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: Briumvi™ (ublituximab) **Injection (J2329) (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: 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**
- Briumvi 150mg/6ml solution; 1 vial=150 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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- ❑ Has the member been approved for Briumvi™ previously through the Sentara Health Plans pharmacy 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 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.

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- ❑ 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 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 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

*****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

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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 Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Sentara'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.