Ulcerative Colitis

Authorization & Appeals Guide for ZEPOSIA® (ozanimod)

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 ZEPOSIAhcp.com/ulcerative-colitis/

Bristol Myers Squibb™

once-daily ZEPOSIA™ (ozanimod) 0.92 mg capsules

Guide Overview

At Bristol-Myers Squibb (BMS) Company, we believe patient and provider support can be critical components of access, affordability, and adherence. Once the prescriber has decided to prescribe ZEPOSIA® (ozanimod), the ZEPOSIA 360 Support™ Program is ready to help you and your patients navigate the moderately to severely active UC treatment journey.

BMS created this guide to support gastroenterology practices in navigating:

- **Authorizations**
- **Appeals**
- **Patient Support and Resources**

For additional information or patient-specific assistance, please contact your ZEPOSIA 360 Support™ coordinator at 1-833-ZEPOSIA (1-833-937-6742).

The accurate completion of reimbursement- or coverage-related documentation is the responsibility of the healthcare provider and patient. Bristol Myers Squibb and its agents make no guarantee regarding reimbursement for any service or item.

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Contact ZEPOSIA 360 Support™

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

Visit ZEPOSIAhcp.com/ulcerative-colitis

HCP – healthcare provider.

once-daily ZEPOSIA™ (ozanimod) 0.92 mg capsules

Please see Important Safety Information on pages 5-7 and full Prescribing Information and Medication Guide at ZEPOSIAhcp.com/ulcerative-colitis/

ZEPOSIA® (ozanimod)

Indication and Important Safety Information

ZEPOSIA® (ozanimod) Indication and Important Safety Information

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.

ZEPOSIA® (ozanimod) Important Safety Information (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.

ZEPOSIA® (ozanimod) Important Safety Information (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.

ZEPOSIA 360 Support™

For patients prescribed ZEPOSIA® (ozanimod)

ZEPOSIA 360 Support™ to Help Patients Begin Therapy

- **Electronic Start Form and prior authorization (PA) submissions** available through covermymeds®
- **In-home, nationwide screening** with scheduling and appointments available **7 days per week including evenings** for eligible, commercially insured patients
- A free **ZEPOSIA starter kit**
- Eligible, commercially insured patients may receive up to **2 years of ZEPOSIA through the Bridge Program** if there is a delay or denial in coverage
- Eligible, commercially insured patients may pay as little as **$0 in out-of-pocket costs per prescription**, subject to a maximum benefit of $18,000 during a calendar year
- **Local, dedicated support** through an Access and Reimbursement Manager (ARM) team

ZEPOSIA (ozanimod) 0.92 mg capsules 360 SUPPORT™

For additional information, including terms and conditions, please see page 31 in this guide and the HCP website

Getting Started With ZEPOSIA® (ozanimod)

Accessing ZEPOSIA® (ozanimod) Checklist

- ☐ Enroll your patient in ZEPOSIA 360 Support™ electronically through covermymeds® or by faxing the **Start Form** to **1-833-727-7701**

- ☐ If you would like your patient to receive the following support, check the appropriate box on the **Start Form**
  - In-home or in-office screening assistance
  - Free ZEPOSIA starter kit
  - Bridge Program
  - Financial assistance

For additional information, including terms and conditions, please see page **31** in this guide and the **HCP website**

- ☐ Advise your patient to save the ZEPOSIA 360 Support™ Nurse Navigator[a] phone number **1-833-937-6742** in their phone

- ☐ Complete **required screening** or submit screening **clearance form** to ZEPOSIA 360 Support™

- ☐ If required, submit a PA electronically through covermymeds® or directly to the patient's insurance

Contact ZEPOSIA 360 Support™

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

Visit **ZEPOSIAhcp.com/ulcerative-colitis**

[a]Nurse Navigators cannot provide medical advice.

once-daily ZEPOSIA™ (ozanimod) 0.92 mg capsules

Enrolling Your Patient in ZEPOSIA 360 Support™

Access the ZEPOSIA 360 Support™ Program Start Form through covermymeds®, the **HCP website**, or the **HCP portal**

Indicates a field that MUST be completed for this form to be processed.

