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: Briumvi™ (ublituximab) **(Pharmacy)**

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:

- **Initial dose: 150 mg intravenous infusion, followed 2 weeks later by a 2nd 450 mg intravenous infusion**
- **Subsequent doses: single 450 mg intravenous infusion every 6 months**

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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- ❑ Has the member been approved for Briumvi™ previously through the Sentara Health Plans medical department?
  - ❑ Yes ❑ No
- ❑ Member is 18 years of age or older
- ❑ Member must have **ONE** of the following confirmed relapsing forms of multiple sclerosis (MS):
  - ❑ Relapsing-remitting MS (RRMS)*
  - ❑ Active Secondary-progressive MS (SPMS)**
  - ❑ Clinically Isolated Syndrome (CIS)***
- ❑ Member has a confirmed diagnosis of multiple sclerosis (MS) as documented by laboratory report (i.e., MRI)
- ❑ 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: _____		

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

_____

_____

_____

_____

_____

- ❑ 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 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
- ❑ Member has not received a dose of Ocrevus® or Briumvi™ within the past 5 months

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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 to indicate 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 MRI 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 event 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.