

COMMONWEALTH OF VIRGINIA DEPARTMENT OF MEDICAL ASSISTANCE SERVICES Service Authorization (SA) Form

Briumvi™ (ublituximab-xiiy)

If the following information is not complete, correct, or legible, the SA process can be delayed.

Please use one form per member.

Physician Administered Drug: This form is only to be used for members obtaining the medication from a pharmacy through billing the pharmacy benefit at point-of-sale. Please reference <u>Virginia Briumvi Clinical</u> <u>Criteria</u> for members/providers that will obtain the medication through the medical benefit.

WIEWBER INFORMATION				
Last Name:	First Name:			
Medicaid ID Number:	Date of Birth:			
	Weight in Kilograms:			
PRESCRIBER INFORMATION				
Last Name:	First Name:			
NPI Number:				
Phone Number:	Fax Number:			
DRUG INFORMATION				
Drug Name/Form:				
Strength:				
Dosing Frequency:				
Length of Therapy:				
Quantity per Day:				
(Form continued on next page.)				

Virginia DMAS SA Form: Briumvi™ (ublituximab-xiiy)

Memb	er's I	Last r	Name:
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Member's	First Name:
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DI	AGNOSIS AND MEDICAL INFORMATION
Fo	r an initial request, complete the following questions to receive a 6-month approval:
1.	Is the member at least 18 years of age? AND
	☐ Yes ☐ No
2.	Has the member 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)? AND
	☐ Yes ☐ No
3.	Has the member had baseline serum immunoglobulin assessed? AND
	☐ Yes ☐ No
4.	Will the member not receive live or live attenuated vaccines while on therapy or withing 4 weeks prior to the initiation of treatment? AND
	☐ Yes ☐ No
5.	Is the member free of an active infection? AND
	☐ Yes ☐ No
6.	Will Briumvi be used as a single therapy? AND
	☐ Yes ☐ No
7.	Has the member not received a dose of ocrelizumab or ublituximab within the past 5 months? AND
	☐ Yes ☐ No
8.	Does the member have a confirmed diagnosis of multiple sclerosis (MS) as documented by laboratory report (i.e., MRI)? AND
	☐ Yes ☐ No
9.	Does the member have 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
	☐ Yes ☐ No
(Fc	orm continued on next page.)

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Member's Last Name:

Member's First Name:

For a renewal request, complete the following questi	ions to receive a 12-month approval:			
Does the member continue to meet the relevant criteria identified in the initial criteria? AND				
Yes No				
Does the member have an absence of unacceptable toxicity from the drug? AND				
Yes No				
Is the member being continuously monitored for response to therapy indicates a beneficial response?				
∏Yes ∏No				
	ng course is based upon BOTH dissemination in time and ould be obtained (even if criteria are met).			
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			
	locations within the CNS; multifocal)			
■ ≥ 2 clinical attacks; OR	■ ≥ 2 lesions;			
1 clinical attack AND one of the following:	1 lesion AND one of the following:			
MRI indicating simultaneous presence of	Clear-cut historical evidence of a previous attack involving a basic in a distinct content of the second relationship.			
gadolinium-enhancing and non-enhancing lesions a				
any time or by a new T2- hyperintense or	 MRI indicating ≥ 1 T2-hyperintense lesions 			
gadolinium-enhancing lesion on follow-up MRI compared to baseline scan	characteristic of MS in ≥ 2 of 4 areas of the CNS			
	(periventricular, r juxtacortical, infratentorial, or			
CSF-specific oligoclonal bands	spinal cord)			
**Active secondary progressive N	MS (SPMS) is defined as the following:			
■ Expanded Disability Status Scale (EDSS) score ≥ 3.0; AN	D			
 Disease is progressive ≥ 3 months following an initial re 	elapsing-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 nev 	w or unequivocally enlarging T2 contrast-enhancing lesions as			

(Form continued on next page.)

evidenced by MRI

Member's Last Name:

Member's First Name:

***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

Prescriber Signature (Required)

Date

By signature, the physician confirms the above information is accurate and verifiable by member records.

Please include ALL requested information; Incomplete forms will delay the SA process.

Submission of documentation does NOT guarantee coverage by the Department of Medical Assistance Services.

Fax this form to 1-866-940-7328

Pharmacy PA call center: 1-800-310-6826