

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 Ocrevus and Ocrevus Zunovo Clinical 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.)		

Virginia DMAS SA Form: Ocrevus® (ocrelizumab), Ocrevus Zunovo™ (ocrelizumab and hyaluronidase-ocsq) 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 l No 6. Will Ocrevus/Ocrevus Zunovo be used as a single therapy? AND Yes l 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.)

Virginia DMAS SA Form: Ocrevus® (ocrelizumab), Ocrevus Zunovo™ (ocrelizumab and hyaluronidase-ocsq) 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 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 space Dissemination in time (Development of lesions in distinct anatomical (Development/appearance of new CNS lesions over time) locations within the CNS; multifocal) ≥ 2 clinical attacks; OR ≥ 2 lesions; 1 clinical attack and one of the following: 1 lesion and one of the following: MRI indicating simultaneous presence of gadolinium-Clear-cut historical evidence of a previous attack enhancing and non-enhancing lesions at any time or involving a lesion in a distinct anatomical location by a new T2- hyperintense or gadolinium-enhancing MRI indicating ≥ 1 T2-hyperintense lesions lesion on follow-up MRI compared to baseline scan characteristic of MS in ≥ 2 of 4 areas of the CNS CSF-specific oligoclonal bands (periventricular, cortical or 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

(Form continued on next page.)

evidenced by MRI

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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

****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

Prescriber Signature (Required)

Date

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