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)

❑ **Ocrevus®** (ocrelizumab) **(J2350)**	❑ **Ocrevus Zunovo™** (ocrelizumab/hyaluronidase-ocsq) **(J3590)**

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®: 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® 300mg/10ml solution; 1 vial =300 billable units
- **Ocrevus Zunovo™: 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® or Ocrevus Zunovo™ under the Sentara Health Plans pharmacy 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® will be used as single therapy
- ❑ Member has **NOT** received a dose of Ocrevus® or Briumvi™ 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 ≤ 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)**

❑ Avonex® (IFN beta-1b)	❑ Betaseron® (IFN beta-1a)	❑ Copaxone® 20mg (glatiramer acetate)
❑ dimethyl fumarate (generic Tecfidera®)	❑ fingolimod (generic Gilenya®)	❑ Kesimpta® (ofatumumab) *Step- edit required
❑ teriflunomide (generic Aubagio®)	❑ 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).**	
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; ❑ 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	

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****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: • ≥ 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

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.****