

GCHP Medi-Cal Clinical Guidelines Anifrolumab (Saphnelo™)

PA Criteria	Criteria Details
Covered Uses (FDA Approved Indication)	<p>Moderate to severe systemic lupus erythematosus (SLE) in adults who are receiving standard therapy.</p> <p><i>Standard therapy would include medications such as NSAIDs, corticosteroids, antimalarials (e.g., chloroquine, hydroxychloroquine) and immunosuppressives (e.g., cyclophosphamide, azathioprine, mycophenolate or methotrexate).</i></p>
Exclusion Criteria	<ul style="list-style-type: none"> Severe active lupus nephritis or severe active central nervous system lupus. Serous or active infection. Concurrent therapy with a biologic medication such as belimumab or intravenous cyclophosphamide.
Required Medical Information	<p>Initial therapy:</p> <ul style="list-style-type: none"> Fulfilled at least four of the 11 American College of Rheumatology (ACR) classification criteria for SLE. Seropositive for antinuclear antibodies, anti-double-stranded DNA (anti-dsDNA) antibodies, or anti-Smith antibodies. Currently receiving stable treatment with at least one of the following: <ul style="list-style-type: none"> Glucocorticoids (for example, Prednisone, Methylprednisone, etc.) An Antimalarial Agent (hydroxychloroquine or chloroquine) Immunosuppressants (Azathioprine, Mycophenolate, Methotrexate, etc.) <p>Renewal:</p> <ul style="list-style-type: none"> Positive clinical response demonstrated by at least one or more of the following: <ul style="list-style-type: none"> Improvement in all organs with disease activity at baseline with no new flares. Reduction in the dosages of oral corticosteroids from baseline. Decrease in symptoms or stabilization in at least one SLE related disease manifestation from baseline.
Age Restriction	18 years of age and older.
Prescriber Restrictions	Prescribed or recommended by a rheumatologist, dermatologist, nephrologist, pulmonologist, or other SLE treatment specialist.
Coverage Duration	Initial: Six months; Renewal: 12 months



Other Criteria / Information

Criteria adapted from DHCS April 2024

HCPCS	Description	Dosing, Units
J0491	Injection, anifrolumab-fnia, 1mg (Saphnelo™)	300mg IV every four weeks.

STATUS	DATE REVISED	REVIEW DATE	APPROVED / REVIEWED BY	EFFECTIVE DATE
Created	5/1/2024	8/5/2024	Yoonhee Kim, Clinical Programs Pharmacist Lily Yip, Director of Pharmacy Services	N/A
Approved	N/A	8/14/2024	Pharmacy & Therapeutics (P&T) Committee	3/1/2025
Approved	N/A	7/18/2024	Medical Advisory Committee (MAC)	3/1/2025