

Anifrolumab-fnia (Saphnelo®)

Place of Service  
Office Administration  
Infusion Center Administration  
Home Infusion Administration  
Outpatient Facility Infusion  
Administration

HCPCS: J0491 per 1 mg

Conditions listed in policy (see criteria for details)

- [Systemic lupus erythematosus \(SLE\)](#)

**AHFS therapeutic class:** Immunosuppressive agent

**Mechanism of action:** Type 1 interferon receptor antagonist

### (I) Special Instructions and Pertinent Information

Covered under the Medical Benefit, please submit clinical information for prior authorization review via fax.

#### **\*\* CRITERIA FOR HOSPITAL OUTPATIENT FACILITY ADMINISTRATION\*\***

*AAAAI Guidelines 2011, MCG™ Care Guidelines, 19th edition, 2015, Saphnelo PI, GSK, 12/16*

Members with the following plans: **PPO, Direct Contract HMO, and when applicable, Medi-Cal, 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.

#### **ADMINISTRATION OF 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.

**2) Prior Authorization/Medical Review is required for the following condition(s)**

**Seropositive systemic lupus erythematosus (SLE)**

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

**Covered Doses**

300 mg IV every 4 weeks

**Coverage Period**

Indefinite

**ICD-10:**

M32.0, M32.10-M32.19, M32.8, M32.9

**(3) The following condition(s) DO NOT require Prior Authorization/Preservice**

All requests for Saphnelo® (anifrolumab-fnia) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

**(4) This Medication is NOT medically necessary for the following condition(s)**

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

**(5) Additional Information**

How supplied:

- 300 mg/2 mL single-use vial

**(6) References**

- Saphnelo® (anifrolumab-fnia) [Prescribing information]. Wilmington, DE: AstraZeneca; 9/2022.

## **(7) Policy Update**

Date of last review: 1Q2023

Date of next review: 1Q2024

Changes from previous policy version:

- No clinical change to policy following routine annual review.

*BSC Drug Coverage Criteria to Determine Medical Necessity  
Reviewed by P&T Committee*