Policy Number	**RX501.138**
Policy Effective Date	**10/15/2025**

Anifrolumab-fnia

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Disclaimer

Medical policies are a set of written guidelines that support current standards of practice. They are based on current generally accepted standards of and developed by nonprofit professional association(s) for the relevant clinical specialty, third-party entities that develop treatment criteria, or other federal or state governmental agencies. A requested therapy must be proven effective for the relevant diagnosis or procedure. For drug therapy, the proposed dose, frequency and duration of therapy must be consistent with recommendations in at least one authoritative source. This medical policy is supported by FDA-approved labeling and/or nationally recognized authoritative references to major drug compendia, peer reviewed scientific literature and generally accepted standards of medical care. These references include, but are not limited to: MCG care guidelines, DrugDex (IIa level of evidence or higher), NCCN Guidelines (IIb level of evidence or higher), NCCN Compendia (IIb level of evidence or higher), professional society guidelines, and CMS coverage policy.

Carefully check state regulations and/or the member contract.

Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Legislative Mandates

EXCEPTION: For HCSC members residing in the state of Ohio, § 3923.60 requires any group or individual policy (Small, Mid-Market, Large Groups, Municipalities/Counties/Schools, State Employees, Fully-Insured, PPO, HMO, POS, EPO) that covers prescription drugs to provide for the coverage of any drug approved by the U. S. Food and Drug Administration (FDA) when it is prescribed for a use recognized as safe and effective for the treatment of a given indication in one or more of the standard medical reference compendia adopted by the United States Department of Health and Human Services or in medical literature even if the FDA has not approved the drug for that indication. Medical literature support is only satisfied when safety and efficacy has been confirmed in two articles from major peer-reviewed professional medical journals that present data supporting the proposed off-label use or uses as generally safe and effective. Examples of accepted journals include, but are not limited to, Journal of

American Medical Association (JAMA), New England Journal of Medicine (NEJM), and Lancet. Accepted study designs may include, but are not limited to, randomized, double blind, placebo controlled clinical trials. Evidence limited to case studies or case series is not sufficient to meet the standard of this criterion. Coverage is never required where the FDA has recognized a use to be contraindicated and coverage is not required for non-formulary drugs.

Coverage

Anifrolumab-fnia (Saphnelo®) **may be considered medically necessary** for the treatment of active systemic lupus erythematosus (SLE) in adult patients when the individual meets **all** the following criteria:

- Diagnosis of moderate to severe SLE, without severe active central nervous system lupus or severe active lupus nephritis; and
- Laboratory testing has documented the presence of autoantibodies (e.g., antinuclear antibodies [ANA], anti-double-stranded DNA [Anti-dsDNA], anti-Smith [Anti-Sm], anti-Sjögren's-syndrome-related antigen A [Anti-Ro/SSA], anti-Sjögren's-syndrome-related antigen B [Anti-La/SSB]); and
- Currently receiving at least one standard of care treatment for active systemic lupus erythematosus (e.g., antimalarials, corticosteroids, or immunosuppressants) that is NOT a biologic; and
- Not receiving Saphnelo in combination with other biologics used to treat SLE (e.g., belimumab, rituximab).

Anifrolumab-fnia (Saphnelo®) **is considered experimental, investigational and/or unproven** for all other non-Food and Drug Administration approved indications.

Policy Guidelines

None.

Description

Systemic lupus erythematosus (SLE), an autoimmune disease in which the immune system attacks its own tissue, is the most common type of lupus. It causes widespread inflammation and tissue damage in the affected organs, including the joints, skin, brain, lungs, kidneys, and blood vessels. Although causes of SLE are unknown, it's believed to be linked to environmental, genetic, and hormonal factors, with seriousness ranging from mild to life-threatening.

A variety of symptoms may be experienced including fatigue, skin rashes, fevers, and pain or swelling in the joints. Other symptoms may include sun sensitivity, oral ulcers, arthritis, lung, heart or kidney problems, seizures, psychosis, and blood cell and immunological abnormalities.

