EVH Clinical Guideline 5071.CC for Saphnelo (anifrolumab-fnia)

Guideline Number: EVH_CG_5071.CC	**Applicable Codes**	
"Evolent" refers to Evolent Health LLC and Evolent Specialty Services, Inc. 		
Original Date: May 2023	**Last Revised Date:** January 2026	**Implementation Date:** March 2026

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STATEMENT

General Information

- *It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Medical Policy Committee.*
- *If the established criteria are not met, the request is referred to a Medical Director for review, if required for the plan and level of request.*

Purpose

The purpose of this guideline is to define the prior authorization process for Saphnelo (anifrolumab-fnia).

Scope

This guideline applies to all practitioners who are involved in providing the requested drug. This guideline is specific to the Health Plan's medical benefit.

INITIAL REVIEW CRITERIA

The request must meet all of the criteria listed below.

- Must be prescribed by, or in consultation with, a rheumatologist
- Must be age 18 years or older
- Must have a diagnosis of moderate to severe systemic lupus erythematosus (SLE)
- Must have an adequate trial (of at least 3 months) of the following with an inadequate response or significant side effects/toxicity or have a contraindication to these therapies:
  - Hydroxychloroquine **AND**
  - Azathioprine OR Methotrexate OR Mycophenolate
- Must be on concomitant therapy with an SLE regimen comprised of any of the following (alone or in combination): corticosteroids, antimalarials, and immunosuppressives
- Must have chart note documentation or an attestation from the prescriber of all the following:
  - Member must NOT have severe active lupus nephritis or severe active central nervous system lupus
  - Member must not have evidence of active infection
  - Member must be up to date on all immunizations prior to initiating Saphnelo

- Member must not be on concomitant therapy with biologic therapies, including B-cell targeted therapies
- Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc.) listed in the FDA approved labeling

REAUTHORIZATION CRITERIA

All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. The request must meet all the criteria listed below.

- Must have recent chart note documentation from the prescriber that the member's condition has improved based upon the prescriber's assessment while on therapy
- Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc.) listed in the FDA approved labeling

APPROVAL DURATIONS

Initial Authorization	Up to 1 year
Reauthorization	Same as initial

CODING AND STANDARDS

Codes

Code	Brand	Description
J0491	Saphnelo	Injection, anifrolumab-fnia, 1 mg

Applicable Lines of Business

☐	CHIP (Children's Health Insurance Program)
☐	Commercial
☐	Exchange/Marketplace
☒	Medicaid
☐	Medicare Advantage

BACKGROUND

Definitions

Systemic Lupus Erythematosus (SLE) – a chronic inflammatory autoimmune condition that can cause disease of the skin, heart, lungs, kidneys, joints, and/or nervous system

POLICY HISTORY

Date	Summary
January 2026	• Added dosing criterion to reauthorization criteria
May 2023	• New Guideline

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Administrative Services Medical Policy Committee

Disclaimer

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REFERENCES

1. Saphnelo (anifrolumab) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; August 2024.
2. Belmont HM. Treatment of systemic lupus erythematosus - 2013 update. Bull Hosp Jt Dis (2013) 2013; 71:208.