

SENTARA COMMUNITY PLAN (MEDICAID)

MEDICAL 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 1-844-305-2331**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization can be delayed.**

Drug Requested: Non-preferred ocrelizumab products (Medical)

<input type="checkbox"/> Ocrevus® (ocrelizumab) (J2350)	<input type="checkbox"/> Ocrevus Zunovo™ (ocrelizumab/hyaluronidase-ocsq) (J2351)
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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: _____

- Standard Review. In checking this box, the timeframe does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.

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 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**)

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

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) course 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)
<ul style="list-style-type: none"> <input type="checkbox"/> ≥ 2 clinical attacks; OR <input type="checkbox"/> Simultaneous presence of gadolinium enhancing and non-enhancing lesions at any time; OR <input type="checkbox"/> A new T2-hyperintense or gadolinium enhancing lesion on follow-up MRI 	<ul style="list-style-type: none"> <input type="checkbox"/> MRI indicating typical lesions in ≥ 2 of 5 areas of the CNS (optic nerve, intracortical or juxtacortical, periventricular, infratentorial, or spinal cord); OR <input type="checkbox"/> 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:	
<ul style="list-style-type: none"> <input type="checkbox"/> Expanded Disability Status Scale (EDSS) score ≥ 3.0; AND <input type="checkbox"/> 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 <ul style="list-style-type: none"> • ≥ 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 <u>ALL</u> of the following:	
<ul style="list-style-type: none"> <input type="checkbox"/> A monophasic clinical episode with member-reported symptoms and objective findings reflecting a focal or multifocal inflammatory demyelinating event in the CNS <input type="checkbox"/> Neurologic symptom duration of at least 24 hours, with or without recovery <input type="checkbox"/> Absence of fever or infection <input type="checkbox"/> 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**

For urgent reviews: Practitioner should call Sentara Health Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Sentara Health’s definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member’s ability to regain maximum function.

*****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.****