Medical Drug Clinical Criteria

Subject:	Saphnelo (anifrolumab-fnia)		
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Overview

This document addresses the use of Saphnelo (anifrolumab-fnia), an IV administered type I interferon (IFN) receptor antagonist, for the treatment of moderate to severe systemic lupus erythematosus (SLE) as add-on treatment to standard therapy, such as corticosteroids, antimalarials, and/or immunosuppressants. Type I IFNs plays a key role in the pathophysiology of SLE, and increased type I IFN signaling is associated with greater disease activity and severity.

The American College of Rheumatology (ACR) uses the ACR classification criteria to diagnose an individual with SLE. The ACR requires 4 of these 11 criteria simultaneously or in succession for an individual to be classified as having SLE: malar rash, discoid rash, photosensitivity, oral ulcers, arthritis, serositis, renal disorders, neurological disorder, hematological disorder, immunological disorder, and anti-nuclear antibody.

The SELENA-SLEDAI (Safety of Estrogens in Systemic Lupus Erythematosus National Assessment -- Systemic Lupus Erythematosus Disease Activity Index) is a system used to evaluate the activity of lupus in clinical studies. This system is used for quantification of lupus disease, primarily for the purpose of determining whether a new drug evaluated for the disease is effective. The SELENA-SLEDAI is a slightly modified version of the SLEDAI and was developed by the NIH. It is a weighted index in which signs and symptoms, laboratory tests, and physician's assessment for each of nine organ systems are given a weighted score and summed up if present at the time of the visit or in the preceding 10 days. The maximum theoretical score for the SELENA-SLEDAI is 105 (all 24 descriptors present simultaneously) with 0 indicating inactive disease. The SLEDAI-2000 (SLEDAI-2K) is another modification of SLEDAI to allow for documentation of persistent disease activity, including rash, alopecia, mucosal ulcers, and proteinuria. Scoring of SLEDAI-2K is similar to SELENA-SLEDAI.

One of the most common and serious complications of systemic lupus erythematosus is lupus nephritis (LN), or kidney inflammation. If SLE is poorly controlled, LN may lead to irreversible kidney damage and the eventual need for dialysis or kidney transplant. Saphnelo has not been evaluated in patients with severe active lupus nephritis or severe active central nervous system lupus, and therefore, not recommended in these situations per label.

Definitions

Antinuclear antibody (ANA) titer = measures the concentration of antinuclear autoantibodies in the blood
Typical Scale Reported
< 1:40 = typically considered normal or negative
1:40 = low positive; considered to be common in health individuals
1:80 = low positive; could be significant depending on other signs/symptoms
1:160 = moderate positive
1:320 = high positive
>1:320 = very high positive

Clinical Criteria

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Saphnelo (anifrolumab-fnia)

Initial requests for Saphnelo (anifrolumab-fnia) may be approved if the following criteria are met:

I. Individual is 18 years of age or older; **AND**
II. Individual has a diagnosis of Systemic Lupus Erythematosus per the American College of Rheumatology (ACR); **AND**
III. Disease is considered moderate to severe, and is active while on current treatment regimen for SLE; **AND**
IV. Documentation is provided that individual's diagnosis has been verified by history of positive anti-nuclear antibody (ANA) titer greater than or equal to 1:80 or history of positive anti-dsDNA based on lab reference range; **AND**
V. Individual's SLE disease remains active while on corticosteroids, antimalarials, or immunosuppressants (alone or as combination therapy) for at least the last 30 days; **AND**
VI. Individual is using in combination with standard therapy (for example, corticosteroids, antimalarials, and/or immunosuppressants [but not other biologics or cyclophosphamide]).

Continuation requests for Saphnelo (anifrolumab-fnia) may be approved if all of the following criteria are met:

I. Documentation is provided showing improvement in disease activity following treatment with Saphnelo (anifrolumab-fnia) indicating a therapeutic response; **AND**
II. Individual is using in combination with standard therapy (for example, corticosteroids, antimalarials, and/or immunosuppressants [but not other biologics]).

Saphnelo (anifrolumab-fnia) may not be approved for the following:

I. Individual has evidence of severe active central nervous system lupus (such as psychosis or seizures); **OR**
II. Individual has evidence of severe active lupus nephritis (defined as proteinuria greater than 6 gm/d, serum creatinine greater than 2.5 mg/dl, or requiring dialysis); **OR**
III. Individual is using in combination with another biologic (including, but not limited to, B-cell targeted therapies or belimumab) or voclosporin**.**

Approval Duration:
Initial requests: 6 months
Continuation requests: 1 year

Quantity Limits

Saphnelo (anifrolumab-fnia) Quantity Limits

Drug	Limit
Saphnelo (anifrolumab-fnia) 300 mg/2 mL vial	1 vial per 28 days
Saphnelo (anifrolumab-fnia) 120 mg/0.8 mL syringe/autoinjector	4 syringes/autoinjectors per 28 days

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS

C9399	Unclassified drugs or biologicals [when specified as Saphnelo (anifrolumab-fnia) subcutaneous (SC)]
J0491	Injection, anifrolumab-fnia, 1 mg [Saphnelo intravenous (IV)]
J3590	Unclassified biologics [when specified as Saphnelo (anifrolumab-fnia) subcutaneous (SC)]

ICD-10 Diagnosis

Document History

Revised: 08/14/2026
Document History:

- 08/14/2026 – Annual Review: Remove SLEDAI score, and specific dsDNA thresholds. Remove continuation criteria regarding active CNS lupus and lupus nephritis to streamline with non-approvable criteria. Remove select non-approvable criteria. Add new dosage form prefilled syringe/autoinjector to quantity limits. Coding Reviewed: No changes.
- 06/08/2026 – Select Review: Add new Saphnelo syringe/autoinjector to quantity limits. Coding Reviewed: Updated description for HCPCS J0491 and added HCPCS NOC C9399, J3590 for Saphnelo subcutaneous. 08/15/2025 – Annual Review: Remove restriction for use with cyclophosphamide. Coding Reviewed: No changes.
- 08/16/2024 – Annual Review: Clarify diagnosis requirements for SLE. Coding Reviewed: No changes.
- 08/18/2023 – Annual Review: No changes. Coding Reviewed: No changes.
- 08/19/2022 – Annual Review: No changes. Coding reviewed: No changes.
- 09/13/2021 – Annual Review: Wording and formatting changes. Coding Reviewed: No changes. Effective 1/1/2022 Added HCPCS C9086. Effective 4/1/2022 Added HCPCS J0491. Removed HCPCS J3490, J3590, C9086. Added ICD-10-CM M32.0-M32.9. Removed All Diagnoses pend.
- 08/20/2021 –Select Review: Add new clinical criteria document for Saphnelo (anifrolumab-fnia). Coding reviewed: Added HCPCS J3490, J3590. Added all diagnoses pend.

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