| Market Applicability | | | | |
|---|---|---|---|---|
| **Market** | **GA** | **MD** | **NJ** | **NY** |
| **Applicable** | X | X | X | X |

# Zeposia (ozanimod)

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

| Medications | Quantity Limit |
|---|---|
| Zeposia (ozanimod) Starter Pack | 1 pack per fill, one time (starting dose titration regimen, 7 day supply) |
| Zeposia (ozanimod) Starter Kit | 1 pack per fill, one time (starting dose titration regimen, 7 day supply packaged with 0.92 mg capsules, 30 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); **AND**
II. Individual has been on Zeposia (ozanimod);
**OR**
III. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response (including but not limited to confirmed clinical relapse, new or enlarged lesions on MRI or confirmed disability progression) or intolerance to dimethyl fumarate (generic Tecfidera);
**OR**
IV. Individual is requesting Zeposia to treat concomitant relapsing multiple sclerosis and moderate to severe ulcerative colitis;

**OR**
V. Individual is 18 years of age or older; **AND**
VI. Individual has moderate to severe ulcerative colitis; **AND**
VII. Individual has had an inadequate response to, is intolerant of or has a contraindication to conventional therapy (including 5-aminosalicylic acid products, systemic corticosteroids or immunosuppressants); **AND**

| Market Applicability | | | | |
|---|---|---|---|---|
| **Market** | **GA** | **MD** | **NJ** | **NY** |
| **Applicable** | X | X | X | X |

VIII. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response or intolerance to ONE (1) preferred biologic agent [Current preferred biologic includes – Avsola (infliximab- axxq), Humira (adalimumab)] unless the following criteria are met:
   A. Individual has been receiving and is maintained on a stable dose of Zeposia;
   **OR**
   B. Individual has any of the following concomitant clinical conditions:
      1. Demyelinating disease; **OR**
      2. Malignancy [such as but not limited to, solid or hematologic cancers and excluding superficial skin cancers (such as basal and squamous cell)]; **OR**
      3. Individual has Tuberculosis infection;
   **OR**
   C. The preferred agent(s) do not have activity against a concomitant clinical condition and Zeposia does. Examples include but may not be limited to the following:
      1. Concomitant relapsing multiple sclerosis: Zeposia is preferred.

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

I. Concurrent use with other MS disease modifying agents (including Aubagio, Avonex, Bafiertam, Betaseron, Copaxone/Glatiramer/Glatopa, Extavia, Gilenya, Lemtrada, Mavenclad, Mayzent, Ocrevus, Plegridy, Ponvory, Rebif, Tecfidera, Tysabri and Vumerity); **OR**
II. Concurrent use with tumor necrosis factor (TNF) inhibitors, Xeljanz/XR or other biologic agents (including Stelara 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. Concurrent use 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 a diagnosis of hepatic impairment; **OR**
IX. Individual is using to treat non-active secondary progressive multiple sclerosis.

| Market Applicability | | | | |
|---|---|---|---|---|
| **Market** | **GA** | **MD** | **NJ** | **NY** |
| **Applicable** | X | X | X | X |

**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: June 6, 2021.
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.; 2021; Updated periodically.
5. Olek MJ, Howard J. Clinical presentation, course and prognosis of multiple sclerosis in adults. Last updated: July 23, 2020. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed: July 29, 2020.
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: April 26, 2021.
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.






This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.