MOLINA HEALTHCARE

Service Authorization (SA) Form

Briumvi™ (ublituximab-xiiy) and Ocrevus® (ocrelizumab)

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

Please use one form per member.

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.)

Revised: 06012024 | Effective: 07012024

VA-ALL-PF-16717-24

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

10. **Ocrevus Specific:** Does the member have a diagnosis of primary progressive MS (PPMS)**** AND meet the following:

    a. Is the member less than 65 years of age? **AND**

    b. Does the member have an expanded disability status scale (EDSS) score of ≤ 6.5?

    ☐ 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 <u>BOTH</u> dissemination in time and space. Unless contraindicated, MRI should be obtained (even if criteria are met).**	
<u>Dissemination in time</u> (*Development/appearance of new CNS lesions over time*)	**<u>Dissemination in space</u>** (*Development of lesions in distinct anatomical*

• ≥ 2 clinical attacks; **OR**
• 1 clinical attack <u>AND</u> 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 Molina Healthcare.

The completed form may be: **FAXED to (844) 278-5731**, or you may call (800) 424-4518 (TTY: 711).