Medical Policy

Healthcare Services Department

Policy Name	Policy Number	Scope
Anifrolumab-fnia (Saphnelo®)	MP-RX-FP-80-23	☒ MMM MA ☒ MMM Multihealth

Service Category

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

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).

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) 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.

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Approved Indications

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

Other Uses

i. N/A

Applicable Codes

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.

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

ICD-10	Description
M32.0-M32.9	Systemic lupus erythematosus (SLE)

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.

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Clinical Criteria

anifrolumab-fnia (Saphnelo®)

A. Criteria For Initial Approval

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**

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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

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. Conditions not Covered

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

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

A. Individual has evidence of severe active central nervous system lupus (such as psychosis or seizures);
OR

B. 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

C. Individual is using in combination with another biologic (including, but not limited to, B-cell targeted therapies or belimumab), voclosporin, or cyclophosphamide;
OR

D. Individual has human immunodeficiency virus (HIV) infection, hepatitis B virus infection, or hepatitis C virus infection (NCT01438489, NCT02446912, NCT02446899).

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D. Authorization Duration

i. Approval Duration

a. Initial Approval Duration: 6 months

b. Reauthorization Approval Duration: 1 year

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	Limit
Saphnelo (anifrolumab-fnia) 300 mg/2 mL vial	1 vial per 28 days

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Reference Information

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2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2022. URL: http://www.clinicalpharmacology.com. Updated periodically.
3. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: July 13, 2022.
4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
5. Furie R, Khamashta M, Merrill JT, et al. Anifrolumab, an Anti-Interferon-α Receptor Monoclonal Antibody, in Moderate-to-Severe Systemic Lupus Erythematosus. Arthritis Rheumatol. 2017 Feb;69(2):376-386. doi: 10.1002/art.39962.
6. Furie R, Morand E, Bruce I, et. al. Type I interferon inhibitor anifrolumab in active systemic lupus erythematosus (TULIP-1): a randomised, controlled, phase 3 trial. The Lancet. Rheumatology. 2019 Nov;1(4):E208-E219. Available at: https://www.thelancet.com/journals/lanrhe/article/PIIS2665-9913(19)30076-1/fulltext#%20.
7. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
8. Morand EF, Furie R, Tanaka Y, et. al; TULIP-2 Trial Investigators. Trial of Anifrolumab in Active Systemic Lupus Erythematosus. N Engl J Med. 2020 Jan 16;382(3):211-221. doi: 10.1056/NEJMoa1912196. Epub 2019 Dec 18.
9. NCT01438489. U.S. National Library of Medicine, ClinicalTrials.gov website. https://clinicaltrials.gov/ct2/show/NCT01438489?term=NCT01438489&draw=2&rank=1.
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.

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

Revision Type	Summary of Changes	P&T Approval Date	UM/CMPC Approval Date
Annual Review. 7/29/2025	Wording and formatting changes. Coding Reviewed: No changes.	8/25/2025	9/8/2025
Annual Review. 8/19/2024	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 02/15/2024	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