

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 1375-4
Program	Prior Authorization/Notification
Medication	Zeposia® (ozanimod)
P&T Approval Date	12/2021, 12/2022, 12/2023, 12/2024
Effective Date	3/1/2025

1. Background:

Zeposia® (ozanimod) is a sphingosine 1-phosphate receptor modulator indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults and moderately to severely active ulcerative colitis (UC) in adults.

2. Coverage Criteria^a:

<p>A. <u>Multiple Sclerosis</u></p> <p>1. <u>Authorization</u></p> <p>a. Zeposia will be approved based on the following criterion:</p> <p>(1) Diagnosis of multiple sclerosis (MS)</p> <p style="text-align: center;">Authorization will be issued for 12 months.</p> <p>B. <u>Ulcerative Colitis</u></p> <p>1. <u>Initial Authorization</u></p> <p>a. Zeposia will be approved based on <u>both</u> of the following criteria:</p> <p>(1) Diagnosis of moderately to severely active ulcerative colitis</p> <p style="text-align: center;">-AND-</p> <p>(2) Patient is not receiving Zeposia in combination with a targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Entyvio (vedolizumab), Omvoh (mirikizumab-mrkz), Olumiant (baricitinib), Orencia (abatacept), Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab), Stelara (ustekinumab), Tremfya (guselkumab), Xeljanz (tofacitinib)]</p> <p style="text-align: center;">Authorization will be issued for 12 months.</p> <p>2. <u>Reauthorization</u></p> <p>a. Zeposia will be approved based on <u>both</u> of the following criteria:</p>
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(1) Documentation of positive clinical response to Zeposia therapy

-AND-

(2) Patient is not receiving Zeposia in combination with a targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Entyvio (vedolizumab), Omvoh (mirikizumab-mrkz), Olumiant (baricitinib), Orencia (abatacept), Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab), Stelara (ustekinumab), Tremfya (guselkumab), Xeljanz (tofacitinib)]

Authorization will be issued for 12 months.

^a State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits and/or Step Therapy may be in place.

4. References:

1. Zeposia [package insert]. Summit, NJ: Cellegene Corporation; August 2024.

Program	Prior Authorization/Notification – Zeposia (ozanimod)
Change Control	
12/2021	New program.
12/2022	Annual review. Added Rinvoq as JAK inhibitor example. Added state mandate footnote.
12/2023	Annual review. Updated not to be used in combination drugs. Updated reference.
12/2024	Annual review. No change to coverage criteria. Updated examples of not to be used in combination with no change to clinical intent.