Medical Policy

Healthcare Services Department

Policy Name	Policy Number	Scope
Saphnelo (anifrolumab-fnia)	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 drug approved by the Food and Drug Administration (FDA) for the treatment of f moderate to severe systemic lupus erythematosus (SLE) as add-on treatment to standard therapy, such as corticosteroids, antimalarials, and/or immunosuppressants.

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

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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.

Approved Indications

A. of moderate to severe systemic lupus erythematosus (SLE) as add-on treatment to standard therapy, such as corticosteroids, antimalarials, and/or immunosuppressants

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.

Saphnelo (anifrolumab-fnia)

A. Prescriber Specialties

i. N/A

B. 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
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 antidsDNA 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 not other biologics or cyclophosphamide]).

C. 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])

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), voclosporin, or cyclophosphamide; 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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D. Authorization Duration

i. Approval Duration

a. Initial Approval Duration: 6 months

b. Reauthorization Approval Duration: 1 year

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Limits or Restrictions

A. 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

Reference Information

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Policy History

Revision Type	Summary of Changes	P&T Approval Date	MPCC Approval Date
Policy Inception	Elevance Health's Medical Policy adoption.	N/A	11/30/2023

Revised: 8/19/23