SLE can affect people of all ages, including children. Women of childbearing ages – 15 to 44 years – are at greatest risk; and women of all ages are affected more than men (by nearly 10 women for every 1 man). In the United States, the disease is more common in African Americans, Asian Americans, African Caribbeans, and Hispanic Americans than non-Hispanic white people. (2)

There is no cure for SLE. The goal of treatment is to control symptoms. Severe symptoms that involve the heart, lungs, kidneys, and other organs often need treatment by specialists. Immunosuppressive drugs that inhibit activity of the immune system are among the types of medications used. Hydroxychloroquine, corticosteroids (e.g., prednisone), nonsteroidal anti-inflammatory drugs (NSAIDs) and methotrexate may be used alone or together, depending on the severity of the disease. Biologic medicines, such as anifrolumab, belimumab, and rituximab may be helpful for some people. (2)

The outcome for people with SLE has improved in recent years. Many people with SLE have mild symptoms and prognosis depends on disease severity. Most people with SLE will require medicines for a long time. However, in the United States, SLE is one of the top 20 leading causes of death in females between the ages of 5 and 64. (2)

Anifrolumab
Anifrolumab is a type I interferon (IFN) receptor antagonist for the treatment of patients with moderate to severe SLE – but without severe active lupus nephritis or neuropsychiatric SLE – who are receiving standard therapy. Anifrolumab blocks the activity of type I IFNs, including IFN-alpha, IFN-beta, and IFN-kappa, which are cytokines that are elevated in many patients with SLE, and mutations in these IFN signaling pathways have been linked to disease susceptibility. Anifrolumab's role in therapy is still being defined, but there appears to be a particular benefit for patients with skin and joint involvement. (3)

Regulatory Status
Anifrolumab-fnia (Saphnelo®) was approved by the U.S. Food and Drug Administration (FDA) on August 2, 2021, for the treatment of adults with moderate to severe systemic lupus erythematosus (SLE) who are receiving standard therapy. The use of Saphnelo has not been evaluated in patients with severe lupus nephritis or severe active central nervous system lupus. The FDA does not recommend the use of Saphnelo in these situations. (1)

Rationale

This policy is based on the U.S. Food and Drug Administration (FDA) labeled indications for anifrolumab-fnia (Saphnelo®), as well as professional society guidelines.

Anifrolumab-fnia (Saphnelo®) (1)
The safety and efficacy of Saphnelo were evaluated in three 52-week treatment period, multicenter, randomized, double-blind, placebo-controlled studies (Trial 1 [NCT01438489], Trial

2 [NCT02446912], and Trial 3 [NCT02446899]). Patients were diagnosed with systemic lupus erythematosus (SLE) according to the American College of Rheumatology (1982 revised) classification criteria. All patients were ≥18 years of age and had moderate to severe disease, with a SLE Disease Activity Index 2000 (SLEDAI-2K) score ≥6 points, organ level involvement based on British Isles Lupus Assessment Group (BILAG) assessment, and a Physician's Global Assessment (PGA) score ≥1, despite receiving standard SLE therapy consisting of either one or any combination of oral corticosteroids (OCS), antimalarials and/or immunosuppressants at baseline. Patients continued to receive their existing SLE therapy at stable doses during the clinical trials, with the exception of OCS (prednisone or equivalent) where tapering was a component of the protocol. Patients who had severe active lupus nephritis and patients who had severe active central nervous system lupus were excluded. The use of other biologic agents and cyclophosphamide were not permitted during the trials; patients receiving other biologic therapies were required to complete a wash-out period of at least 5 half-lives prior to enrollment. All three studies were conducted in North America, Europe, South America, and Asia. Patients received anifrolumab-fnia or placebo, administered by intravenous infusion, every 4 weeks.

