United Healthcare Community Plan

COMMONWEALTH OF VIRGINIA DEPARTMENT OF MEDICAL ASSISTANCE SERVICES

Service Authorization (SA) Form

Ocrevus® (ocrelizumab), Ocrevus Zunovo™ (ocrelizumab and hyaluronidase-ocsq)

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

Please use one form per member.

Physician Administered Drug: This form is only to be used for members obtaining the medication from a pharmacy through billing the pharmacy benefit at point-of-sale. Please reference Appendix B: Physician Administered Drug Criteria for members/providers that will obtain the medication through the medical benefit.

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

For an initial request, complete the following questions to receive a 6-month approval:

1. Is the member at least 18 years of age?

   ☐ Yes ☐ No

2. Has the member been screened for the presence of Hepatitis B virus (HBV) prior to initiating treatment AND does not have active disease (i.e., positive HBsAg and anti-HBV tests)? **AND**

   ☐ Yes ☐ No

3. Has the member had baseline serum immunoglobulin assessed? **AND**

   ☐ Yes ☐ No

4. Will the member not receive live or live attenuated vaccines while on therapy or within 4 weeks prior to the initiation of treatment? **AND**

   ☐ Yes ☐ No

5. Is the member free of an active infection? **AND**

   ☐ Yes ☐ No

6. Will Ocrevus/Ocrevus Zunovo be used as a single therapy? **AND**

   ☐ Yes ☐ No

7. Has the member not received a dose of ocrelizumab or ublituximab within the past 5 months? **AND**

   ☐ Yes ☐ No

8. Does the member have a confirmed diagnosis of multiple sclerosis (MS) as documented by laboratory report (i.e., MRI)? **AND**

   a. Does the member have a diagnosis of a relapsing form of MS [i.e., relapsing-remitting MS (RRMS)*, active secondary progressive disease (SPMS)**, or clinically isolated syndrome (CIS)***]? **OR**

   b. Does the member have a diagnosis of primary progressive MS (PPMS)*? **AND**

      i. Is the member less than 65 years of age? **AND**

      ii. Does the member have an expanded disability status scale (EDSS) score of ≤ 6.5?

      ☐ Yes ☐ No

(Form continued on next page.)

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

For a renewal request, complete the following questions to receive a 12-month approval:

1. Does the member continue to meet the relevant criteria identified in the initial criteria? **AND**

   ☐ Yes ☐ No

2. Does the member have an absence of unacceptable toxicity from the drug? **AND**

   ☐ Yes ☐ No

3. Is the member being continuously monitored for response to therapy that indicates a beneficial response?

   ☐ Yes ☐ No

***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

(Form continued on next page.)

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

***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

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