The Start Form cannot be processed without the patient or patient representative signature. eSignatures may be provided at www.BMSesign.com

Advise your patient to save the ZEPOSIA 360 Support™ Nurse Navigator phone number **1-833-937-6742** in their phone

Enroll in ZEPOSIA 360 Support™ by submitting the Start Form

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

Enroll online at covermymeds®

If you need assistance, our support team is happy to help

Call ZEPOSIA 360 Support™ at **1-833-ZEPOSIA (1-833-937-6742)**
(translation services available)

Visit **ZEPOSIAhcp.com/ulcerative-colitis**

[a]Nurse Navigators cannot provide medical advice.

once-daily ZEPOSIA™ (ozanimod) 0.92 mg capsules

Screenings

Screening for all patients prior to first dose – Within the last 6 months

Obtain blood work

- Complete blood count (CBC), including lymphocyte count (within the last 6 months or after discontinuation of prior UC therapy)
- Transaminase and total bilirubin levels

One-time electrocardiogram (ECG) to determine whether pre-existing conduction abnormalities are present

Screening only for select patients prior to first dose

With a history of uveitis, macular edema, or diabetes mellitus – ophthalmic evaluation of the fundus, including the macula

Without documentation of history of varicella-zoster virus/chicken pox, or documentation of a full course of vaccination, test for antibodies

- If live *attenuated* immunizations are required, administer at least 1 month prior to initiation

Evaluate current and prior medications before initiation of treatment

If screening assistance is requested on the Start Form, the prescriber must review screening results and provide clearance for the patient to start therapy. Submit the baseline testing clearance form by fax 1-833-727-7701 or through covermymeds®.

Screenings May Be Completed in Your Office or in the Patient's Home

In-office

Commercially insured patients may be reimbursed for out-of-pocket costs associated with required screenings, subject to a maximum benefit of $2,000 during a calendar year.

To request reimbursement, contact the ZEPOSIA 360 Support™ Program at 1-833-ZEPOSIA.

In-home

Patients may receive screenings in their home, administered by a medical technician. The patient's insurance will not be billed, and the patient will not be responsible for any out-of-pocket costs.

If appropriate, certain at-risk patients may also receive their ophthalmic exam in their home.

In-home, nationwide screening with scheduling and appointments available 7 days per week including evenings for eligible, commercially insured patients

Please see page 13 for a complete list of screenings

For additional information, including terms and conditions, please see page 31 in this guide and the HCP website

ZEPOSIA® (ozanimod) Starter Kit

A free ZEPOSIA starter kit containing a 7-day starter pack and a maintenance supply is available

You may request a starter kit for your patient by selecting the appropriate box on the Start Form

In order to receive a starter kit, the patient must be prescribed ZEPOSIA for an FDA-approved indication, must not be receiving a 37-day sample from your office, and the Start Form must be submitted directly to ZEPOSIA 360 Support™

For additional information, including terms and conditions, please see page 31 in this guide and the HCP website

ZEPOSIA Starter Kit

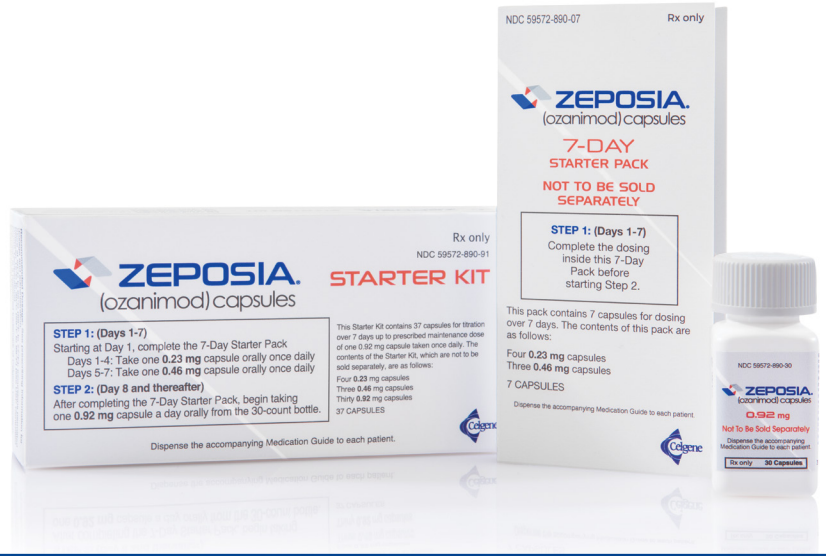
7-day starter pack

A blister pack with 7 capsules for the 7-day, dose-titration period

+

30-day supply

30 capsules of the maintenance dose (0.92 mg) for the first full month of therapy