Efficacy of Saphnelo was established based on assessment of clinical response using the composite endpoints, the British Isles Lupus Assessment Group based Composite Lupus Assessment (BICLA) and the SLE Responder Index (SRI-4).

BICLA response at Week 52 was defined as improvement in all organ domains with moderate or severe activity at baseline:

- Reduction of all baseline BILAG A to B/C/D and baseline BILAG B to C/D, and no BILAG worsening in other organ systems, as defined by ≥1 new BILAG A or ≥2 new BILAG B;
- No worsening from baseline in SLEDAI-2K, where worsening is defined as an increase from baseline of >0 points in SLEDAI-2K;
- No worsening from baseline in patients' lupus disease activity, where worsening is defined by an increase ≥0.30 points on a 3-point PGA visual analogue scale (VAS);
- No discontinuation of treatment;
- No use of restricted medication beyond the protocol-allowed threshold.

SRI-4 response was defined as meeting each of the following criteria at Week 52 compared with baseline:

- Reduction from baseline of ≥4 points in the SLEDAI-2K;
- No new organ system affected as defined by 1 or more BILAG A or 2 or more BILAG B items compared to baseline;
- No worsening from baseline in the patients' lupus disease activity defined by an increase ≥0.30 points on a 3-point PGA visual analogue scale (VAS);
- No discontinuation of treatment;
- No use of restricted medication beyond the protocol-allowed threshold.

Trial 1 randomized 305 patients (1:1:1) who received anifrolumab-fnia, 300 mg or 1000 mg, or placebo for up to 52 weeks. The primary endpoint was a combined assessment of the SRI-4 and the sustained reduction in OCS (<10 mg/day and ≤OCS dose at week 1, sustained for 12 weeks) measured at Week 24.

Trial 2 and 3 were similar in design. Trial 2 randomized 457 patients who received anifrolumab-fnia 150 mg, 300 mg, or placebo (1:2:2). Trial 3 randomized 362 patients (1:1) who received anifrolumab-fnia 300 mg or placebo. The primary endpoints were improvement in disease activity evaluated at 52 weeks, measured by SRI-4 in Trial 2 and BICLA in Trial 3 (defined above). The common secondary efficacy endpoints included in both studies were the maintenance of OCS reduction, improvement in cutaneous SLE activity, and flare rate. During Weeks 8-40, patients with a baseline OCS ≥10 mg/day were required to taper their OCS dose to ≤7.5 mg/day, unless there was worsening of disease activity. Both studies evaluated the efficacy of anifrolumab-fnia 300 mg versus placebo; a dose of 150 mg was also evaluated for dose-response in Trial 2.

Patient demographics and disease characteristics were generally similar and balanced across treatment arms (Table 1).

Table 1. Demographics and Baseline Characteristics

	Total Population		
	Trial 1 (N=305)	**Trial 2 (N=457)**	**Trial 3 (N=362)**
Mean Age (years)	40	41	42
Female (%)	93	92	93
White (%)	42	71	60
Black/African American (%)	13	14	12
Asian (%)	7	5	17
Hispanic or Latino (%)	42	19	30
Baseline SLEDAI-2K Score			
Mean (SD)	10.9 (4.1)	11.3 (3.72)	11.5 (3.76)
≥10 points, n (%)	182 (60)	328 (72)	260 (72)
BILAG organ system scoring (Overall)			
At least one A, n (%)	152 (50)	217 (48)	176 (49)
No A and at least 2 Bs, n (%)	134 (44)	211 (46)	169 (47)
Positive Anti-dsDNA levels n (%)	185 (77)	207 (45)	159 (44)
Abnormal ANA, n (%)	299 (98)	412 (90)	325 (90)
Abnormal Complement C3 level, n (%)	119 (39)	157 (34)	144 (40)
Abnormal Complement C4 level, n (%)	74 (24)	95 (21)	95 (26)
Baseline SLE treatment			
OCS, n (%)	258 (85)	381 (83)	292 (81)
Antimalarials, n (%)	219 (72)	334 (73)	252 (70)
Immunosuppressants, n (%)	150 (49)	214 (47)	174 (48)

SLEDAI-2K score: Systemic Lupus Erythematosus Disease Activity Index 2000; BILAG: British Isles Lupus Assessment Group; Anti-dsDNA: anti-double-stranded DNA; ANA: anti-nuclear antibodies; SLE: systemic lupus erythematosus; OCS: oral corticosteroids.

