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CardinalCare
Virginia's Medicaid Program

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 Virginia Briumvi Clinical Criteria for members/providers that will obtain the medication through the medical benefit.

MEMBER 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.)

Member's Last Name: **Member's First Name:**

DIAGNOSIS AND MEDICAL INFORMATION

For 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

(Form continued on next page.)

Member's Last Name: **Member's First Name:**

For a renewal request, complete the following questions to receive a 12-month approval:

1. Does the member continue to meet the relevant criteria identified in the initial criteria? **AND**

   ☐ Yes ☐ No

2. Does the member have an absence of unacceptable toxicity from the drug? **AND**

   ☐ Yes ☐ No

3. Is the member being continuously monitored for response to therapy indicates a beneficial response?

   ☐ Yes ☐ No

***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 locations within the CNS; multifocal)
▪ ≥ 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, r 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	

(Form continued on next page.)

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.

The completed form may be: **FAXED TO 800-932-6651**, phoned to 800-932-6648, or mailed to:
Prime Therapeutics Management LLC/Attn: GV – 4201
P.O. Box 64811, St. Paul, MN 55164-0811