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 and 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. Avonex (interferon beta-1a); **OR**
   B. Rebif (interferon beta-1a); **OR**
   C. Betaseron (interferon beta-1b); **OR**
   D. Extavia (interferon beta1-1b); **OR**
   E. Tecfidera (dimethyl fumarate); **OR**
   F. Glatopa (glatiramer);

OR

IV. Individual has active secondary progressive multiple sclerosis (confirmed Expanded Disability Status Scale (EDSS) progression in the previous two years).

Mayzent (siponimod) may **not** be approved for the following:

I. Concurrent use with other MS disease modifying agents (such as Aubagio, Gilenya, Mavenclad, Tecfidera, Tysabri, Lemtrada, Ocrevus, Copaxone/Glatopa, Extavia, Rebif, Avonex, Plegridy, or Betaseron); **OR**

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

II. Individuals who have 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.

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: April 22, 2019.
2. Devonshire V, Havrdova E, Radue EW, et al. Relapse and disability outcomes in patients with multiple sclerosis treated with fingolimod: subgroup analyses of the double-blind, randomised, placebo-controlled FREEDOMS study. *Lancet Neurol*. 2012; 11:420-28. DOI: http://dx.doi.org/10.1016/S1474-4422(12)70056-X.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; Updated periodically.
5. Olek MJ, Gonzalez-Scarano F, Dashe JF. Clinical presentation, course and prognosis of multiple sclerosis in adults. Last updated June 28, 2018. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed: June 29, 2018.
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: June 28, 2018.