Randomization was stratified by disease severity (SLEDAI-2K score at baseline, <10 vs ≥10 points), OCS dose on Day 1 (<10 mg/day vs ≥10 mg/day prednisone or equivalent) and interferon gene signature test results (high vs low).

The reduction in disease activity seen in the BICLA and SRI-4 was related primarily to improvement in the mucocutaneous and musculoskeletal organ systems. Flare rate was reduced in patients receiving Saphnelo compared to patients who received placebo although the difference was not statistically significant.

BICLA responder analysis: BICLA was the primary endpoint in Trial 3; anifrolumab-fnia 300 mg demonstrated statistically significant and clinically meaningful efficacy in overall disease activity compared with placebo, with greater improvements in all components of the composite endpoint. In Trial 1 and 2 BICLA was a pre-specified analysis. The BICLA results are presented in Table 2.

Table 2. BICLA Response Rate at Week 52

	Trial 1[1,2]		**Trial 2[1,2]**		**Trial 3[3]**	
	Anifrolumab-fnia 300 mg (N=99)	**Placebo (N=102)**	**Anifrolumab-fnia 300 mg (N=180)**	**Placebo (N=184)**	**Anifrolumab-fnia 300 mg (N=180)**	**Placebo (N=182)**
BICLA Response Rate[4]						
Responder, n (%)	54 (54.6)	27 (25.8)	85 (47.1)	55 (30.2)	86 (47.8)	57 (31.5)
Difference in Response Rates (95% CI)	28.8 (15.7, 41.9)		17.0 (7.2, 26.8)		16.3 (6.3, 26.3) p-value=0.001	
Components for BICLA Response[4]						
BILAG Improvement, n (%)	54 (54.5)	28 (27.5)	85 (47.2)	58 (31.5)	88 (48.9)	59 (32.4)
No Worsening of SLEDAI-2K, n (%)	73 (73.7)	61 (59.8)	121 (67.2)	104 (56.5)	122 (67.8)	94 (51.6)
No Worsening of PGA, n (%)	76 (76.8)	62 (60.8)	117 (65.0)	105 (57.1)	122 (67.8)	95 (52.2)

