Mass General Brigham
Health Plan

# Zeposia (ozanimod)
# Effective 01/01/2027

| | | | |
|---|---|---|---|
| **Plan** | ☐ MassHealth UPPL<br>☒ Commercial/Exchange | **Program Type** | ☒ Prior Authorization<br>☐ Quantity Limit<br>☐ Step Therapy |
| **Benefit** | ☒ Pharmacy Benefit<br>☐ Medical Benefit | | |
| **Specialty Limitations** | This medication has been designated specialty and must be filled at a contracted specialty pharmacy. | | |
| **Contact Information** | **Medical Benefit**<br>**Pharmacy Benefit** | Phone: 833-895-2611<br>Phone: 800-711-4555 | Fax: 888-656-6671<br>Fax: 844-403-1029 |
| **Exceptions** | N/A | | |

**Overview**

Zeposia (ozanimod) is a sphingosine 1-phosphate receptor modulator indicated for the treatment of:

1. Relapsing forms of multiple sclerosis, including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.
2. Treatment of moderately to severely active ulcerative colitis in adults.

**Coverage Guidelines**

If member is new to the plan (as evidenced by coverage effective date of less than or equal to 90 days), submission of medical records documenting that the member is currently receiving treatment with the requested drug, excluding when the product is obtained as samples or via manufacturer's patient assistance programs

**OR**

Approval will be granted when all the following diagnosis-specific criteria are met:

**<u>Multiple Sclerosis</u>**

1. Diagnosis of relapsing forms of multiple sclerosis, including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease.
2. Member is 18 years of age or older

**<u>Moderately to Severely Active Ulcerative Colitis</u>**

1. Diagnosis of moderately to severely active ulcerative colitis
2. ONE of the following:
    a. Trial and failure, contraindication, or intolerance to ONE of the following conventional therapies:
        i. 6-mercaptopurine
        ii. Aminosalicylate (e.g., mesalamine, olsalazine, sulfasalazine)
        iii. Azathioprine
        iv. Corticosteroids (e.g., prednisone)
    b. Disease severity warrants systemic biologic or targeted synthetic therapy as first-line therapy
3. Trial and failure, contraindication, or intolerance to TWO of the following:
    a. Adalimumab-aaty, adalimumab-adaz, or Hadlima
    b. Omvoh

c. Rinvoq
d. Simponi
e. Skyrizi
f. Selarsdi, Steqeyma, or Yesintek
g. Tremfya
h. Velsipity

**Continuation of Therapy**

Requests for reauthorization will be approved when all of the following diagnosis-specific criteria are met:

**Multiple Sclerosis:**

1. Submission of medical records (e.g., chart notes) demonstrating member is experiencing disease stability or improvement on the requested medication

**Ulcerative Colitis:**

1. Submission of medical records (e.g., chart notes) documenting an improvement in the member's condition, as evidenced by low disease activity or improvement in signs and symptoms of the condition

**Limitations**

1. Initial approvals and reauthorizations for ulcerative colitis will be granted for 24 months
2. Initial approvals and reauthorizations for multiple sclerosis will be granted for 12 months.
3. The following quantity limits apply:

| Drug Name and Dosage Form | Quantity Limitation |
|---|---|
| Zeposia capsule | 1 capsule per day |
| Zeposia Starter pack | 1 pack per 365 days |

**References**


1. Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA clinical practice guidelines on the management of moderate to severe ulcerative colitis. Gastroenterol. 2020;158:1450-1461.
2. Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG clinical guideline: ulcerative colitis in adults. Am J Gastroenterol. 2019;114:384-413.
3. Zeposia (ozanimod) [prescribing information]. Summit, NJ: Bristol-Myers Squibb Company; August 2024.


**Review History**

11/17/2021 – Created and Reviewed Nov P&T. Effective 01/01/2022.
03/15/2023 – Reviewed and Updated for March P&T; added Rinvoq as a preferred agent along with Humira and Stelara for Ulcerative Colitis. Effective 6/1/2023
11/15/2023 – Reviewed and Updated for November P&T; removed TB requirement. Clarified adult members for Multiple sclerosis. Effective 1/1/24.
09/11/2024 – Reviewed and updated for September P&T. Removed “documented” from the UC diagnosis requirement. Removed age requirement from UC criteria. Added presentation requirements for UC diagnosis and specified the conventional therapies to be tried and failed. Updated the biologic step through requirements for UC. Effective 12/01/2024.
10/09/2024 – Reviewed and updated at October P&T. Effective 12/1/2024: updated ulcerative colitis criteria conventional therapy requirement to remove documentation requirement. Effective 1/1/2025: updated ulcerative colitis criteria to include Amjevita (Nuvaila) as a preferred adalimumab product and included Omvoh

and Wezlana as preferred biologic step options. Added Tremfya as a biologic step option for ulcerative colitis. Updated reauthorization criteria to require documentation of clinical improvement.
05/14/2025 – Reviewed and updated at May P&T. Updated criteria for ulcerative colitis to remove disease characteristic requirement and allow for approval if disease severity warrants systemic biologic as first-line therapy. Effective 07/1/2025.
06/11/2025 – Reviewed and updated for June P&T. Added Velsipity as a previous trial option for ulcerative colitis. Effective 09/01/2025.
07/09/2025 – Reviewed and updated for July P&T. Updated reauthorization criteria for multiple sclerosis. Effective 09/01/2025.
09/10/2025 - Reviewed and updated at September P&T. Added Yesintek as an Ustekinumab trial option. Effective 10/15/2025.
10/08/2025 – Reviewed and updated at October P&T. Updated policy to reflect that Selarsdi, Steqeyma and Yesintek are the preferred Ustekinumab trial options. Updated policy to reflect that Humira, Hadlima, Simlandi and Yuflyma are the preferred adalimumab trial options. Effective 01/01/2026.
03/11/2026 – Reviewed and updated for March P&T. Administrative update - changing verbiage in reauthorization criteria from “documentation is submitted” to “submission of medical records (e.g., chart notes…” and updating language for members who are new to the Plan. Effective 05/01/2026.
04/15/2026 – Reviewed and updated for April P&T. Updating previous trial language for ulcerative colitis to allow for bypassing conventional therapy if member has severe disease that warrants a biologic or targeted synthetic therapy as first-line therapy. Updating approval length for ulcerative colitis to 24 months. Effective 08/16/2026.
09/09/2026 – Reviewed and updated at September P&T. Updating preferred adalimumab products throughout policy. Effective 01/01/2027.
10/14/2026 – Reviewed and updated at October P&T. Removing Xeljanz/tofacitinib as a previous trial option. Effective 01/01/2027.