Humana. CareSource™

PHARMACY POLICY STATEMENT
Kentucky Medicaid

DRUG NAME	Mayzent (siponimod)
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) QUANTITY LIMIT— see **Dosage allowed** below
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Mayzent (siponimod) is a **non-preferred** product and will only be considered for coverage under the **pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

RELAPSING-REMITTING MULTIPLE SCLEROSIS, ACTIVE SECONDARY PROGRESSIVE MULTIPLE SCLEROSIS (SPMS)[1], CLINICALLY ISOLATED SYNDROME

For **initial** authorization:

1. Member is 18 years old or older; AND
2. Medication must be prescribed by, or in consultation with, or under the guidance of a neurologist; AND
3. A complete blood count (CBC) must be obtained before treatment start; AND
4. Member has ALL of the following:
   a) CYP29C genotype determination documented;
   b) An evaluation of the fundus, including the macula;
   c) Cardiac evaluation; AND
5. A potential risk of progressive multifocal leukoencephalopathy (PML) was discussed with member before starting Mayzent; AND
6. Member must **not** have experienced myocardial infarction, unstable angina, stroke, TIA, decompensated heart failure requiring hospitalization or Class III/IV heart failure within the last 6 months; AND
7. Member must **not** have history or presence of Mobitz Type II second-degree or third-degree atrioventricular (AV) block or sick sinus syndrome, unless patient has a functioning pacemaker; AND
8. Member must have documentation in chart notes that baseline QTc interval is not greater than 500 msec; AND
9. Member must **not** currently be receiving treatment with Class Ia or Class III anti-arrhythmic drugs.
10. **Dosage allowed:** Titration is required for treatment initiation (see prescribing information of the drug for details). The recommended maintenance dosage is 2 mg. The recommended maintenance dosage in patients with a CYP2C9*1/*3 or *2/*3 genotype is 1 mg.

If member meets all the requirements listed above, the medication will be approved for 6 months.

For **reauthorization**:
1. Member must be in compliance with all other initial criteria.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Mayzent (siponimod) not medically necessary for the treatment of the diseases that are not listed in this document.

DATE	ACTION/DESCRIPTION
05/07/2019	New policy for Mayzent created.

References:

1. Mayzent [package insert]. East Hanover, New Jersey: Novartis Pharmaceuticals Corporation, March 2019.
2. FDA News Release: FDA approves new oral drug to treat multiple sclerosis. Available at: https://www.fda.gov/news-events/press-announcements/fda-approves-new-oral-drug-treat-multiple-sclerosis.
3. Lublin FD, Reingold SC, Cohen JA, et al. Defining the clinical course of multiple sclerosis. The 2013 revisions. Neurology® 2014;83:278–286.

Effective date: 09/26/2019
Revised date: 06/28/2019

[1]CareSource considers active secondary progressive multiple sclerosis (SPMS) as one of the relapsing forms of multiple sclerosis (MS). Majority of patients would have MS started as a relapsing-remitting course of disease where episodes of worsening function (relapses) are followed by recovery periods (remissions). When episodes of remissions are not completed it can leave patient with remaining disabilities that can, in some cases, worsen over time. SPMS occurred when disability progresses independently of relapses. A non-active SPMS defined as no new relapses over time in patient with SPMS.