FDA – Food and Drug Administration.
Image above is for illustrative purposes only. Actual product packaging may vary.

once-daily ZEPOSIA™ (ozanimod) 0.92 mg capsules

Please see Important Safety Information on pages 5-7 and full Prescribing Information and Medication Guide at ZEPOSIAhcp.com/ulcerative-colitis/

Coverage and Access to ZEPOSIA® (ozanimod)

Coverage Scenarios

ZEPOSIA 360 Support™ will complete a benefit verification to determine your patient's coverage and out-of-pocket costs for ZEPOSIA® (ozanimod). Benefit verification results will be faxed to your office and may note that your patient's insurance requires additional information based on one of the coverage scenarios outlined below.

1 COVERED: Prior authorization required

Payer requires an authorization to obtain:

- Additional information about your patient's diagnosis and medical history
- Clinical rationale for the course of treatment
- Confirmation of prescription by a specialist

Tip: Review the PA checklist on page 18 and template letters of medical necessity on pages 23-28.

2 COVERED: Step therapy required

Payer may require your patient to try and fail 1 or more UC therapies prior to approving coverage for ZEPOSIA

Tip: More than half of all US states have enacted laws to address step therapy requirements.

For additional information on your state, contact your ARM team. Review the step therapy template letter on page 25.

3 NOT COVERED: Formulary exception may be available

If ZEPOSIA is not covered because it is not listed on the payer's formulary, you or your patient may be able to request a formulary exception

Tip: For additional information on formulary exceptions, please see page 19 and a formulary exception template letter on page 26.

Prior Authorization (PA) Checklist

PA best practices

covermymeds® offers electronic prior authorization (ePA) support including submission and tracking of ePAs

Review the PA requirements for your patient's plan and the submission options (eg, by covermymeds®, electronic transaction, secure email, online portal, phone, or fax)

Tip: Many plans have a PA request form available on their websites. Be sure you use the correct form for the patient's health plan. Payers may also have multiple versions of forms for different plans (eg, Medicare Advantage vs private commercial offering)

If the PA form is general and doesn't include rationale for treatment and a summary of the patient's diagnosis and history, you may consider submitting a letter of medical necessity and/or supporting medical information

Where to find information

If you have enrolled your patient in ZEPOSIA 360 Support™, the program will send you PA requirements. For additional information, contact ZEPOSIA 360 Support™ or your patient's health insurance plan

You can call the plan or visit their website to review PA submission options. ZEPOSIA 360 Support™ can also assist with this process

Tip: If you determine that the authorization request is urgent or requires expedited review, consider noting this on the top of the request.

Package configuration	Tablet strength	NDC number
Bottles of 30	0.92 mg ozanimod	59572-820-30
7-day starter pack	7-capsule starter pack containing: (4) 0.23 mg ozanimod capsules and (3) 0.46 ozanimod mg capsules	59572-810-07
Starter kit (7-day starter pack and 0.92 mg 30-count bottle)	37-capsule starter kit including: one 7-capsule starter pack containing: (4) 0.23 mg ozanimod capsules and (3) 0.46 mg ozanimod capsules and one bottle containing: (30) 0.92 mg ozanimod capsules	59572-890-91 59572-890-07 59572-890-30

NDC – National Drug Code.

