SENTARA COMMUNITY PLAN
(MEDICAID)

PHARMACY PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-800-750-9692**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If the information provided is not complete, correct, or legible, the authorization process can be delayed.**

Multiple Sclerosis Drugs

Drug Requested: (check box below that applies):

PREFERRED DRUGS		
❑ **Avonex®** ❑ **Avonex® Adm Pack**	❑ **Copaxone® 20 mg syringe**	❑ **dalfampridine ER** (generic for Ampyra®)** **(PA required)**
❑ **dimethyl fumarate and starter pack** (generic Tecfidera™)	❑ **fingolimod** (generic Gilenya®)	❑ **Kesimpta® (Step Edit)**
❑ **Teriflunomide** (generic Aubagio®)		
Non-Preferred Drugs **All Non-Preferred Medications Require Prior Authorization (member must have tried and failed at least two (2) of the preferred MS drugs)**		
❑ **Ampyra®** (PA required)**	❑ **Aubagio®**	❑ **Bafiertam™**
❑ **Betaseron®**	❑ **Briumvi™** (PA required)**	❑ **Copaxone® 40mg syringe**
❑ **Extavia® Kit**	❑ **Gilenya®**	❑ **glatiramer 20mg syringe**
❑ **Glatopa™**	❑ **Mavenclad®**	❑ **Mayzent®**
❑ **Ocrevus®** (PA required)**	❑ **Ocrevus Zunovo™ ** (PA required)**	❑ **Plegridy®**
❑ **Ponvory™**	❑ **Rebif® SQ** ❑ **Rebif Rebidose Pen®**	❑ **Tascenso ODT®**
❑ **Tecfidera®** ❑ **Tecfidera® Starter Pack**	❑ **Tysabri® **(PA required)**	❑ **Vumerity®**
❑ **Zeposia®**		

**** (Please note: Ampyra®, Briumvi™, Ocrevus®, Ocrevus Zunovo™ and Tysabri® require a separate PA form) All agents require adherence to the documented package insert age and diagnosis.**

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MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member Sentara #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Name/Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight (if applicable): _____ **Date weight obtained:** _____

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

1. Is member at least 18 years of age?
   - ❑ Yes ❑ No
2. Has the member had a baseline magnetic resonance imaging (MRI) before initiating the first treatment course (within 3 months prior to start of therapy)?
   - ❑ Yes ❑ No
3. Indicate all that apply:
   - ❑ Relapsing-remitting Disease (RRMS) *
   - ❑ Secondary Progressive Disease (SPMS) ** with relapses
   - ❑ Clinically Isolated Syndrome (CIS) ***
   - ❑ Member has had ≥1 relapse within the previous two years
   - ❑ Member has new and unequivocally enlarging T2 contrast enhancing lesions as evidenced by MRI and has had ≥ 1 relapse in the previous 12 months
   - ❑ Other: _____

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4. Has the member had a treatment failure or contraindication to other agents used to treat multiple sclerosis (MS)? List previous medications (include drug name/dose):
   ❑ Yes ❑ No

   List previous medications (include drug name/dose): _____
5. Will Mavenclad®, Mayzent®, Ponvory™ **OR** Zeposia® be used as a single-agent therapy?
   ❑ Yes ❑ No
6. Has the member been tested for antibodies to the varicella zoster virus (VZV) or received immunization for VZV four weeks prior to beginning therapy?
   ❑ Yes ❑ No
7. Has the member been screened for the presence of tuberculosis according to local guidelines?
   ❑ Yes ❑ No
8. Has the member been evaluated and screened for the presence of hepatitis B and hepatitis C virus (HBV/HCV prior to initiating treatment?)
   ❑ Yes ❑ No
9. Patient has tried and failed at least **two (2)** of the following **PREFERRED** drugs:

❑ **Avonex®**	❑ **Copaxone® 20mg syringe**	❑ **Dimethyl fumarate** (generic Tecfidera™)
❑ **fingolimod** (generic Gilenya®)	❑ **Kesimpta® (step edit)**	❑ **teriflunomide** (generic Aubagio®)

10. Provide clinical evidence that the **Preferred** drug(s) will not provide adequate benefit and list pharmaceutical drugs attempted and outcome.

