

## GCHP Medi-Cal Clinical Guidelines Belimumab (Benlysta™)

PA Criteria	Criteria Details
<b>Covered Uses (FDA Approved Indication)</b>	<ul style="list-style-type: none"> <li>Active lupus nephritis who are receiving standard therapy.</li> <li>Active systemic lupus erythematosus (SLE) who are receiving standard therapy.</li> </ul>
<b>Exclusion Criteria</b>	<ul style="list-style-type: none"> <li>Severe active CNS lupus.</li> <li>Use in combination with other biologics (e.g., TNF inhibitors).</li> <li>Active infection.</li> </ul>
<b>Required Medical Information</b>	<p>Dosage form that is being requested for administration during the medical visit (Prefilled Autoinjectors vs. Prefilled Syringes vs. Vials)</p> <ul style="list-style-type: none"> <li>Benlysta™ Autoinjectors and Prefilled syringe: FDA approved for self or caregiver administration with proper training.</li> <li>Benlysta™ Vials: FDA approved for administration by health care provider.</li> </ul> <p><b>Active lupus nephritis</b></p> <ul style="list-style-type: none"> <li>Concurrent therapy on calcineurin inhibitors (e.g., cyclosporine, tacrolimus), corticosteroids, or immunosuppressives (e.g., azathioprine, mycophenolate) AND</li> <li>Kidney biopsy results confirming active lupus nephritis.</li> </ul> <p><b>SLE</b></p> <ul style="list-style-type: none"> <li>Concurrent therapy on hydroxychloroquine, corticosteroids, immunosuppressives (e.g., azathioprine, methotrexate, or mycophenolate) or NSAIDs AND</li> <li>Positive anti-nuclear antibody test with titer of &gt; 1:80 HEp<sub>2</sub> or equivalent positive test.</li> </ul> <p>Renewal will require favorable response to belimumab.</p>
<b>Age Restriction</b>	5 years of age and older
<b>Prescriber Restrictions</b>	Rheumatologist or Nephrologist
<b>Coverage Duration</b>	<b>Vials:</b> Initial Six months; Renewal 12 months
<b>Other Criteria / Information</b>	<p>Criteria adapted from DHCS March 2024 &amp; MCG</p> <p>Belimumab (Benlysta™) is available for self-administration in the form of an autoinjector and a prefilled syringe, which are administered by the member or a caregiver at home. Benlysta™ autoinjector or prefilled syringes should be provided to the member by a pharmacy through pharmacy benefit.</p>



	HCPCS	Description	Dosing, Units
	J0490	Injection belimumab 10mg (Benlysta™ autoinjector, prefilled syringe, vial)	10mg/kg IV at two-week intervals for the first three doses then at four-week interval thereafter.

STATUS	DATE REVISED	REVIEW DATE	APPROVED / REVIEWED BY	EFFECTIVE DATE
Created	5/1/2024	5/1/2024	Yoonhee Kim, Clinical Programs Pharmacist Lily Yip, Director of Pharmacy Services	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