Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

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 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 or intolerance to one of the following:

A. One preferred beta interferon agent:

1. Avonex (interferon beta-1a); **OR**
2. Rebif (interferon beta-1a); **OR**
3. Betaseron (interferon beta-1b); **OR**
4. Extavia (interferon beta1-1b);

OR

B. Tecfidera (dimethyl fumarate);

OR

C. Glatopa (glatiramer) or glatiramer.

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

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

I. Concurrent use with other MS disease modifying agents (including Aubagio, Avonex, Betaseron, Copaxone/Glatiramer/Glatopa, Extavia, Gilenya, Lemtrada, Mavenclad, Mayzent, Ocrevus, Plegridy, Rebif, Tecfidera, Tysabri and Vumerity); **OR**
II. 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**
III. 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**
IV. Individual has severe untreated sleep apnea; **OR**
V. Concurrent use with a monoamine oxidase (MAO) inhibitor (including but not limited to selegiline, phenelzine and linezolid); **OR**
VI. Individual has an active acute or chronic infection at the initiation of therapy; **OR**
VII. 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: April 20, 2020.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2020; Updated periodically.
4. Olek MJ, Howard J. Clinical presentation, course and prognosis of multiple sclerosis in adults. Last updated: June 11, 2019. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed: July 20, 2019.
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: July 20, 2019.

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.