UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 2264-7
Program	Prior Authorization/Medical Necessity
Medication	Zeposia® (ozanimod)
P&T Approval Date	12/2021, 5/2022, 1/2023, 4/2023, 4/2024, 10/2024, 11/2024
Effective Date	2/1/2025

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]:

A. Multiple Sclerosis

1. **Authorization**

a. **Zeposia** will be approved based on the following criterion:

(1) Diagnosis of multiple sclerosis (MS)

Authorization will be issued for 12 months.

B. Ulcerative Colitis (UC)

1. **Initial Authorization**

a. **Zeposia** will be approved based on **all** of the following criteria:

(1) Diagnosis of moderately to severely active UC

-AND-

(2) **One** of the following:

(a) Patient has had prior or concurrent inadequate response to a therapeutic course of oral corticosteroids and/or immunosuppressants (e.g., azathioprine, 6-mercaptopurine)

-OR-

(b) Patient has been previously treated with a biologic or targeted synthetic DMARD FDA-approved for the treatment of ulcerative colitis as documented by claims history or submission of medical records (Document drug, date, and duration of therapy) [e.g., adalimumab, Simponi

(golimumab), Stelara (ustekinumab), Xeljanz (tofacitinib), Rinvoq (upadacitinib)].

-AND-

(3) **One** of the following:

(a) History of failure, contraindication, or intolerance to **two** of the following preferred products (document drug, date, and duration of trial):

i. One of the preferred adalimumab products (i.e. Adalimumab-adaz (unbranded Hyrimoz), Amjevita for Nuvaila, Humira)
ii. Entyvio (vedolizumab)
iii. Omvoh (mirikizumab-mrkz)
iv. Rinvoq (upadacitinib)
v. Simponi (golimumab)
vi. Skyrizi (risankizumab)
vii. Stelara (ustekinumab)
viii. Tremfya (guselkumab)
ix. Xeljanz/Xeljanz XR (tofacitinib)

-OR-

(b) **Both** of the following:

i. Patient is currently on Zeposia therapy as documented by claims history or submission of medical records (Document drug, date, and duration of therapy):

-AND-

ii. Patient has **not** received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from the Bristol Myers Squibb sponsored Zeposia 360 Support Program (e.g. sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Zeposia*

-AND-

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

-AND-

(5) Prescribed by or in consultation with a gastroenterologist

*Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the Bristol Myers Squibb sponsored Zeposia 360 Support Program **shall be required** to meet initial authorization criteria as if patient were new to therapy.

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Zeposia** will be approved based on **both** of the following criteria:

(1) Documentation of positive clinical response to Zeposia therapy

-AND-

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

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 may be in place.

4. References:

1. Zeposia [package insert]. Summit, NJ: Celegene Corporation; August 2023.
2. Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA clinical practice guidelines on the management of moderate to severe ulcerative colitis. Gastroenterology. 2020; 158(5):1450-61.

Program	Prior Authorization/Medical Necessity – Zeposia® (ozanimod)
Change Control	
12/2021	New program.
5/2022	Added Xeljanz and Rinvoq as preferred products for failure, contraindication, or intolerance for Ulcerative Colitis and added Rinvoq as an example of JAK inhibitor. Updated reference.
1/2023	Updated step therapy requirements to Humira or Amjevita. Updated listed examples from Humira to adalimumab.

4/2023	Updated step therapy requirement from Humira or Amjevita to one of the preferred adalimumab products and added the footnote “For a list of preferred adalimumab products please reference drug coverage tools.”
4/2024	Annual review. Updated not used in combination examples with no change to clinical intent. Updated reference.
10/2024	Updated step requirement noting Adalimumab-adaz (unbranded Hyrimoz), Amjevita for Nuvaila, and Humira as preferred adalimumab products with no change to clinical intent. Removed preferred adalimumab footnote. Added Entyvio, Omvoh and Skyrizi as step therapy agents.
11/2024	Added Tremfya as a step therapy agent.