

# 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.**

### **Drug Requested:** Non-preferred ocrelizumab products (Pharmacy)

<input type="checkbox"/> <b>Ocrevus<sup>®</sup></b> (ocrelizumab) (J2350)	<input type="checkbox"/> <b>Ocrevus Zunovo<sup>™</sup></b> (ocrelizumab/hyaluronidase-ocsq) (J3590)
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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: \_\_\_\_\_

### **Recommended Dosage and Administration:**

- **Ocrevus<sup>®</sup>: IV: 300 mg once on day 1, followed by 300 mg once 2 weeks later; subsequent doses of 600 mg are administered once every 6 months (beginning 6 months after the first 300 mg dose)**
  - Initial dose: 300 billable units (300 mg/10 mL) on day 1 and day 15
  - Subsequent doses: 600 billable units (600 mg) every 6 months
  - Ocrevus<sup>®</sup> 300mg/10ml solution; 1 vial =300 billable units
- **Ocrevus Zunovo<sup>™</sup>: SUBQ: ocrelizumab 920 mg/hyaluronidase 23,000 units once every 6 months**

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**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.

**Initial Authorization: 6 months**

**Diagnosis - Relapsing-Remitting MS indication**

- Has the member been approved for Ocrevus<sup>®</sup> or Ocrevus Zunovo<sup>™</sup> under the Sentara Health Plans medical department?
  - Yes     No
- Member is 18 years of age or older
- Member has 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)
- Member had baseline serum immunoglobulin assessed
- Member will **NOT** receive live or live attenuated vaccines while on therapy or within 4 weeks prior to the initiation of treatment
- Member is free of an active infection
- Ocrevus<sup>®</sup> will be used as single therapy
- Member has **NOT** received a dose of Ocrevus<sup>®</sup> or Briumvi<sup>™</sup> within the past 5 months
- Member has a confirmed diagnosis of multiple sclerosis (MS) as documented by laboratory report (i.e., MRI)
- Member has 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**
- Member has a diagnosis of primary progressive MS (PPMS)\*\*\*\*
  - Member is less than 65 years of age
  - Member has an expanded disability status scale (EDSS) score of  $\leq 6.5$
- Member has tried and failed at least **TWO (2)** of the following preferred agents (**verified by chart notes or pharmacy paid claims; check each tried**)

<input type="checkbox"/> Avonex <sup>®</sup> (IFN beta-1b)	<input type="checkbox"/> Betaseron <sup>®</sup> (IFN beta-1a)	<input type="checkbox"/> Copaxone <sup>®</sup> 20mg (glatiramer acetate)
<input type="checkbox"/> dimethyl fumarate (generic Tecfidera <sup>®</sup> )	<input type="checkbox"/> fingolimod (generic Gilenya <sup>®</sup> )	<input type="checkbox"/> Kesimpta <sup>®</sup> (ofatumumab) *Step- edit required
<input type="checkbox"/> teriflunomide (generic Aubagio <sup>®</sup> )	<input type="checkbox"/> Other: _____	

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

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**Reauthorization: 12 months.** 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.

- Member continues to meet the relevant criteria identified in the initial criteria
- Member has an absence of unacceptable toxicity from the drug
- Member is being continuously monitored for response to therapy indicates a beneficial response

**\*\*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).**

<b>Dissemination in time</b> (Development/appearance of new CNS lesions over time)	<b>Dissemination in space</b> (Development of lesions in distinct anatomical)
<ul style="list-style-type: none"> <li><input type="checkbox"/> <math>\geq 2</math> clinical attacks; <b>OR</b></li> <li><input type="checkbox"/> 1 clinical attack <b>AND</b> one of the following:               <ul style="list-style-type: none"> <li>• 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</li> <li>• CSF-specific oligoclonal bands</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li><input type="checkbox"/> <math>\geq 2</math> lesions;</li> <li><input type="checkbox"/> 1 lesion <b>AND</b> one of the following:               <ul style="list-style-type: none"> <li>• Clear-cut historical evidence of a previous attack involving a lesion in a distinct anatomical location</li> <li>• MRI indicating <math>\geq 1</math> T2-hyperintense lesions characteristic of MS in <math>\geq 2</math> of 4 areas of the CNS (periventricular, juxtacortical, infratentorial, or spinal cord)</li> </ul> </li> </ul>

**\*\*Active secondary progressive MS (SPMS) is defined as the following:**

- Expanded Disability Status Scale (EDSS) score  $\geq 3.0$ ; **AND**
- Disease is progressive  $\geq 3$  months following an initial relapsing-remitting course (i.e., EDSS score increase by 1.0 in members with EDSS  $\leq 5.5$  or increase by 0.5 in members with EDSS  $\geq 6$ ); **AND**
  - $\geq 1$  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 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:
  - $\geq 1$  T2-hyperintense lesion characteristic of MS in one or more of the following regions of the CNS: periventricular, cortical or juxtacortical, or infratentorial
  - $\geq 2$  T2-hyperintense lesions in the spinal cord
  - Presence of CSF-specific oligoclonal bands

**Medication being provided by: Please check applicable box below.**

- Location/site of drug administration:** \_\_\_\_\_  
**NPI or DEA # of administering location:** \_\_\_\_\_

**OR**

- 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.\****