Criteria-Based Consultation Prescribing Program CRITERIA FOR DRUG COVERAGE

Siponimod (Mayzent)

Notes:

Quantity Limits: No

Initiation (new start) criteria, criteria for current Kaiser Permanente members already taking the medication who have not been reviewed previously, and criteria for new members entering Kaiser Permanente already taking the medication who have not been reviewed previously: Non-formulary siponimod (Mayzent) will be covered on the prescription drug benefit for 12 months when the following criteria are met:

- Prescribed by a Neurologist
- Diagnosis of Relapsing form of Multiple Sclerosis (MS), including:
 - Non-Progressive Relapsing MS
 - Progressive Relapsing MS
 - Relapsing Remitting MS
- Patient has failed an adequate trial of, or patient has an allergy or intolerance to:
 - Rituximab product
 - Fingolimod (Gilenya)
 - Ozanimod (Zeposia)
 - Ponesimod (Ponvory)
- CYP2C9 genotype has been confirmed prior to start, and the following are met:
 - Patient does NOT have CYP2C9*3/*3 genotype (Siponimod is contraindicated in this genotype)
 - For genotype CYP2C9*1/*3 and *2/*3 dose does not exceed 1 mg/day
 - o For all other genotypes dose should not exceed 2 mg/day
- Patient does NOT have any of the following:
 - Contraindications/serious precautions# to siponimod use (see below)
 - o QTc interval of 500 milliseconds or greater

<u>Continued use criteria for patients previously approved per the above criteria who are currently stable on the medication</u>: Non-formulary **siponimod (Mayzent)** will continue to be covered on the prescription drug benefit for <u>12 months</u> when the following criteria are met:

- Continues to be prescribed by neurologist
- Patient does NOT have any of the following:
 - Contraindications/serious precautions# to siponimod use (see below)

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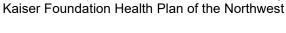
- Patient has had a scheduled appointment (telephone, video, or office visit) with neurologist within the past 12 months
- Patient has completed the following labs within the past 6 months:
 - Complete blood cell count with differential (CBC w/ diff)
 - Liver function test (alanine aminotransferase, ALT)

#: Contraindications/serious precautions to siponimod use include:

- Myocardial infarction in the last 6 months
- Unstable angina in the last 6 months
- Stroke, or transient ischemic attack in the last 6 months
- Decompensated heart failure requiring hospitalization, or class III or IV HF in the last 6 months
- Mobitz type II second- or third-degree atrioventricular block, sick sinus syndrome, or sinoatrial block, unless the patient has a functioning pacemaker
- Heart Rate less than 55 beats per minute

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