If your patient will be receiving a free ZEPOSIA starter kit, PA is required for the maintenance dose only.

once-daily ZEPOSIA™ (ozanimod) 0.92 mg capsules

Please see Important Safety Information on pages 5-7 and full Prescribing Information and Medication Guide at ZEPOSIAhcp.com/ulcerative-colitis/

Navigating Exceptions and Appeals

Navigating formulary exceptions

An exception may be requested to obtain a product that is not included in a plan's formulary or to request removal of a utilization management requirement for a formulary product, such as:

- **Step therapy requirement not met**
- **Product is non-preferred**
- **Quantity limit exceeded**

Navigating appeal requests

If a coverage determination for ZEPOSIA® (ozanimod) is unfavorable, the treating HCP or patient may submit an appeal. To increase the chance of appeal success:

- Ensure the appeal is organized and clearly written with supporting clinical information
- Provide clinical rationale as to why the preferred product is not appropriate for the patient
- If an appeal is denied, a peer-to-peer review may be available. For additional information, contact ZEPOSIA 360 Support™

Refer to the health plan's specific guidelines for additional information

Bridge Program

BMS is committed to making ZEPOSIA® (ozanimod) accessible to appropriate patients

Eligible, commercially insured patients may receive up to 2 years of ZEPOSIA through the Bridge Program if there is a delay or denial in coverage

Patient is eligible to continue receiving ZEPOSIA up to 2 years

- **Submit a prior authorization**
- Share the prior authorization determination with ZEPOSIA 360 Support™
- **Submit an appeal** (within 90 days)
- Share the appeal determination with ZEPOSIA 360 Support™

If you need assistance, our support team is happy to help

Call ZEPOSIA 360 Support™ at
1-833-ZEPOSIA (1-833-937-6742)
(translation services available)

Please visit ZEPOSIAportal.com

For additional information, including terms and conditions, please see page 31 in this guide and the HCP website

Template Letters

Supporting Information

The example templates in this section may be used to support requests for access to ZEPOSIA® (ozanimod). The letters should be submitted with relevant medical records, on your practice's letterhead, and signed by the prescriber.

The following supporting information may be included within the letters:

Disease summary may include the following if applicable

- Patient's diagnosis, condition, and history
- Previous therapies used to treat UC and the patient's response to those therapies
- Description of the patient's recent symptoms
- Documentation of required screenings
- Other relevant medical information

Treatment plan

- The treatment plan should include the dosage and treatment escalation schedule, as appropriate

Additional documentation

- Denial letter
- Prescribing Information
- Food and Drug Administration (FDA) approval letter
- Clinical practice guidelines
- Clinical notes and medical records

The information provided in the template letter is for informational purposes for patients who have been prescribed ZEPOSIA. These template letters are not intended to substitute for a prescriber's independent clinical decision making.

Letter of Medical Necessity for Patients Not Actively on Treatment

[Date]
[Health Plan Name]
ATTN: [Department]
[Medical/Pharmacy Director Name]
[Health plan address][City, State Zip]

Name: [Patient's Name]
DOB: [XX/XX/XXXX]
Patient Policy ID Number: [Policy ID #]
Reference Number: [Reference #]
Date(s) of Service: [XX/XX/XXXX]

Re: Letter of Medical Necessity for ZEPOSIA® (ozanimod)

Dear [Medical/Pharmacy Director Name],

I am writing on behalf of [patient's name] to request coverage for ZEPOSIA® (ozanimod) for the treatment of [diagnosis], *International Classification of Diseases, 10th Revision, Clinical Modification* diagnosis code [diagnosis code]. I have reviewed your drug coverage policy and believe that the appropriate treatment decision at this time is to initiate treatment with ZEPOSIA. This letter provides the clinical rationale and relevant information about the patient's medical history.

ZEPOSIA is a sphingosine 1-phosphate (S1P) receptor modulator that was approved by the US Food and Drug Administration in 2021 for the treatment of moderately to severely active ulcerative colitis (UC) in adults.

The patient is [a/an age]-year-old [male/female/other gender identification] who was diagnosed with [diagnosis] on [date]. Below is the rationale for prescribing ZEPOSIA based on my patient's disease summary.

[Insert disease summary]

I am requesting this coverage because [insert reason(s) for medical necessity]. Please see attached documents to support my clinical findings.

Considering the patient's history and condition, I believe treatment with ZEPOSIA is medically necessary for my patient. Please contact me at [physician's phone number] or via email at [physician's email] should you have questions or need additional information.