    _____

    _____

    _____

    _____

    _____
11. Step-Edit for Kesimpta®:
    ❑ Trial and failure of dimethyl fumarate (generic Tecfidera®) or a **preferred injectable** is required for approval ❑ Yes ❑ No

    If **YES**, provide drug name/form/strength: _____

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MEDICAL NECESSITY: Provide clinical evidence that the **Preferred injectable drug** will not provide adequate benefit.

_____

_____

_____

_____

_____

Recommended Dosage for Mavenclad

- Oral: 3.5 mg/kg over 2-year treatment course, administered as 1.75 mg/kg in each year. Divide the

1.75 mg/kg dose over 2 cycles, each cycle lasting 4 to 5 consecutive days; do not administer more than 2 tablets (20mg) /day. Following the administration of 2 treatment courses, do not administer additional Mavenclad treatment during the next 2 years.

Administration of First Treatment Course

- First Course/First Cycle: start any time
- First Course/Second Cycle: administer 23 to 27 days after the last dose of First Course/First Cycle

Administration of Second Treatment Course

- Second Course/First Cycle: administer at least 43 weeks after the last dose of First Course/Second Cycle
- Second Course/Second Cycle: administer 23 to 27 days after the last dose of Second Course/First Cycle

Dose of MAVENCLAD per Cycle by Patient Weight in Each Treatment Course

Weight Range	Dose in mg (Number of 10 mg Tablets) per Cycle	
kg	First Cycle	Second Cycle
40* to less than 50	40 mg (4 tablets)	40 mg (4 tablets)
50 to less than 60	50 mg (5 tablets)	50 mg (5 tablets)
60 to less than 70	60 mg (6 tablets)	60 mg (6 tablets)
70 to less than 80	70 mg (7 tablets)	70 mg (7 tablets)
80 to less than 90	80 mg (8 tablets)	70 mg (7 tablets)
90 to less than 100	90 mg (9 tablets)	80 mg (8 tablets)
100 to less than 110	100 mg (10 tablets)	90 mg (9 tablets)
110 and above	100 mg (10 tablets)	100 mg (10 tablets)

*The use of MAVENCLAD in patients weighing less than 40 kg has not been investigated

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a. Is the lymphocyte count ≥ 800 cells/mL prior to start of therapy?
   ❑ Yes ❑ No

b. Please attest that women of childbearing age are not pregnant and that members of reproductive potential must use effective contraception during treatment with therapy and for at least six months after the last dose.
   ❑ Yes ❑ No

c. Does the member have human immunodeficiency virus (HIV) infection?
   ❑ Yes ❑ No

12. **Mayzent® Specific**

a. Has the member been tested for CYP2C9 variant status to determine genotyping (required for dosing)?
   ❑ Yes ❑ No

13. **Mayzent®, Ponvory™ OR Zeposia® Specific**

a. Please attest that women of childbearing age are not pregnant and that members of reproductive potential must use effective contraception during treatment.
   ❑ Yes ❑ No

b. Has the member obtained a baseline electrocardiogram (ECG)?
   ❑ Yes ❑ No

c. Has the member had a baseline ophthalmic evaluation of the fundus, including the macula, before starting treatment?
   ❑ Yes ❑ No

14. Before using **Mayzent®, Ponvory™ OR Zeposia®**, please attest that the member does **NOT** have any of the following:

- Recent myocardial infarction
- Unstable angina
- Stroke
- Transient Ischemic Attack
- Decompensated heart failure with hospitalization
- Class III/IV heart failure within the previous 6 months
- Prolonged QTc interval at baseline (>500 msec)
- CYP2C9*3/*3 genotype (**Mayzent® ONLY)**
- History of Mobitz Type II second or third-degree atrioventricular block or sick sinus syndrome (unless treated with a functioning pacemaker)
  ❑ Yes ❑ No

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15. Can you confirm that **Mayzent®** will **NOT** be used in combination with the following?
    - Moderate or strong CYP3A4 inducers (e.g., modafinil, efavirenz) in members with a CYP2C9*1/*3 and CYP2C9*2/*3 genotypes; **OR**
    - Drug regimens that contain CYP2C9/CY3A4 dual inhibitors (e.g., fluconazole); **OR**
    - Moderate CYP2C9 inhibitor plus a moderate-to-strong CYP3A4 inhibitor; **OR**
    - Other antineoplastic, immunosuppressive or immunomodulating drugs.

