

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

Mayzent (siponimod)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Mayzent (siponimod) tablets	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Mayzent (siponimod) may be approved if the following criteria are 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 Mayzent (siponimod); **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. Betaseron (interferon beta-1b); **OR**
 3. Extavia (interferon beta1-1b); **OR**
 4. Rebif (interferon beta-1a);
 - OR**
 - B. Tecfidera (dimethyl fumarate);
 - OR**
 - C. Glatopa (glatiramer) or glatiramer.

Mayzent (siponimod) 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, Ocrevus, Plegridy, Rebif, Tecfidera and Tysabri); **OR**

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.

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- II. Individual who has been tested for CYP2C9 genotype and are homozygous for CYP2C9*3 (i.e., CYP2C9*3/*3 genotype); **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 or sick sinus syndrome, unless individual has a functioning pacemaker; **OR**
- V. Individual has an active acute or chronic infection at the initiation of therapy; **OR**
- VI. Individual is using to treat non-active secondary progressive multiple sclerosis.

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

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: July 21, 2019.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; 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.

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CRX-ALL-0463-19