Zeposia (ozanimod)

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

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**
IV. Individual has had an inadequate response to or is intolerant of conventional therapy [including 5-aminosalicylic acid products, systemic corticosteroids or immunosuppressants (such as thiopurines)]; **OR**
V. Individual has a contraindication to 5-ASA products or systemic corticosteroids or thiopurines;

AND

A. Documentation is provided that individual has had a trial and inadequate response or intolerance to TWO (2) preferred biologic agents [Current preferred biologics include –Humira (adalimumab), Selarsdi – brand, Simlandi – brand, Simponi (golimumab), Stelara – brand, Skyrizi (risankizumab-rzaa), Tremfya (guselkumab), Ustekinumab - unbranded]. 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 has been receiving and is maintained on a stable dose of Zeposia. Medication samples/coupons/discount cards are excluded from consideration as a trial.;

OR

C. Documentation is provided that individual has latent tuberculosis infection;

OR

D. Zeposia may be approved if individual has concomitant relapsing multiple sclerosis, and documentation is provided.

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 27, 2024.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Feuerstein JD, Issacs KL, Schneider Y, et al. American Gastroenterological Association Clinical Practice Guidelines on the Management of Moderate to Severe Ulcerative Colitis. Gastroenterology 2020; 158:1450-1461.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc. Updated periodically.
5. Olek MJ, Howard J. Clinical presentation, course and prognosis of multiple sclerosis in adults. Last updated: April 26, 2024. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed: October 27, 2024.
6. 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 27, 2024.
7. Rubin DT, Ananthakrishnan AN, Siegel CA et al. American College of Gastroenterology Clinical Guideline: Ulcerative Colitis in Adults. Am J Gastroenterol 2019; 114:384-413.

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.