	<b>Johns Hopkins HealthCare LLC</b> <b>Pharmacy Public</b> <b>Pharmacy Management Drug Policies</b>	<i>Policy Number</i>	MEDS140
		<i>Effective Date</i>	10/20/2021
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	<i>Subject</i> <b>Zeposia</b>	<i>Page</i>	1 of 2

This document applies to the following Participating Organizations:

Priority Partners

**Keywords:** Zeposia

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## **I. POLICY**


- A. Zeposia (ozanimod) will require prior authorization for appropriate use. The process for initiating a prior authorization request can be found in policy PHARM 20.
  1. PPMCO members are subject to the Priority Partners formulary, available at [www.ppmco.org](http://www.ppmco.org).
  2. USFHP members are subject to prior authorization criteria, step-edits and days-supply limits outlined in the Tricare Policy Manual. Tricare Policy supersedes JHHC Medical/Pharmacy Policies. Tricare limits may be accessed at: [http://pec.ha.osd.mil/formulary\\_search.php?submenuheader=1](http://pec.ha.osd.mil/formulary_search.php?submenuheader=1)

## **II. POLICY CRITERIA**

- A. **Zeposia** may be approved for patients who meet the following:
  1. Multiple Sclerosis
    - a. Patient is 18 years of age or older
    - b. Documentation showing ONE of the following:
      - I. History of clinically isolated syndrome (CIS) confirmed by MRI
      - II. Diagnosis of relapsing-remitting multiple sclerosis (RRMS) confirmed by MRI
      - III. Diagnosis of secondary progressive multiple sclerosis (SPMS) with a current relapse
    - c. Documented trial and inadequate response to injectable therapy, evidenced by frequent relapses, increasing MRI disease activity, or progressive disability
    - d. Documented trial and inadequate response to either generic dimethyl fumarate or Gilenya
  2. Ulcerative Colitis
    - a. Patient is 18 years of age or older
    - b. Documentation showing a diagnosis of moderate to severe ulcerative colitis
    - c. Documented trial and inadequate response to immunosuppressants, such as corticosteroids, azathioprine, or 6-mercaptopurine (6-MP)
    - d. Documented trial and inadequate response, or intolerance to adalimumab

## **III. AUTHORIZATION PERIOD/LIMITATIONS**

- A. Initial approval will be restricted to 6 months of therapy

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- B. Approval for continuation of therapy can be extended in up to 12-month intervals with documentation showing the patient's clinical improvement from treatment as supported by one of the following condition-indicated outcomes:
1. Multiple Sclerosis:
    - a. Reduction in clinical relapses
    - b. Lack of new or enlarging lesion per MRI evaluation
  2. Ulcerative colitis:
    - a. Reduction in gastrointestinal signs and symptoms
    - b. Prolonged clinical remission and mucosal healing

#### IV. EXCLUSIONS

- A. Zeposia will not be approved for the following:
1. Patients with severe untreated sleep apnea
  2. Patients that have experienced a myocardial infarction, unstable angina, stroke, transient ischemic attack (TIA), decompensated heart failure requiring hospitalization, or Class III or IV heart failure within 6 months of initiation
  3. Patients with Mobitz type II second-degree or third degree atrioventricular (AV) block, sick sinus syndrome, or sinoatrial block, unless they have a functioning pacemaker
  4. Patients taking a monoamine oxidase (MAO) inhibitor
  5. Concurrent therapy with another disease-modifying MS therapy, or biologic UC therapy
  6. Any indications that are not FDA-approved, or guideline-supported
- B. The use of physician samples, or manufacturer product discounts, does not guarantee coverage under the provisions of the medical and/or pharmacy benefit. All pertinent criteria must be met in order to be eligible for benefit coverage.

#### V. REFERENCES

1. Zeposia [prescribing information]. Summit, NJ: Celgene Corporation; May 2021.
2. Rae-Grant A, 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 Apr 24;90(17):777-788.
3. Rubin DT, Ananthakrishnan AN, Siegel CA, Sauer BG, Long MD. ACG Clinical Guideline: Ulcerative Colitis in Adults. *Am J Gastroenterol*. 2019 Mar;114(3):384-413.
4. Feuerstein JD, et al. AGA Clinical Practice Guidelines on the Management of Moderate to Severe Ulcerative Colitis. *Gastroenterology*. 2020 Apr;158(5):1450-1461.

#### VI. APPROVALS

Signature on file at JHHC

DATE OF REVISION	SUMMARY OF CHANGE
10/20/2021	Policy Creation

Review Date: 10/20/2021

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