Thank you for your time and immediate attention to this request.

Sincerely,

[Provider name, contact information, and signature]

Enclosures: [List and attach additional documents to support your treatment rationale]

Letter of Medical Necessity for Patients Currently on Treatment

[Date]
[Health Plan Name]
ATTN: [Department]
[Medical/Pharmacy Director Name]
[Health plan address][City, State Zip]

Name: [Patient's Name]
DOB: [XX/XX/XXXX]
Patient Policy ID Number: [Policy ID #]
Reference Number: [Reference #]
Date(s) of Service: [XX/XX/XXXX]

Re: Letter of Medical Necessity for ZEPOSIA® (ozanimod)

Dear [Medical/Pharmacy Director Name],

I am writing on behalf of [patient's name] to request coverage for ZEPOSIA® (ozanimod) for the treatment of [diagnosis], *International Classification of Diseases, 10th Revision, Clinical Modification* diagnosis code [diagnosis code]. I have reviewed your drug coverage policy and believe that the appropriate treatment decision at this time is to discontinue [current drug name] and initiate treatment with ZEPOSIA. This letter provides the clinical rationale and relevant information about the patient's medical history and treatment.

ZEPOSIA is a sphingosine 1-phosphate (S1P) receptor modulator that was approved by the US Food and Drug Administration in 2021 for the treatment of moderately to severely active ulcerative colitis (UC) in adults.

The patient is [a/an age]-year-old [male/female/other gender identification] who was diagnosed with [diagnosis] on [date]. Below is the rationale for prescribing ZEPOSIA based on my patient's disease summary.

[Insert disease summary]

I am requesting this coverage because [insert reason(s) for medical necessity]. Please see attached documents to support my clinical findings.

Considering the patient's history and condition, I believe treatment with ZEPOSIA is medically necessary for my patient. Please contact me at [physician's phone number] or via email at [physician's email] should you have questions or need additional information.

Thank you for your time and immediate attention to this request.

Sincerely,

[Provider name, contact information, and signature]

Enclosures: [List and attach additional documents to support your treatment rationale]

Step Therapy Letter

[Date]
[Health Plan Name]
ATTN: [Department]
[Medical/Pharmacy Director Name]
[Health plan address][City, State Zip]

[Patient's Name]
[Date of Birth]
Patient Policy ID Number: [ID #]
Reference Number: [# if available]
[Dates of Service]

Re: Letter Requesting Approval for Use of ZEPOSIA® (ozanimod) capsules

Dear [Medical/Pharmacy Director Name],

I am writing on behalf of [patient's name] to request coverage for ZEPOSIA® (ozanimod), for the treatment of [diagnosis], ICD-10-CM diagnosis code [diagnosis code]. ZEPOSIA is a sphingosine 1-phosphate (S1P) receptor modulator that was approved by the US Food and Drug Administration (FDA) in 2021 for the treatment of moderately to severely active ulcerative colitis (UC) in adults.

I have reviewed your drug coverage requirement and believe that the appropriate treatment decision at this time is to initiate treatment with ZEPOSIA. This letter outlines the patient's medical history and previous treatments (if applicable) that support my recommendation for ZEPOSIA as the appropriate treatment option.

The patient is [a/an age]-year-old [male/female/other gender identification] who was diagnosed with [diagnosis] on [date]. Below is a rationale for prescribing ZEPOSIA based on my patient's disease summary.

- [Insert disease summary]
- [If appropriate, insert past drugs and treatments that were tried and failed and patient's response to these therapies (eg, intolerable side effects).]
- [Brief description of the patient's recent conditions, and any other patient characteristics or relevant clinical considerations]

I have prescribed ZEPOSIA, and am requesting this coverage because of the following rationale:

- [Please provide clinical rationale for treatment]
- [If applicable, please provide additional supporting information (eg, patient-specific data, information from the ZEPOSIA Prescribing Information, clinical trial data that may be relevant to the patient's treatment, and/or clinical peer-reviewed literature)]
- [If applicable, provide appropriate state step-therapy legislation evidence, include statute (if available)]

Considering the patient's history and condition, I believe treatment with ZEPOSIA is the appropriate option for my patient. Please contact me at [physician's phone number] or via email at [physician's email] should you have questions or need additional information.

