom/sign suggestive of an increase in intracranial pressure, a complete physical and neurological examination should be conducted. Symptoms of PRES are usually reversible but may evolve into ischemic stroke or cerebral hemorrhage. Delay in diagnosis and treatment may lead to permanent neurological sequelae. If PRES is suspected, treatment with ZEPOSIA should be discontinued.

Unintended Additive Immunosuppressive Effects From Prior Immunosuppressive or Immune-Modulating Drugs: When switching from drugs with prolonged immune effects, the half-life and mode of action of these drugs must be considered to avoid unintended additive immunosuppressive effects while at the same time minimizing risk of disease reactivation. Initiating treatment with ZEPOSIA after treatment with alemtuzumab is not recommended.

Immune System Effects After Stopping ZEPOSIA: After discontinuing ZEPOSIA, the median time for lymphocyte counts to return to the normal range was 30 days with approximately 90% of patients in the normal range within 3 months. Use of immunosuppressants within this period may lead to an additive effect on the immune system, therefore caution should be applied when initiating other drugs 4 weeks after the last dose of ZEPOSIA.

Most Common Adverse Reactions (≥ 4%): liver test increased, upper respiratory infection, and headache.

Use in Specific Populations: Hepatic Impairment: Use is not recommended.

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Bristol Myers Squibb is committed to transparency. For information on the list price of ZEPOSIA as well as information regarding average out-of-pocket costs and assistance programs, please visit ZEPOSIA.com/price.

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