Medical Policy

Utilization Management and Clinical Medical Policy

Policy Name:	Policy Number:	Scope:	Origination Date:	Effective Date:
Anifrolumab-fnia (Saphnelo®)	**MP-RX-FP-80-23**	☒ **MMM MA** ☒ **MMM MultiHealth**	**11/30/2023**	**7/22/2026**
			Last Review Date: **7/22/2026**	**Frequently Revision:** **Annual**

Service Category:

☐ Anesthesia
☐ Surgery
☐ Radiology Procedures
☐ Pathology and Laboratory Procedures
☐ Medicine Services and Procedures
☐ Evaluation and Management Services
☐ DME/Prosthetics or Supplies
☒ Other: Part B Drugs

Service Description:

This document addresses the use of Saphnelo® (anifrolumab-fnia), a type I interferon (IFN) receptor antagonist approved by the Food and Drug Administration (FDA) for the treatment of moderate to severe systemic lupus erythematosus (SLE), who are receiving standard therapy.

Background Information:

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) currently recognizes the 2019 EULAR/ACR classification criteria for systemic lupus erythematosus. These criteria require a positive antinuclear antibody (ANA) test as an entry criterion, followed by weighted additive clinical and immunologic criteria; a total score of 10 or more points, including at least one clinical criterion, classifies an individual as having SLE.

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.

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Saphnelo is also available as a subcutaneous injection (pen); however, the subcutaneous formulation is not addressed in this policy, which is limited to the intravenous Part B product.

Approved Indications

A. Treatment of adult patients with moderate to severe systemic lupus erythematosus (SLE), who are receiving standard therapy.

Other Uses

A. None.

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Medical Necessity Guidelines:

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.

anifrolumab-fnia (Saphnelo®)

A. Criteria For Initial Approval (*Provider must submit documentation [such as office chart notes, lab results, pathology reports, imaging studies, and any other pertinent clinical information] supporting the patient's diagnosis for the drug and confirming that the patient has met **all** approval criteria.)*

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. Documentation is provided that disease is considered moderate to severe, and is active and documented by a SLEDAI-2K score greater than or equal to 6 while on current treatment regimen for SLE; **AND**
iv. Documentation is provided that individual has a positive anti-nuclear antibody (ANA) titer greater than or equal to 1:80 or anti-dsDNA greater than or equal to 30 IU/mL; **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 no other biologics or cyclophosphamide]).

B. Criteria For Continuation of Therapy

Continuation requests for Saphnelo® anifrolumab-fnia may be approved if 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 has no evidence of severe active central nervous system lupus (such as psychosis or seizures); **AND**
iii. Individual has no 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); **AND**
iv. Individual is using in combination with standard therapy (for example, corticosteroids, antimalarials, and/or immunosuppressants [but not other biologics or cyclophosphamide])

C. Authorization Duration

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i. Initial Approval Duration: 6 months
ii. Reauthorization Approval Duration: 1 year

D. Conditions Not Covered

Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive):

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; **OR**
iv. Individual has human immunodeficiency virus (HIV) infection, hepatitis B virus infection, or hepatitis C virus infection (NCT01438489, NCT02446912, NCT02446899).

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Limits or Restrictions:

A. Therapeutic Alternatives

The list below includes preferred alternative therapies recommended in the approval criteria and may be subject to prior authorization.

i. N/A

B. Quantity Limitations

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines. The chart below includes dosing recommendations as per the FDA-approved prescribing information.

Drug	Recommended Dosage	Limit
Saphnelo (anifrolumab-fnia) 300 mg/2 mL vial	• 300 mg IV every 4 weeks	• 1 vial per 28 days
Exceptions		
• When transitioning patients from intravenous administration to subcutaneous administration of Saphnelo, administer the first subcutaneous injection approximately 2 weeks after the last intravenous infusion. • When transitioning patients from subcutaneous administration to intravenous administration of Saphnelo, administer the first intravenous infusion approximately 3 to 4 weeks after the last subcutaneous injection.		

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Codes Information:

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

ICD-10 Diagnostic Codes:

Codes	Description
M32.0-M32.9	Systemic lupus erythematosus (SLE)

HCPCS Codes:

Codes	Description
J0491	Injection, anifrolumab-fnia, 1 mg [Saphnelo]

Reference Information:

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10. NCT02446899. U.S. National Library of Medicine, ClinicalTrials.gov website. https://clinicaltrials.gov/ct2/show/NCT02446899?term=NCT02446899&draw=1&rank=1.
11. NCT02446912. U.S. National Library of Medicine, ClinicalTrials.gov website. https://clinicaltrials.gov/ct2/show/NCT02446912?term=NCT02446912&draw=2&rank=1.

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Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.

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Policy History:

Type of Review	Summary of Changes	P&T Approval Date	UM/CMPC Approval Date
Annual Review	Updated Background Information to clarify that Saphnelo is now available as a subcutaneous injection; however, this policy applies only to the intravenous Part B product. Updated the SLE classification language to align with current ACR/EULAR criteria. Removed restriction for use with cyclophosphamide in Conditions not Covered. Updated the quantity limits table to add recommended dosage and instructions for switching between products. Coding reviewed: No changes. Updated reference information and incorporated new policy template.	7/13/2026	7/22/2026
Annual Review	Wording and formatting changes. Coding Reviewed: No changes.	8/25/2025	9/8/2025
Annual Review	Added: Other Uses, Therapeutic alternatives, Federal statement. Wording and formatting changes. Added generic name to the document name. Clarify diagnosis requirements for SLE. Coding Reviewed: No changes.	3/14/2025	4/2/2025
Select Review	Update statement for criteria for initial approval: Provider must submit documentation [such as office chart notes, lab results, pathology reports, imaging studies, and any other pertinent clinical information] supporting the patient's diagnosis for the drug and confirming that the patient has met all approval criteria.	3/14/2025	4/2/2025
Policy Inception	8/19/2023: Elevance Health's Medical Policy adoption.	N/A	11/30/2023

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