

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: Ocrevus[®] (ocrelizumab) Injection (J2350/C9494) (Medical)

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: _____

DEA OR NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

Dosing Schedule: _____ Length of Therapy: _____

Diagnosis: _____ ICD Code, if applicable: _____

Weight: _____ Date: _____

- 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:

- Initial dose: 300 mg intravenous infusion, followed 2 weeks later by a 2nd 300 mg intravenous infusion
- Subsequent doses: single 600 mg intravenous infusion every 6 months
- Ocrevus[®] 300mg/10ml solution; 1 vial =300 billable units

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

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❑ Diagnosis - Relapsing-Remitting MS indication

- ❑ Has the member been approved for Ocrevus® 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 _____	

- ❑ 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 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)
<ul style="list-style-type: none"> <input type="checkbox"/> ≥ 2 clinical attacks; OR <input type="checkbox"/> 1 clinical attack AND one of the following: <ul style="list-style-type: none"> • 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 	<ul style="list-style-type: none"> <input type="checkbox"/> ≥ 2 lesions; <input type="checkbox"/> 1 lesion AND one of the following: <ul style="list-style-type: none"> • 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:	
<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 even 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 	

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****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 (check box below that applies):

- 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.****