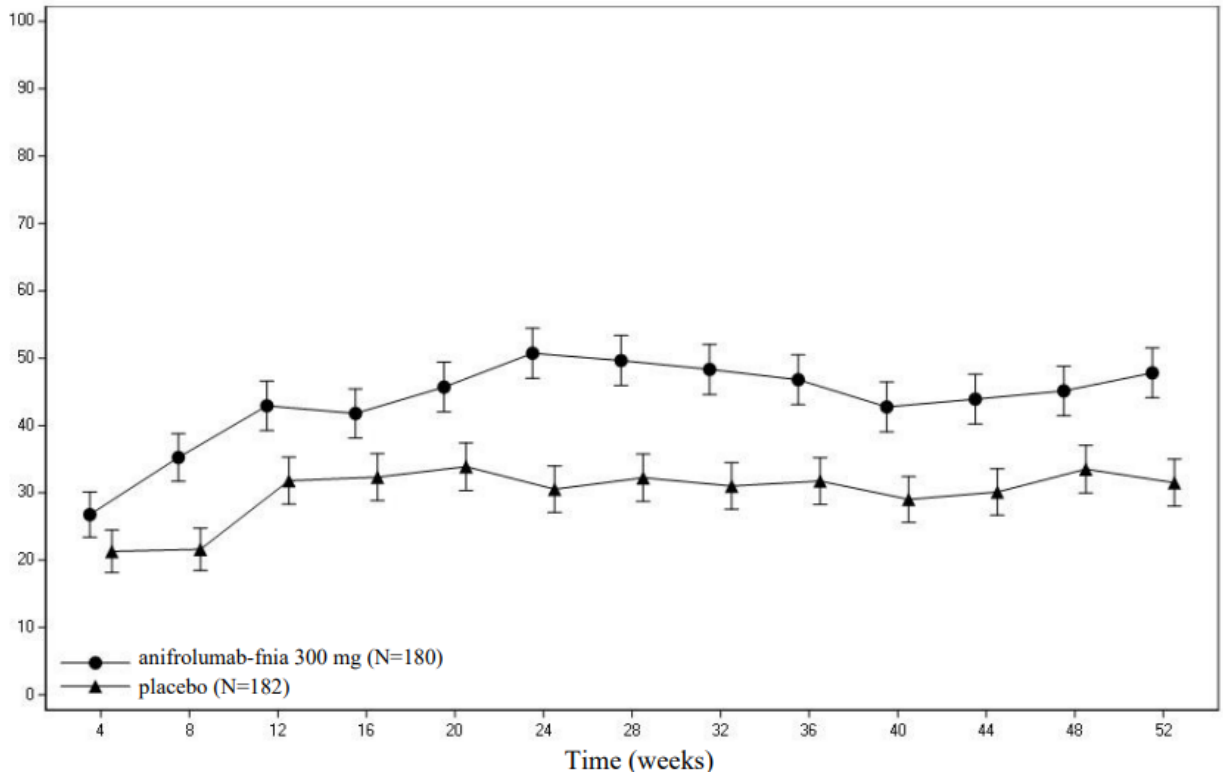
BICLA: British Isles Lupus Assessment Group based Composite Lupus Assessment; BILAG: British Isles Lupus Assessment Group; SLEDAI-2K: Systemic Lupus Erythematosus Disease Activity Index 2000; PGA: Physician's Global Assessment score; CI: confidence interval.

The response rates and associated difference and 95% CI are calculated using a Cochran-Mantel-Haenszel approach adjusted for stratification factors. The reported percentages for the components are unadjusted.
[1] Not formally tested in a pre-specified testing scheme and findings should be interpreted with caution.
[2] Based on post-hoc analysis.
[3] Primary endpoint.
[4] In all 3 trials, patients who discontinued investigational product or initiated restricted medications beyond the protocol-specified thresholds are considered non-responders. For consistency, the results for Trial 2 represent the post-hoc analysis using the restricted medication thresholds as defined in Trial 3.

In Trial 3, examination of subgroups by age, race, gender, ethnicity, disease severity [SLEDAI-2K at baseline], and baseline OCS use did not identify differences in response to anifrolumab-fnia.

Figure 1 shows the proportion of BICLA responders through the 52-week treatment period in Trial 3.

Figure 1. Trial 3: Proportion (%) of BICLA Responders by Visit[1]



BICLA: British Isles Lupus Assessment Group based Composite Lupus Assessment.
[1] The same patients may not have responded at each timepoint.

SRI-4 responder analysis: SRI-4 was the primary endpoint in Trial 2; treatment with anifrolumab-fnia did not result in statistically significant improvements over placebo. In Trials 1 and 3, SRI-4 was a pre-specified analysis. The SRI-4 results are presented in Table 3.

