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

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 mg/10 mL on day 1 and day 15
  - Subsequent doses: 600 mg every 6 months
  - Ocrevus® 300mg/10ml solution; 1 vial
- **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 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 has a baseline assessment of serum immunoglobulin
- ❑ Member will **NOT** receive live or live attenuated vaccines while on therapy or within 4 weeks prior to the initiation of treatment
- ❑ Member is immunocompetent and free of an active infection
- ❑ Ocrevus®/Ocrevus Zunovo™ will be used as single therapy
- ❑ Member has **NOT** received a dose of Ocrevus®/Ocrevus Zunovo™ 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)	❑ 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.

_____

_____

_____

_____

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 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).

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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 (members 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 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

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.****

***Approved by the Pharmacy and Therapeutic Committee**: 5/18/2017
REVISED/UPDATED/REFORMATTED: ~~5/30/2017; 6/30/2017; 8/6/2017; 12/12/2017; 9/28/2018; 3/18/2019; 7/7/2019; 9/24/2019; 6/30/2021; 5/13/2022; 6/4/2022; 6/17/2022; 6/19/2024; 12/9/2024, 1/22/2025; 4/4/2025,~~ **3/20/2026**