

<b>Policy Name:</b>	<b>Saphnelo (anifrolumab-fnia)</b>	<b>Policy #:</b>	<b>3130P</b>
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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 and Health Alliance Northwest 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; December 2023.
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, Kostopoulous M, Alunno A, et al. 2019 update of the EULAR recommendations for the management of systemic lupus erythematosus. *Ann Rheum Dis*. 2019 Jun;78(6):736-745.

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