Table 3. SRI-4 Response Rate at Week 52

	Trial 1[1]		Trial 2[2]		Trial 3[1]	
	Anifrolumab-fnia 300 mg (N=99)	**Placebo (N=102)**	**Anifrolumab-fnia 300 mg (N=180)**	**Placebo (N=184)**	**Anifrolumab-fnia 300 mg (N=180)**	**Placebo (N=182)**
SRI-4 Response Rate[3]						
Responder, n (%)	62 (62.8)	41 (38.8)	88 (49.0)	79 (43.0)	100 (55.5)	68 (37.3)
Difference in Response Rates (95% CI)	24.0 (10.9, 37.2)		6.0 (-4.2, 16.2)		18.2 (8.1, 28.3)	
Components of SRI-4 Response[3]						
SLEDAI-2K Improvement, n (%)	62 (62.6)	41 (40.2)	89 (49.4)	80 (43.5)	101 (56.1)	71 (39.0)
No Worsening of BILAG, n (%)	75 (75.8)	61 (59.8)	119 (66.1)	105 (57.1)	125 (69.4)	94 (51.6)
No Worsening of PGA, n (%)	76 (76.8)	62 (60.8)	117 (65.0)	105 (57.1)	122 (67.8)	95 (52.2)

SRI-4: Systemic Lupus Erythematosus Responder Index; BILAG: British Isles Lupus Assessment Group; SLEDAI-2K: Systemic Lupus Erythematosus Disease Activity Index 2000; PGA: Physician's Global Assessment score; CI: confidence interval.

The response rates and associated difference and 95% CI are calculated using a Cochran-Mantel-Haenszel approach adjusted for stratification factors. The reported percentages for the components are unadjusted.

[1] Not formally tested in a pre-specified testing scheme and findings should be interpreted with caution.

[2] Primary endpoint.

[3] In all 3 studies, patients who discontinued investigational product or initiated restricted medications beyond the protocol-specified thresholds are considered non-responders. For consistency, the results presented for Trial 2 represent the post-hoc analysis using the restricted medication thresholds as defined in Trial 3. The most commonly involved SLEDAI-2K organ domains were mucocutaneous, musculoskeletal and immune.

Effect on Concomitant Steroid Treatment: In Trial 3, among the 47% of patients with a baseline OCS use ≥10 mg/day, anifrolumab-fnia demonstrated a statistically significant difference in the proportion of patients able to reduce OCS use by at least 25% to ≤7.5 mg/day at Week 40 and maintain the reduction through Week 52 (p-value = 0.004); 52% (45/87) of patients in the anifrolumab-fnia group versus 30% (25/83) in the placebo achieved this level of steroid reduction (difference 21% [95% CI 6.8, 35.7]). Consistent trends in favor of anifrolumab-fnia compared to placebo, on effect of reduction of OCS use, were observed in Trial 1 and 2, but the difference was not statistically significant.

Summary of Evidence

Based on three 52-week treatment period, multicenter, randomized, double-blind, placebo-controlled studies, the U.S. Food and Drug Administration (FDA) approved anifrolumab-fnia (Saphnelo®) for the treatment of adults with moderate to severe systemic lupus erythematosus who are receiving standard therapy. Therefore anifrolumab-fnia (Saphnelo®) is considered medically necessary in adult patients when the individual meets all the criteria outlined in the coverage section of this medical policy document. Anifrolumab-fnia is not recommended for patients with severe active lupus nephritis or severe active central nervous system lupus as the efficacy has not been evaluated. Anifrolumab-fnia is considered experimental, investigational, and/or unproven for those conditions and any other non-FDA approved conditions not listed in the coverage section of this medical policy document.

Practice Guidelines and Position Statements

European League Against Rheumatism (EULAR) and the American College of Rheumatology (ACR) Classification Criteria for Systemic Lupus Erythematosus

In 2019, updated classification criteria for systemic lupus erythematosus (SLE) jointly supported by EULAR and the ACR were issued. Multiple classification domains were specified. Antinuclear antibodies (ANA) as well as SLE-specific antibodies anti-double-stranded DNA (anti-dsDNA) or anti-Smith (Anti-Sm) antibodies were among the laboratory tests supporting the criteria for a SLE diagnosis. (4)

The British Society for Rheumatology (BSR)