    ❑ Yes ❑ No
16. Can you confirm **Zeposia®** will **NOT** be used in combination with the following?
    - Will **NOT** be initiating therapy after previous treatment with alemtuzaumab; **OR**
    - Monoamine oxidase inhibitor (MAOI) (e.g., selegiline, phenelzine, linezolid); **OR**
    - Drugs known to prolong the QT-interval (e.g., fluoroquinolone or macrolide antibiotics, venlafaxine, fluoxetine, quetiapine, ziprasidone, sumatriptan, zolmitriptan); **OR**
    - Strong cytochrome p450 2C8 (CYP2C8) inhibitors (e.g., gemfibrozil) or inducers (e.g., rifampin); **OR**
    - BCRP inhibitors (e.g., cyclosporine, eltrombopag); **OR**
    - Adrenergic or serotonergic drugs which can increase norepinephrine or serotonin (e.g., opioids, selective serotonin reuptake inhibitors (SSRIs), selective norepinephrine reuptake inhibitors (SNRIs), tricyclics, tyramine; **OR**
    - Foods with large amounts of tyramine (e.g., >150mg), such as aged cheeses, cured meats, craft/unfiltered beers, beans); **OR**
    - Other antineoplastic, immunosuppressive or immunomodulating drugs (**Note**: if there is a history of prior use of these drugs, consider possible unintended additive immunosuppressive effects) **AND**
    - Patient will **NOT** receive live vaccines during and at least 4 weeks prior to and 12 weeks after treatment; **AND**
    - Patient does **NOT** have an active infection, including clinically important localized infections

    ❑ Yes ❑ No

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Definitive diagnosis of MS with a relapsing-remitting course is based upon BOTH dissemination in time and space. Unless contraindicated, MRI should be obtained (even if criteria are met).	
Dissemination in time (Development/appearance of new CNS lesions over time)	**Dissemination in space** (Development of lesions in distinct anatomical)
❑ ≥ 2 clinical attacks; **OR** ❑ 1 clinical attack **AND** one of the following: • MRI indicating simultaneous presence of gadolinium-enhancing and non-enhancing lesions at any time or by a new T2- hyperintense or gadolinium-enhancing lesion on follow-up MRIS compared to baseline scan • CSF-specific oligoclonal bands	❑ ≥ 2 lesions; **OR** ❑ 1 lesion **AND** one of the following: • Clear-cut historical evidence of a previous attack involving a lesion in a distinct anatomical location • MRI indicating ≥ 1 T2-hyperintense lesions characteristic of MS in ≥ 2 of 4 areas of the CNS (periventricular, juxtacortical, infratentorial, or spinal cord)
**** Active secondary progressive MS (SPMS) is defined as the following:**	
❑ Expanded Disability Status Scale (EDSS) score ≥ 3.0; **AND** ❑ Disease is progressive ≥ 3 months following an initial relapsing-remitting course (i.e., EDSS score increase by 1.0 in members with EDSS ≤ 5.5 or increase by 0.5 in members with EDSS ≥ 6); **AND** • ≥ 1 relapse within the previous 2 years; **OR** • Member has gadolinium-enhancing activity OR new or unequivocally enlarging T2 contrast- enhancing lesions as evidenced by MRI	
*****Definitive diagnosis of CIS is based upon <u>ALL</u> of the following:**	
❑ A monophasic clinical episode with member-reported symptoms and objective findings reflecting a focal or multifocal inflammatory demyelinating even in the CNS ❑ Neurologic symptom duration of at least 24 hours, with or without recovery ❑ Absence of fever or infection ❑ Member is not known to have multiple sclerosis	
******Definitive diagnosis of MS with a primary progressive course is based upon the following:**	
❑ 1 year of disability progression independent of clinical relapse; **AND** ❑ **TWO** of the following: • ≥ 1 T2-hyperintense lesion characteristic of MS in one or more of the following regions of the CNS: periventricular, cortical or juxtacortical, or infratentorial • ≥ 2 T2-hyperintense lesions in the spinal cord • Presence of CSF-specific oligoclonal bands	

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Medication being provided by Specialty Pharmacy - PropriumRx

Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.*

Previous therapies will be verified through pharmacy paid claims or submitted chart notes.*