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

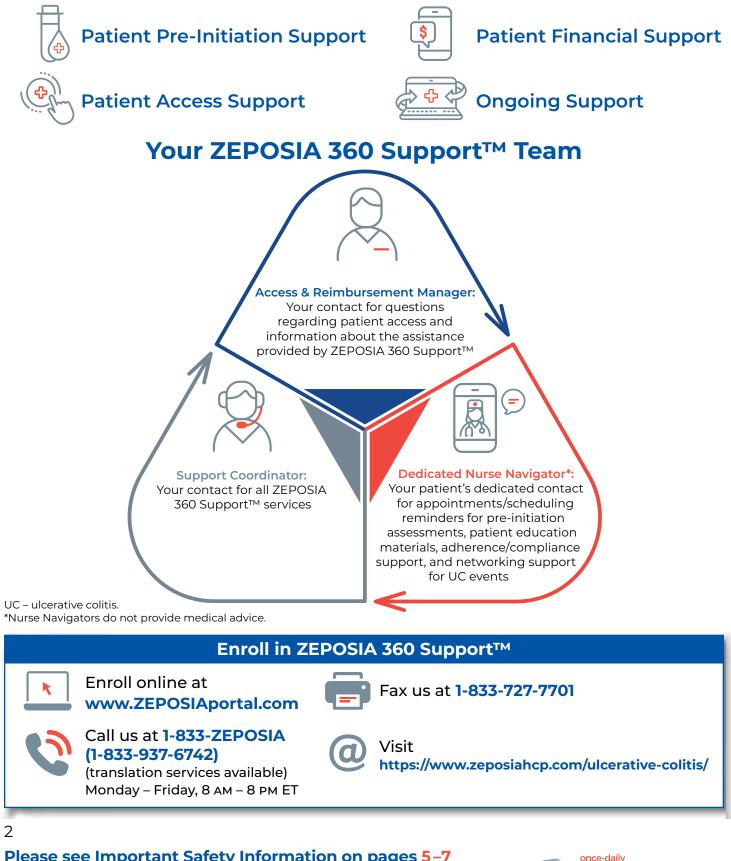
Please see Important Safety Information on pages <u>5–7</u> and <u>full Prescribing Information</u> and <u>Medication Guide</u> at <u>http://www.zeposiahcp.com/ulcerative-colitis/</u>.



lll Bristol Myers Squibb



ZEPOSIA 360 Support[™] Program Overview



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



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



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

	Netw [Internation]	SNR .	Note Providence	Date:	Nama, Pullim 1 Prot							
	DOB/D-Company Partners Facility (Differential Frame (D-C)	A Design of the local of the lo	Califier (Hotory C) Roundary (Hotory C) 4	A PROVIDE AND A DESCRIPTION	Pattern Factory C Northeast (1996)							
	Early of service (concerne)	Conception of the local sectors of the local sector	Control of Services (1979) 1970	The train Date	Energy of Service (1975) 197							
In Recard to Annual Despite to 20000 loans		We jurise of Harding Second in 2010 of Spectrum		In later of lateral he fill that includes								
In the other sectors and		the literature has been		The second second second second								
	the second se											
and writing in John of a survey of the regard and interactional Charlestonic of Deemer, 101 Bester, 21 second: An The Bridge 1999 Transmission	nge fo 2000 til stanned forte lagtered dit. Nge for 2000 til standard for the lagtered dit.	International Description of Despension, Diff. Research, Onco. Residenced and diversity and a static scattering and the sec-		Even unling a Carbon of Lancer France, Sa Anguard Association Re-The Interference (Francesco), international Caro, National Algo- diagnosis and a composition of the Interference (Interference)).								
Currents 2000 A since an your formulary feature / a performed in up and add that any apartocities featured they be filled.	n maanting on anoption for 2000 Align in an Antikan a Disk thick, be serviced as a president for the patient reag-	period day clinic and reader tradement with 20108A. I with material data the patient's trademic factory and material platfields is a period operation of the patients forth		Reservers any experience with invaring partners, with intervention partnership to define and model at testing to the second at the before smallers the filtered attractions and related in the second at the								
	And the second se	Administration in 2021 for the traverse of moderate your	the that was approved by the strated and (mag areas were shorted as setting (setting) and (mag									
Debble company in provide the term of the provide the second system of the debble of t		All speak to the copy of a log sector speak to the copy of the speak to the copy of the speak to the copy of the speak to		2004 As a simple of impacts (2004 model) and 2004 model of the set of th								
							realizati solare in response in the local. Considering the patient's Starry encounded and being treatment of "A In read-only researcy for registrant.					
							Tark its for you time and immediate attention to the	Nord.	Taria		ability of the second s	the party of the party of the
							Stands.		Designment provide service and prove		There are, for your time indicate and the manufacture of the segment.	
						Respondence in the second seco	and the second diversion	pretty.				
Alarma (La real construction of the second				Plasta faits and a Miname, and Alfred								
	Providence (marging) Providence (marging)	Name (Associations) 000 (Print Association) Pater (April (Charles (Source (Charles (International Activity	Sante (march channe) Gelle Schwarz (march ch								
	APR Description	DOB (HERADAN) Palent Rating & Australia (Herada) Settempo Nanther (Herada)	ATTA Double of the second	Seller Protection (Control of Control of Con								
	And Department (Institution) (Institution) (Institution) (Institution)	DOB (HERADING)	NCA Contraction (Social and Social Contraction (Social and Social Contraction (Social Cont	grine providences								
	And Street or Street land	DOB (HERADAN) Palent Rating & Australia (Herada) Settempo Nanther (Herada)	ATTA Designed in the second	Seller Protection (Control of Control of Con								
	And Department (Institution) (Institution) (Institution) (Institution)	DOB (HERADAN) Palent Rating & Australia (Herada) Settempo Nanther (Herada)	NCA Contraction (Social and Social Contraction (Social and Social Contraction (Social Cont	Seller Protection (Control of Control of Con								
	APR (supported) provide memory (supported) provid	DD (ordered) Particle 2474 (2) foreign (2014) (2014) Millionale Agenty (2014) (2014) Galid d'Annas (2016) (2014) Galid d'Annas (2016) (2014) (2014) Galid d'Annas (2014) (2014) (2014) (2014) (2014) d'Annas (2014) (2014) (2014) (2014) (2014) (2014)	All No Comparison (Note on All Annual Comparison) Note on All Annual Comparison Note on All Annual C	Billio (Antonios) Patrice and Antonio Antonio Antonio Balancia de Antonio Antonio Antonio Designi d'Antonio (Antonio A								
	Alley Structures () Long on the structure of the	DB (2014)	eff (a Europerson) history and examples and example history and examples and examples history and examples and examples history and examples and examples and history and	Billio (Antonios) Patrice and Antonio Antonio Antonio Balancia de Antonio Antonio Antonio Designi d'Antonio (Antonio A								
	Alth Structures) Index (or set in the set in t	Sile (Include) Sile (Include)	Hit is Desirement Desire and examples and examples Desire and examples Desire and examples Desire and examples and and and Desire and and and and and and Desire and and and and Desire and and and and Desire and and and Desire and and and Desire and	Use an average of the second s								
	And Supervised And Supervised And Supervised And Supervised Bit Supervised B	Description Descripti Descripti Description Description Description	REF (Countering) Ref	The second secon								
	Mits Strangenover manufacture and an anti- manufacture and an anti- manufacture and an anti- manufacture and anti- manufacture anti- manu	See The Section of th	All The Company C	The Share Sh								
	High Strangensky Handler Strangensky Hand		All Concerning Automation and Automation Automation and Automation and Automation Automation and Automation Automati	An end of the end of t								
	And the second s	An experimental and a second an	Alter and an annual and an annual and annual and annual an	We have a set of the set of								
	 Markansen, Santanana, Santana, Santana, Santana, Santana, Santan		All Experiments and the second secon	We have a set of the set of								
	 March March March		Alter and an antibal a									
	<pre>encode set of the set of the</pre>		An example of the exa									
	An and a second se		Alter and an antibal a									
	An and a second se		Alter and an antibal a									

A Helpful Or Support You Your ZEPOS	in Man IA Patier	aging nts	,
Helphal, Practical, and Se			
Page Party of Page 1 and a submitted of the Page 1 and 1 an	in other reactor for a		
ha Arthui Azhika antonaki Miyozif di adah, da pris	the set is still a read	k tr harthing youthte Thanser" Pearset.	alther,
An Efficient Print In Martin	and Barbara Canada		
And a second sec	-		
The All Cost Patient areas with a 1 forder costs that report attends	for family separate		-
Catling Stated is Easy			
Contract of BECKENNEL Law 1 "Recolling of Black "Recolling and the patients			
		V ZEF	205

Portal Assist

prescriptions

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

Support in Eligible	
Patients' Homes	
DECOMPTION AND REAL PROVIDE OF THE REAL	
States Strates	
With 20 NOSEA 360 Support" banding assessment is say in	a surface and
Assessments for all Raisels Rive to that Draw-onthis line and Assessment	
According - Second and the second sec	
White the last of the all shades and the second second the second the last second the second se	digiting digiting
Research the for the barrier barrier to the total barr provide a second	
ef funte autorite adente a resultagi anti disente i dan disetta autorite antidati antidati antidati antidati alternativa	
Be 64 Providing extension to Director Annual Providence of the Pro	The state of
Support for Exactline Assessments is among involve minimum to the linest to energy error the inner line for the second data many in the linest support to our errors	
 Address of the period party and efficiency without any fairly period of the period of the period of the period. An experiod to the period of the period beam of the period of the period. An experiod of the period of the period of the period of the period of the period of the period of the period of the period of the period of the period of the period of the period of the period of the period of the period of the period of the period of the period o	the latter

In-Home Support Overview

Provides brief overview of in-home support available to patients

	POILA MASICOLAT
VERIFICATION OF BASELINE TEST COMPLETION	For to MED Age 201
ANTEROCTIONS FOR MALTINGAR PROVIDER AND/OR ANTIGATION DEPERSION/ANTER CONTRACTOR ANTERNA ANTERNA CONTRACTOR ANTERNA ANTERNA CONTRACTOR ANTERNA CON	
C management of the second	
PATIENT INFORMATION	
	-
Correst Contractor	Circleson .
NEALTHCARE PROVIDEN'S AUTHORIZATION Subject of the second	
Automation in the second secon	

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



CoverMyMeds Overview

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



Baseline Assessment Assistance Brochure

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

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



3



Enroll in ZEPOSIA 360 Support™

Enroll online at www.ZEPOSIAportal.com



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



Fax us at 1-833-727-7701



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

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



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 SIP 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 <u>full Prescribing</u> <u>Information</u> and <u>Medication Guide</u> at <u>http://www.zeposiahcp.com/ulcerative-colitis/</u>.



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 SIP 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 <u>full Prescribing</u> <u>Information</u> and <u>Medication Guide</u> at <u>http://www.zeposiahcp.com/ulcerative-colitis/</u>.





Macular Edema: SIP 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 SIP 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.

Please see the <u>full Prescribing Information</u> and <u>Medication Guide</u>, available at <u>http://www.zeposiahcp.com/ulcerative-colitis/</u>.

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.

ZEPOSIA, ZEPOSIA 360 Support and ZEPOSIA logo are trademarks of Celgene Corporation, a Bristol Myers Squibb company.