In 2018, the BSR published a guideline for the management of systemic lupus erythematosus in adults. ANA, anti-dsDNA, and Anti-Sm tests were discussed as being highly predictive of a diagnosis of SLE in patients with relevant clinical features. The guideline also discusses other lab tests, including those for anti-Sjögren's-syndrome-related antigen A (Anti-Ro/SSA), anti-Sjögren's-syndrome-related antigen B (Anti-La/SSB). These latter two tests are less specific as markers for the presence of SLE and may be found in other autoimmune rheumatic disorders. However, they do occur in lupus patients, especially those with photosensitivity and subacute cutaneous lupus.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	None
HCPCS Codes	J0491

*Current Procedural Terminology (CPT®) ©2024 American Medical Association: Chicago, IL.

References

U.S. Food and Drug Administration Label:

1. FDA. Highlights of prescribing information Saphnelo® (anifrolumab-fnia). U.S. Food and Drug Administration (8/2024). Available at <https://www.accessdata.fda.gov> (accessed August 14, 2025).

Other:

2. Horowitz, DM. Systemic lupus erythematosus. Medline Plus. Updated Jan 28, 2025. Available at <https://www.medlineplus.gov> (accessed August 21, 2025).
3. Wallace, Daniel J. Overview of the management and prognosis of systemic lupus erythematosus in adults. In: UpToDate, Pisetsky DS, Rigby WFC, Case SM (Eds), UpToDate, Waltham, MA. Available at <https://www.uptodate.com> (accessed August 18, 2025).
4. Aringer M, Costenbader KH, Daikh DI, et al. 2019 EULAR/ACR Classification Criteria for Systemic Lupus Erythematosus. Arthritis Rheumatol. Sep 2019; 71(9):1400-1412. PMID 31385462
5. Gordon C, Amissah-Arthur MB, Gayed M, et al. The British Society for Rheumatology guideline for the management of systemic lupus erythematosus in adults. Rheumatology. January 2018; 57(1):e1–e45. PMID 29029350

Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision

Date	Description of Change
10/15/2025	Document updated with literature review. The following changes were made to Coverage: 1) Replaced “is” with “may be” in initial medical necessity statement; and 2) Removed “immunoglobulin therapy or” from combination therapy criteria; and 3) Removed "for the treatment of individuals" and added “non-Food and Drug Administration approved” to existing experimental, investigational and/or unproven statement. Added references 2, 4 and 5; others updated and some removed.

06/15/2024	Reviewed. No changes.
09/15/2023	Document updated with literature review. Coverage unchanged. References updated.
07/15/2022	Reviewed. The following change was made to Coverage: removed this phrase from the experimental, investigational and/or unproven statement as those indications are included in the first bullet point for the conditionally covered criteria: "…including but not limited to, severe active lupus nephritis or severe active central nervous system lupus." No other changes made.
01/01/2022	New medical document. Anifrolumab-fnia (Saphnelo™) is considered medically necessary for the treatment of active systemic lupus erythematosus (SLE) in adult patients when the individual meets all the following criteria: Diagnosis of moderate to severe systemic lupus erythematosus (SLE), without severe active central nervous system lupus or severe active lupus nephritis; and Laboratory testing has documented the presence of autoantibodies (e.g., antinuclear antibodies [ANA], anti-double-stranded DNA [Anti-dsDNA], anti-Smith [Anti-Sm], anti-Sjögren's-syndrome-related antigen A [Anti-Ro/SSA], anti-Sjögren's-syndrome-related antigen B [Anti-La/SSB]); and Currently receiving at least one standard of care treatment for active systemic lupus erythematosus (e.g., antimalarials, corticosteroids, or immunosuppressants) that is NOT a biologic; and Not receiving Saphnelo in combination with immunoglobulin therapy or other biologics used to treat systemic lupus erythematosus (SLE) (e.g., belimumab, rituximab). Anifrolumab-fnia (Saphnelo™) is considered experimental, investigational and/or unproven for the treatment of individuals for all other indications, including but not limited to, severe active lupus nephritis or severe active central nervous system lupus.