

Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	December 17, 2021

Saphnelo™ (anifrolumab-fnia)

LENGTH OF AUTHORIZATION: Up to 1 year

INITIAL REVIEW CRITERIA:

- Patient must be ≥ 18 years of age.
- Patient must have a diagnosis of moderate to severe systemic lupus erythematosus (SLE) including a positive autoantibody test.
- Patient is up to date with all vaccinations prior to initiating therapy.
- Patient must not receive live or live-attenuated vaccine concurrently with treatment.
- Patient must not have severe active central nervous system lupus or severe active lupus nephritis.
- Patient must not have clinically significant active infection.
- Saphnelo will be used in combination with standard therapy, except biologics.

CONTINUATION OF THERAPY:

- Patient met initial review criteria.
- Documentation of improved clinical response.
- Dosing is appropriate as per labeling or is supported by compendia.

DOSING AND ADMINISTRATION:

- Refer to product labeling at <https://www.accessdata.fda.gov/scripts/cder/daf/>
- Available as: 300 mg/2 mL single-dose vial.