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

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.

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

1. Patient is receiving their first infusion of Saphnelo or is being re-initiated on Saphnelo after at least 6 months off therapy. *Subsequent doses will require medical necessity for continued use in the hospital outpatient facility site of care.*

OR

Additional clinical monitoring is required during administration as evidenced by one of the following:

2. Patient has experienced a previous severe adverse event on Saphnelo based on documentation submitted.
3. Patient continues to experience moderate to severe adverse events on Saphnelo based on documentation submitted, despite receiving premedication such as acetaminophen, steroids, diphenhydramine, fluids, etc.
4. Patient is clinically unstable based on documentation submitted.
5. Patient is physically or cognitively unstable based on documentation submitted.

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