Thank you for your time and immediate attention to this request.

Sincerely,

[Provider name, contact information, and signature]

Formulary Exception Letter

[Date]
[Health Plan Name]
ATTN: [Department]
[Medical/Pharmacy Director Name]
[Health plan address][City, State Zip]

Name: [Patient's Name]
DOB: [XX/XX/XXXX]
Patient Policy ID Number: [Policy ID #]
Reference Number: [Reference #]
Date(s) of Service: [XX/XX/XXXX]

Re: Request for Formulary Exception for ZEPOSIA® (ozanimod)

Dear [Medical/Pharmacy Director Name],

I am writing on behalf of [patient's name] to request coverage for ZEPOSIA® (ozanimod) for the treatment of [diagnosis], *International Classification of Diseases, 10th Revision, Clinical Modification* diagnosis code [diagnosis code]. Your reason[s] for the denial [is/are] [reason(s)].

Currently, ZEPOSIA is not on your formulary; however, I am requesting an exception for ZEPOSIA to be available as a preferred drug and ask that any applicable National Drug Code blocks be removed so a prescription for my patient may be filled.

ZEPOSIA is a sphingosine 1-phosphate (S1P) receptor modulator that was approved by the US Food and Drug Administration in 2021 for the treatment of moderately to severely active ulcerative colitis (UC) in adults.

The patient is [a/an age]-year-old [male/female/other gender identification] who was diagnosed with [diagnosis] on [date]. Below is the rationale for prescribing ZEPOSIA based on my patient's disease summary.

[Insert disease summary]

I am requesting this exception because [insert reasons]. Considering the patient's history and condition, I believe treatment with ZEPOSIA is medically necessary for my patient.

Please contact me at [physician's phone number] or via email at [physician's email] should you have questions or need additional information.

Thank you for your time and immediate attention to this request.

Sincerely,

[Provider name, contact information, and signature]

Enclosures: [List and attach additional documents to support your treatment rationale]

Letter of Appeal for Patients Not Actively on Treatment

[Date]
[Health Plan Name]
ATTN: [Department]
[Medical/Pharmacy Director Name]
[Health plan address][City, State Zip]

Name: [Patient's Name]
DOB: [XX/XX/XXXX]
Patient Policy ID Number: [Policy ID #]
Reference Number: [Reference #]
Date(s) of Service: [XX/XX/XXXX]

Re: Letter of Appeal for ZEPOSIA® (ozanimod)

Dear [Medical/Pharmacy Director Name],

I am writing on behalf of [patient's name] to request reconsideration of your denial of coverage for ZEPOSIA® (ozanimod) for the treatment of [diagnosis], *International Classification of Diseases, 10th Revision, Clinical Modification* (ICD-10-CM) diagnosis code [diagnosis code]. Your reason[s] for the denial [is/are] [reason(s)].

Based on my experience with treating patients with [diagnosis], ICD-10-CM diagnosis code [diagnosis code], and the patient's condition and medical history, I believe treatment with ZEPOSIA is appropriate and medically necessary. This letter provides the clinical rationale and relevant information about the patient's medical history and treatment.

ZEPOSIA is a sphingosine 1-phosphate (S1P) receptor modulator that was approved by the US Food and Drug Administration in 2021 for the treatment of moderately to severely active ulcerative colitis (UC) in adults.

The patient is [a/an age]-year-old [male/female/other gender identification] who was diagnosed with [diagnosis] on [date]. Below is the rationale for prescribing ZEPOSIA based on my patient's disease summary.

[Insert disease summary]

[Supporting information as requested by the plan in the denial letter]

This is my [level of request] prior authorization appeal. A copy of the [level of denial] denial letter is included along with medical notes in response to the denial. Considering the patient's history and condition, I believe treatment with ZEPOSIA is medically necessary for my patient.

Please contact me at [physician's phone number] or via email at [physician's email] should you have questions or need additional information.

Thank you for your time and immediate attention to this request.

