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 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).

Mayzent (siponimod) 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, Kesimpta, Lemtrada, Mavenclad, Ocrevus, Plegridy, Ponvory, Rebif, Tascenso ODT, Tecfidera, Tysabri, Vumerity and Zeposia); **OR**
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.

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 7, 2022.
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.; 2022; Updated periodically.
5. Olek MJ, Howard J. Clinical presentation, course and prognosis of multiple sclerosis in adults. Last updated: May 9, 2022. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed: September 7, 2022.
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: September 7, 2022.

~~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 31, 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: June 15, 2021. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed: July 31, 2021.~~
~~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: July 31, 2021.~~