

Pharmacy Drug Policy & Procedure

Policy Name:	Saphnelo (anifrolumab-fnia)	Policy #:	3130P
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Purpose of the Policy

The purpose of this policy is to define coverage criteria for Saphnelo.

Statement of the Policy

Health Alliance Medical Plans will approve the use of Saphnelo under the specialty medical benefit if the following criteria are met.

Criteria

1. Coverage Criteria

- 1.1 Diagnosis of active systemic lupus erythematosus (SLE)
- 1.2 Age 18 years or older
- 1.3 Prescribed by or with a rheumatologist (musculoskeletal doctor)
- 1.4 Documented compliance with hydroxychloroquine or chloroquine, unless contraindicated
 - Compliance defined as possession of 150-days' worth of drug in 6 months
- 1.5 Documented trial and failure of or contraindication to treatment with at least one other standard of therapy: prednisone, azathioprine, leflunomide, mycophenolate mofetil, methotrexate, NSAIDs

2. Exclusion Criteria

- 2.1 Saphnelo will not be covered if used in combination with Benlysta or with biologic agents
- 2.2 Member currently has severe active central nervous lupus
- 2.3 Member currently has severe active lupus nephritis

3. Approval Period

- 3.1 Initial: 12 months
- 3.2 Subsequent Approvals: 12 months with documentation of positive response to therapy

CPT Codes

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HCPCS Codes

J0491	Injection, anifrolumab-fnia, 1 mg
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References

1. Saphnelo (anifrolumab) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; June 2024.
2. Tummala R, Abreu G, Pineda L, et al. Safety profile of anifrolumab in patients with active SLE: an integrated analysis of phase II and III trials. *Lupus Sci Med*. 2021;8(1):e000464.
3. Rovin BH, Adler SG, Barratt J, et al (Kidney Disease: Improving Global Outcomes (KDIGO) Glomerular Diseases Work Group). KDIGO 2021 Clinical Practice Guideline for the Management of Glomerular Diseases. *Kidney Int*. 2021 Oct;100(4S):S1-S276.
4. Fanouriakis A, Kostopoulou M, Andersen J, et al. EULAR recommendations for the management of systemic lupus erythematosus: 2023 update. *Ann Rheum Dis*. 2024 Jan 2;83(1):15-29.



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