

anifrolumab-fnia (Saphnelo)

Commercial 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 (SLE)

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 Health and Safety Code section 1367.21 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.

For billing purposes, drugs must be submitted with the drug's assigned HCPCS code (as listed in the drug policy) and the corresponding NDC (national drug code). An unlisted, unspecified, or miscellaneous code should not be used if there is a specific code assigned to the drug.

Members with the following plans: **PPO, Direct Contract HMO, and when applicable, ASO, Shared Advantage, HMO (non-direct)** may be required to have their medication administered at a preferred site of service, including the home, a physician's office, or an independent infusion center not associated with a hospital.

For members that cannot receive infusions in the preferred home or ambulatory setting AND meet one of the following criteria points, drug administration may be performed at a hospital outpatient facility infusion center.

CRITERIA FOR HOSPITAL OUTPATIENT FACILITY ADMINISTRATION

MCG Care Guidelines, 19th edition, 2015

ADMINISTRATION OF THIS DRUG IN THE HOSPITAL OUTPATIENT FACILITY SITE OF CARE REQUIRES ONE OF THE FOLLOWING: (*Supporting Documentation must be submitted*)

1. Patient is starting new therapy with Saphnelo (allowed for first dose). Subsequent doses will require medical necessity for continued use in the hospital outpatient facility site of care.
2. Patient is being re-initiated on Saphnelo after being off therapy for at least 6 months (allowed for first dose). Subsequent doses will require medical necessity for continued use in the hospital outpatient facility site of care.
3. Additional clinical monitoring is required during administration as evidenced by one of the following:
 - a. Patient has experienced a previous severe adverse event on this drug based on documentation submitted.
 - b. Patient continues to experience moderate to severe adverse events on this drug based on documentation submitted, despite receiving premedication such as acetaminophen, steroids, diphenhydramine, fluids, etc.
 - c. Patient is clinically unstable based on documentation submitted.
 - d. Patient is physically or cognitively unstable based on documentation submitted

Coverage Criteria

The following condition(s) require Prior Authorization/Preservice.

Systemic lupus erythematosus (SLE)

Meets medical necessity if all the following are met:

Initial

1. Prescribed by or in consultation with a rheumatologist
2. Age is consistent with the FDA-approved indication (18 years of age or older)
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)
6. Dose does not exceed the FDA-approved maximum

Reauthorization

1. Patient is responding to therapy (e.g. improvement in lupus symptoms)
2. Dose does not exceed the FDA-approved maximum
3. **Effective 5/1/2026 and after:** Drug will not be used in combination with biologics (e.g., rituximab, Benlysta)

Covered Doses:

Not to exceed 300 mg given intravenously every 4 weeks

Coverage Period:

One year

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: 1Q2026

Changes from previous policy version:

- Systemic lupus erythematosus (SLE): ***Effective 5/1/2026 and after***, reauthorization will require drug not be used in combination with biologics (Rationale: Ensure appropriate use)

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