Sincerely,

[Provider name, contact information, and signature]

Enclosures: [List and attach additional documents to support your treatment rationale]

Letter of Appeal for Patients Currently on Treatment

[Date]
[Health Plan Name]
ATTN: [Department]
[Medical/Pharmacy Director Name]
[Health plan address][City, State Zip]

Name: [Patient's Name]
DOB: [XX/XX/XXXX]
Patient Policy ID Number: [Policy ID #]
Reference Number: [Reference #]
Date(s) of Service: [XX/XX/XXXX]

Re: Letter of Appeal for ZEPOSIA® (ozanimod)

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I am writing on behalf of [patient's name] to request reconsideration of your denial of coverage for ZEPOSIA® (ozanimod) for the treatment of [diagnosis], *International Classification of Diseases, 10th Revision, Clinical Modification* (ICD-10-CM) diagnosis code [diagnosis code]. Your reason[s] for the denial [is/are] [reason(s)].

Based on my experience with treating patients with [diagnosis], ICD-10-CM diagnosis code [diagnosis code], and the patient's condition and medical history, I believe treatment with [current drug name] should be discontinued and replaced with ZEPOSIA as it is appropriate and medically necessary. This letter provides the clinical rationale and relevant information about the patient's medical history and treatment.

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The patient is [a/an age]-year-old [male/female/other gender identification] who was diagnosed with [diagnosis] on [date]. Below is the rationale for prescribing ZEPOSIA based on my patient's disease summary.

[Insert disease summary]

[Supporting information as requested by the plan in the denial letter]

This is my [level of request] prior authorization appeal. A copy of the [level of denial] denial letter is included along with medical notes in response to the denial. Considering the patient's history and condition, I believe treatment with ZEPOSIA is medically necessary for my patient.

Please contact me at [physician's phone number] or via email at [physician's email] should you have questions or need additional information.

Thank you for your time and immediate attention to this request.

Sincerely,

[Provider name, contact information, and signature]

Enclosures: [List and attach additional documents to support your treatment rationale]

Patient Financial Support

Patient Financial Support

Co-Pay Benefits Through ZEPOSIA 360 Support™

Prescription

- **Commercially insured patients may pay as little as $0** in out-of-pocket costs per prescription
- Subject to a **maximum benefit of $18,000** during a calendar year

Medical

- **Commercially insured patients may be reimbursed** for out-of-pocket costs associated with required screenings
- **Subject to a maximum benefit of $2,000** during a calendar year

Note: Patients are responsible for any costs that exceed the maximum amounts

Referrals to independent, third-party foundations

- ZEPOSIA 360 Support™ may provide suggestions for independent third-party foundations that may be able to assist with treatment costs
- These foundations are not affiliated with BMS or any third parties who charge a fee for help with applications or medication refills

For additional information, including terms and conditions, please see page 31 in this guide and the HCP website

Disclaimers

Combined Co-pay Programs (Drug and Medical Benefit)

ZEPOSIA® (ozanimod) Co-pay Program is valid only for patients with commercial (private) insurance. The Program includes a prescription benefit offer for out-of-pocket drug costs and a medical assessment benefit offer for out-of-pocket costs for the initial blood tests and ECG screening where the full cost is not covered by patient's insurance. Patients are not eligible for the prescription benefit offer if they have prescription insurance coverage through a state or federal healthcare program, including but not limited to Medicare, Medicaid, Medigap, CHAMPUS, TRICARE, Veterans Affairs (VA), or Department of Defense (DoD) programs. Patients are not eligible for the medical assessment benefit offer if they have insurance coverage for their prescription or medical assessment through a state or federal healthcare program, or reside in Massachusetts, Minnesota or Rhode Island. Patients who move from commercial plans to state or federal healthcare programs will no longer be eligible. Patient must be 18 years of age or older. Patients pay as little as $0 in out-of-pocket costs per prescription, subject to a maximum benefit of $18,000 during a calendar year. Patients pay as little as $0 in out-of-pocket costs for the medical assessment, subject to a maximum benefit of $2,000. The medical benefit offer only applies to clinical baseline assessment services covered by the Program. Patients are responsible for any costs that exceed the maximum amounts. To receive the medical assessment benefit, an Explanation of Benefits (EOB) form must be submitted, along with copies of receipts for any payments made. The Program expires on December 31, 2023. All Program payments are for the benefit of the patient only. Patients, pharmacists, and prescribers may not seek reimbursement from health insurance, health savings or flexible spending accounts, or any third party, for any part of the prescription or medical assessment benefit received by the patient through this Program. Patient's acceptance of any Program benefit confirms that it is consistent with patient's insurance and that patient will report the value received as may be required by his/her insurance provider. Program valid only in the United States and Puerto Rico. Void where prohibited by law, taxed, or restricted. The Program cannot be combined with any other offer, rebate, coupon, or free trial. The Program is not conditioned on any past, present or future purchase, including refills. The Program is not insurance. Other limitations may apply. Bristol Myers Squibb reserves the right to rescind, revoke, or amend this Program at any time without notice.

