United Healthcare Community Plan

COMMONWEALTH OF VIRGINIA DEPARTMENT OF MEDICAL ASSISTANCE SERVICES

Service Authorization (SA) Form

MULTIPLE SCLEROSIS

If the following information is not complete, correct, or legible, the SA process can be delayed.

Please use one form per member.

MEMBER INFORMATION

Last Name: _____

First Name: _____

Medicaid ID Number: _____

Date of Birth: _____

Weight in Kilograms: _____

PRESCRIBER INFORMATION

Last Name: _____

First Name: _____

NPI Number: _____

Phone Number: _____

Fax Number: _____

DRUG INFORMATION

Drug Name/Form: _____

Strength: _____

Dosing Frequency: _____

Length of Therapy: _____

Quantity per Day: _____

(Form continued on next page.)

Member's Last Name: **Member's First Name:**

DIAGNOSIS AND MEDICAL INFORMATION

1. Is the 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)*** ☐ Primary progressive disease (PPMS)*

   ☐ 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: _____

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

   Previous Medication(s): _____

5. Will Mavenclad®, Mayzent®, Ponvory™, Zeposia® be used as 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

(Form continued on next page.)

Member's Last Name: **Member's First Name:**

9. **Mavenclad® Specific**

   a. Is the lymphocyte count ≥ 800 cells/mL prior to start of therapy?

   ☐ Yes ☐ No

   b. Please attest that members 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

10. **Mayzent® Specific**

   a. Has the member been tested for CYP2C9 variant status to determine genotyping (required for dosing)?

   ☐ Yes ☐ No

11. **Mayzent®, Ponvory™ or Zeposia® Specific**

   a. Please attest that members 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

12. Before using **Mayzent®, Ponvory™ or Zeposia®**, can you 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

(Form continued on next page.)

Member's Last Name: **Member's First Name:**

13. 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

14. Can you confirm **Zeposia®** will **not** be used in combination with the following?:

- Will **not** be initiating therapy after previous treatment with alemtuzumab; **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., > 150 mg), 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

(Form continued on next page.)

Member's Last Name: **Member's First Name:**

***Definitive diagnosis of relapsing-remitting MS (RRMS) OR primary progressive MS (PPMS) is based upon:**

- Dissemination in space (see below) AND one or more of the following:
  - Positive cerebrospinal fluid (CSF) (e.g., presence of oligoclonal bands or kappa free light chain index)
  - Positive central vein sign (CVS) (e.g., presence of six or more lesions with CVS; if fewer than 6 white matter lesions are seen on MRI, the number of CVS positive lesions should outnumber the CVS negative lesions)
  - Dissemination in time (DIT) (see below)
  - Presence of lesions in at least four of five CNS anatomical locations; **OR**
- Lesions present in one CNS site (including members with 12 months or longer progression from onset) **AND** one or more of the following:
  - CSF positivity and CVS positivity
  - CSF positivity and paramagnetic rim lesion (PRL) positivity (e.g., presence of one or more PRL)
  - DIT (see below) and CVS positivity
  - DIT (see below) and PRL positivity

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 locations within the CNS; multifocal)
▪ ≥ 2 clinical attacks; **OR** ▪ Simultaneous presence of gadolinium enhancing and non-enhancing lesions at any time; **OR** ▪ A new T2-hyperintense or gadolinium enhancing lesion on follow-up MRI	▪ MRI indicating typical lesions in ≥ 2 of 5 areas of the CNS (optic nerve, intracortical or juxtacortical, periventricular, infratentorial, or spinal cord); **OR** ▪ In members with progressive disease (patients with 12 months or longer progression from onset), two spinal cord lesions

****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 ALL of the following:**

- A monophasic clinical episode with member-reported symptoms and objective findings reflecting a focal or multifocal inflammatory demyelinating event 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

(Form continued on next page.)

Member's Last Name: **Member's First Name:**

Prescriber Signature (Required) **Date**

I attest that all information is accurate. Yes No

By signature, the physician confirms the above information is accurate and verifiable by member records.

Please include ALL requested information; incomplete forms will delay the SA process.
Submission of documentation does NOT guarantee coverage by the Department of Medical Assistance Services.

Fax this form to 1-866-940-7328

Pharmacy PA Call Center 1-800-310-6826