

PA Criteria	Criteria Details						
<b>Covered Uses (FDA approved indication)</b>	Saphnelo is a type I interferon (IFN) receptor antagonist indicated for the treatment of adult patients with moderate to severe systemic lupus erythematosus (SLE), who are receiving standard therapy.						
<b>Exclusion Criteria</b>	Must not be used with another biologic drug (e.g., Benlysta) or Lupkynis.						
<b>Required Medical Information</b>	<p>Medical records supporting the request must be provided.</p> <p><b>For systemic lupus erythematosus (SLE):</b></p> <ol style="list-style-type: none"> <li>1. Must have tried and failed (defined as an inability to taper the steroid dose and/or have frequent relapses) two of the following in combination: steroid, immunosuppressant, and/or hydroxychloroquine;</li> <li>2. Must have tried and failed (defined above) Benlysta;</li> <li>3. Must have a baseline SELENA-SLEDAI score of six or more; and</li> <li>4. for reauthorization, must have documentation of clinical benefit compared to baseline.</li> </ol>						
<b>Age Restriction</b>	None.						
<b>Prescriber Restrictions</b>	Must be prescribed by or in consultation with a rheumatologist.						
<b>Coverage Duration</b>	One year initial; two years reauthorization. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice.						
<b>Other Criteria/Information</b>	<p>Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document.</p> <table border="1"> <thead> <tr> <th>HCPCS</th> <th>Description</th> <th>Billing Units/How Supplied</th> </tr> </thead> <tbody> <tr> <td>J0491</td> <td>Saphnelo (anifrolumab-fnia)</td> <td><b>Billing unit: 1 mg</b>  300mg/2ml</td> </tr> </tbody> </table>	HCPCS	Description	Billing Units/How Supplied	J0491	Saphnelo (anifrolumab-fnia)	<b>Billing unit: 1 mg</b>  300mg/2ml
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STATUS	DATE REVISED	REVIEW DATE	APPROVED/REVIEWED BY	EFFECTIVE DATE
Created	3/26/2025	3/26/2025	Dawn Shojai, PharmD, Senior Pharmacy Benefit Consultant (PSG)	N/A
Approved	N/A	8/21/2025	Pharmacy & Therapeutics (P&T) Committee	8/21/2025