Zeposia (ozanimod)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	Starter Pack/Kit: One time Capsules: 1 year

Note:
*Preferred products for National, Essential, and Traditional formularies include Humira, Simlandi - brand, Skyrizi, Stelara - brand, Selarsdi - brand, Enbrel, Entyvio, Orencia, Cosentyx, Otezla, Tremfya, Simponi, Ustekinumab – unbranded. *Rinvoq and Xeljanz/Xeljanz XR are the preferred JAK inhibitors.*

Medications	Quantity Limit
Zeposia (ozanimod) Starter Pack	1 pack per fill, one time (starting dose, 7 day supply)
Zeposia (ozanimod) Starter Kit	1 pack per fill, one time (starting dose, 7 day supply packaged with 0.92 mg capsules, 30 day supply)
Zeposia (ozanimod) Starter Kit	1 pack per fill, one time (starting dose, 7 day supply packaged with 0.92 mg capsules, 21 day supply)
Zeposia (ozanimod) 0.92 mg	1 capsule per day

APPROVAL CRITERIA

Requests for Zeposia (ozanimod) may be approved if the following criterion is met:

I. Individual has a diagnosis of relapsing multiple sclerosis (RMS) (including clinically isolated syndrome, relapsing-remitting disease or active secondary progressive disease);

OR

II. Individual is 18 years of age or older; **AND**
III. Individual has moderate to severe ulcerative colitis;

AND

A. Documentation is provided that individual has had a trial and inadequate response or intolerance to TWO (2) preferred agents [Current preferred agents include – Entyvio (vedolizumab), Humira (adalimumab), Selarsdi – brand, Simlandi – brand, Simponi (golimumab), Stelara – brand, Skyrizi (risankizumab-rzaa), Tremfya (guselkumab), Ustekinumab - unbranded]*. A trial of multiple products with the same active ingredient counts as a trial of ONE preferred agent. Medication samples/coupons/discount cards are excluded from consideration as a trial.;

AND

1. Documentation is provided describing the nature of the inadequate response or intolerance for each product tried;

   OR

2. Documentation is provided that a completed FDA MedWatch Adverse Event Reporting Form has been submitted to the FDA for each product tried;

OR

B. Documentation is provided that individual is currently on Zeposia (ozanimod). Medication samples/coupons/discount cards are excluded from consideration as a trial.;

OR

C. Documentation is provided for why the individual is unable to use ALL preferred agents (or all remaining preferred agents if individual has tried any preferred agent) due to one of the following:
   1. The individual is subject to a warning or contraindication that appears in the labeling of ALL preferred products and is not included in the labeling of Zeposia (ozanimod); **OR**
   2. None of the preferred products have activity against the individual's concomitant clinical condition which is covered by Zeposia (ozanimod); **OR**
   3. Remaining preferred agents are TNF antagonists and individual has already been exposed to 1 or more TNF antagonists (i.e. individual is unable to use all preferred agents other than TNF antagonists due to one of the reasons above).

Zeposia (ozanimod) may not be approved for the following:

I. Use in combination with other MS disease modifying agents (including Aubagio, Avonex, Bafiertam, Betaseron, Briumvi, Copaxone/Glatiramer/Glatopa, Extavia, Gilenya, Kesimpta, Lemtrada, Mavenclad, Mayzent, Ocrevus, Ocrevus Zunovo, Plegridy, Ponvory, Rebif, Tascenso ODT, Tecfidera, Tyruko, Tysabri and Vumerity); **OR**
II. Use in combination with tumor necrosis factor (TNF) inhibitors, Xeljanz/XR or other biologic agents (including ustekinumab or Entyvio); **OR**
III. Individual has had a recent (within the past 6 months) occurrence of one of the following:
   A. Myocardial infarction; **OR**
   B. Unstable angina; **OR**
   C. Stroke; **OR**
   D. Transient ischemic attack (TIA); **OR**
   E. Decompensated heart failure requiring hospitalization; **OR**
   F. Class III/IV heart failure; **OR**

IV. Individual has history or presence of Mobitz Type II second- or third-degree atrioventricular (AV) block, sick sinus syndrome or sino-atrial block, unless individual has a functioning pacemaker; **OR**
V. Individual has severe untreated sleep apnea; **OR**
VI. Use in combination with a monoamine oxidase (MAO) inhibitor (including but not limited to selegiline, phenelzine and linezolid); **OR**
VII. Individual has an active acute or chronic infection at the initiation of therapy; **OR**
VIII. Individual has severe hepatic impairment (Child-Pugh Class C); **OR**
IX. Individual is using to treat non-active secondary progressive multiple sclerosis.

Key References:

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: October 22, 2025.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc. Updated periodically.
4. Olek MJ, Howard J. Clinical presentation, course and prognosis of multiple sclerosis in adults. Last updated: April 18, 2025. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed: October 23, 2025.
5. Rae-Grant A, Day GS, Marrie RA, 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; 90: 777-788. Available from: https://www.aan.com/Guidelines/home/GuidelineDetail/898. Accessed: October 23, 2025.
6. Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG clinical guideline update: ulcerative colitis in adults. *Am J Gastroenterol.* 2025;120(6):1187-1224.
7. Singh S, Loftus EV, Limketkai BN, et al. AGA living clinical practice guideline on pharmacological management of moderate-to-severe ulcerative colitis. *Gastroenterology.* 2024;167:130-1343.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.