

anifrolumab-fnia (Saphnelo)**Medical Benefit Drug Policy**Place of Service

Home Infusion Administration

Infusion Center Administration

Office Administration

Outpatient Facility Infusion Administration

Drug Details**USP Category:** IMMUNOLOGICAL AGENTS**Mechanism of Action:** Type 1 interferon receptor antagonist**HCPCS:**

J0491:Injection, anifrolumab-fnia, 1 mg

How Supplied:

300 mg/2 mL single-use vial

Condition(s) listed in policy *(see coverage criteria for details)*

- Systemic lupus erythematosus

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the California Code of Regulations (CCR), Title 22, Section 51303 and 51313 must be met.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

Coverage Criteria**The following condition(s) require Prior Authorization/Preservice.****Systemic lupus erythematosus****Meets medical necessity if all the following are met:**

1. Prescribed by or in consultation with a rheumatologist
2. Patient is ≥ 18 years of age
3. Patient is currently taking one or more of the following drugs: azathioprine, chloroquine, hydroxychloroquine, methotrexate, methylprednisolone, mycophenolate, or prednisone
4. Patient does not have severe active lupus nephritis or severe active CNS lupus
5. Drug will not be used in combination with biologics (e.g., rituximab, Benlysta)

Covered Doses:

300 mg given intravenously every 4 weeks

Coverage Period:

Indefinite

ICD-10:

M32.0, M32.10, M32.11, M32.12, M32.13, M32.14, M32.15, M32.19, M32.8, M32.9

References

1. AHFS. Available by subscription at <http://www.lexi.com>
2. DrugDex. Available by subscription at <http://www.micromedexsolutions.com/home/dispatch>
3. Saphnelo (anifrolumab-fnia) Prescribing Information. AstraZeneca, Wilmington, DE: 8/2024.
4. Fanouriakis A, et al. 2019 update of the EULAR recommendations for the management of systemic lupus erythematosus. *Ann Rheum Dis* 2019; 78:736.

Review History

Date of Last Annual Review: 1Q2025

Changes from previous policy version:

- No clinical change following annual review.

*Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee*