

## GCHP Medi-Cal Clinical Guidelines Ublituximab (Briumvi™)

PA Criteria	Criteria Details
<b>Covered Uses (FDA Approved Indication)</b>	Treatment of relapsing form of multiple sclerosis (MS), including clinically isolated syndrome (CIS), relapsing-remitting disease, and active secondary progressive disease.
<b>Exclusion Criteria</b>	<ul style="list-style-type: none"> <li>• Active infection including hepatitis B and tuberculosis.</li> <li>• Concurrent use with other disease-modifying therapies or immunosuppressives.</li> <li>• Primary progress MS (PPMS).</li> </ul>
<b>Required Medical Information</b>	<p><b>Initial:</b></p> <ul style="list-style-type: none"> <li>• Documentation of MRI of brain with abnormalities consistent with MS</li> <li>• Greater than or equal to two relapses in prior two years or one relapse in the prior year and/or greater than or equal to one T1 gadolinium (Gd) enhancing lesion in the prior year.</li> <li>• No active HBV confirmed by positive results for Hepatitis B surface antigen (HBsAg) and anti-HBV tests.</li> <li>• Must monitor levels of immunoglobulins at the beginning, during, and after discontinuation of treatment – Ublituximab is not covered in presence of documented persistent hypogammaglobulinemia, unless provider submits documentation demonstrating that there is no effective alternative treatment.</li> <li>• Expanded Disability Status Scale (EDSS) 0 to 5.5.</li> </ul> <p><b>Renewal:</b></p> <ul style="list-style-type: none"> <li>• Reduction or stabilization in the total number of magnetic resonance imaging (MRI) T1 gadolinium-enhancing lesions.</li> <li>• Reduction or stabilization in the total number of new or enlarging MRI T2 hyperintense lesions.</li> <li>• Lack of disability progression, defined as an increase in Expanded Disability Status Scale (EDSS) score.</li> <li>• Stabilization, or improvement in at least one symptom such as motor function, fatigue, vision, bowel/bladder function, spasticity, walking / gait, or pain / numbness/tingling sensation.</li> </ul>
<b>Age Restriction</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Neurologist.
<b>Coverage Duration</b>	12 months.



Other Criteria / Information	Criteria adapted from DHCS March 2024		
	<b>HCPCS</b>	<b>Description</b>	<b>Dosing, Units</b>
	J2329	Injection, ublituximab-xiiy, 1mg (Briumvi™)	150mg IV once on day one, followed by 450mg IV once two weeks later; subsequent doses of 450mg every 24 weeks.

STATUS	DATE REVISED	REVIEW DATE	APPROVED / REVIEWED BY	EFFECTIVE DATE
Created	5/1/2024	5/1/2024	Lily Yip, Director of Pharmacy Services; Yoonhee Kim, Clinical Programs Pharmacist	N/A
Approved	N/A	5/15/2024	Pharmacy & Therapeutics (P&T) Committee	3/1/2025
Approved	N/A	7/18/2024	Medical Advisory Committee (MAC)	3/1/2025