ZEPOSIA Free Trial Offer

Patient must have a valid prescription for ZEPOSIA for an FDA-approved indication. Patient must be new to therapy and have not previously received a sample or filled a prescription for ZEPOSIA. Patient is responsible for applicable taxes, if any. This offer is limited to one use per patient per lifetime and is non-transferable. Cannot be combined with any other rebate/coupon, free trial, or similar offer. No substitutions permitted. Patients, pharmacists, and prescribers cannot seek reimbursement for the ZEPOSIA Free Trial from health insurance or any third party, including state or federally funded programs. Patients may not count the ZEPOSIA Free Trial as an expense incurred for purposes of determining out-of-pocket costs for any plan, including Medicare Part D true out-of-pocket costs (TrOOP). Offer is not conditioned on any past, present, or future purchase, including refills. Only valid in the United States and US Territories. Void where prohibited by law or restricted. The program is not insurance. Bristol Myers Squibb reserves the right to rescind, revoke, or amend this offer at any time without notice.

ZEPOSIA In-Home Medical Services Program

Patient must have a valid prescription for ZEPOSIA for an FDA-approved indication. Patient must be commercially insured. Patients are not eligible if they have prescription insurance coverage through a state or federal healthcare program, including but not limited to Medicare, Medicaid, Medigap, CHAMPUS, TRICARE, Veterans Affairs (VA), or Department of Defense (DoD) programs, or reside in Rhode Island. To receive the In-Home Medical Services Program, the prescriber must request in-home assessment assistance through the ZEPOSIA 360 Support program. The patient's insurance will not be billed, and the patient will not be responsible for any out-of-pocket costs. Patients who move from commercial plans to state or federal healthcare programs will no longer be eligible. The program cannot be combined with any other offer, rebate, coupon, or free trial. The program is not conditioned on any past, present, or future purchase, including refills. Only valid in the United States and US Territories. Void where prohibited by law, taxed, or restricted. The program is not insurance. Bristol-Myers Squibb Company reserves the right to rescind, revoke, or amend this program at any time without notice. Other limitations may apply.

Bridge Program

The Bridge Program is available at no cost for eligible, commercially insured, on-label diagnosed patients if there is a delay in determining whether commercial prescription coverage is available, and is not contingent on any purchase requirement, for up to 24 months (dispensed in 30-day increments). The Bridge Program is not available to patients who have prescription insurance coverage through a state or federal healthcare program, including but not limited to Medicare, Medicaid, Medigap, CHAMPUS, TRICARE, Veterans Affairs (VA), or Department of Defense (DoD) programs and is available for no more than 12 months to patients in MA, MN, and RI. Appeal of any prior authorization denial must be made within 90 days or as per payer guidelines, to remain in the program. Eligibility will be re-verified in January for patients continuing into the following year, and may be at other times during program participation. Offer is not health insurance. Once coverage is approved by the patient's commercial insurance plan, the patient will no longer be eligible. Void where prohibited by law, taxed, or restricted. Bristol-Myers Squibb Company reserves the right to rescind, revoke, or amend this program at any time without notice. Other limitations may apply.

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 **https://www.ZEPOSIA.com/ulcerative-colitis/cost/**.

2084-US-2200931 02/23

once-daily
ZEPOSIA™
(ozanimod) | 0.92 mg capsules