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:** _____

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:

- **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)	❑ 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 immunocompetent and free of an active infection
- ❑ Briumvi will be used as single therapy
- ❑ 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:**

- 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).

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, eriventricular, infratentorial, or spinal cord); OR ❑ In members with progressive disease (members with 12 months or longer progression from onset), two spinal cord lesions

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****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 <u>ALL</u> 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

Medication being provided by: **Please check applicable box below.**

❑ **Location/site of drug administration:** _____

NPI or DEA # of administering location: _____

<u>OR</u>

❑ 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.*****

****<u>Previous therapies will be verified through pharmacy paid claims or submitted chart notes.</u>****