Clinical Policy: Anifrolumab-fnia (Saphnelo)

Reference Number: PA.CP.PHAR.551
Effective Date: 10/2021
Last Review Date: 05/2026

Description
Anifrolumab-fnia (Saphnelo™) is type I interferon (IFN) receptor antagonist.

FDA Approved Indication(s)
Saphnelo is indicated for the treatment of adult patients with moderate to severe systemic lupus erythematosus (SLE) who are receiving standard therapy.

Limitation(s) of use: The efficacy of Saphnelo has not been evaluated in patients with severe active lupus nephritis or severe active central nervous system lupus. Use of Saphnelo is not recommended in these situations.

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

It is the policy of PA Health & Wellness® that Saphnelo is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Systemic Lupus Erythematosus (must meet all)**:**

1. Diagnosis of SLE;
2. Prescribed by or in consultation with a rheumatologist;
3. Age ≥ 18 years;
4. Documentation confirms that member is positive for an SLE autoantibody (e.g., anti-nuclear antibody [ANA], anti-double-stranded DNA [anti-dsDNA], anti-Smith [anti-Sm], anti-ribonucleoprotein [anti-RNP], anti-Ro/SSA, anti-La/SSB, antiphospholipid antibody);
5. Prescribed in combination with standard therapy for SLE that includes one or more of the following agents, unless all agents are contraindicated: glucocorticoids (e.g., prednisone), antimalarial (e.g., hydroxychloroquine or chloroquine), non-biologic immunosuppressants (e.g., azathioprine, methotrexate, mycophenolate);
6. Member is not receiving Saphnelo in combination with Lupkynis® or a biologic agent (e.g., Benlysta);
7. Member does not have severe active central nervous system lupus or severe active lupus nephritis;
8. Dose does not exceed one of the following (a or b):
    a. IV: 300 mg (1 vial) every 4 weeks;
    b. SC: 120 mg per week, and one of the following (i or ii):
        i. 1 syringe per week;
        ii. 1 autoinjector per week.

Approval duration: 12 months

B. Other diagnoses/indications
1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53.

II. Continued Therapy

A. Systemic Lupus Erythematosus (must meet all)**:**
1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.PHARM.01) applies;
2. Member is responding positively to therapy;
3. Prescribed in in combination with standard therapy for SLE that includes one or more of the following agents, unless all agents are contraindicated: glucocorticoids (e.g., prednisone), antimalarial (e.g., hydroxychloroquine or chloroquine), non-biologic immunosuppressants (e.g., azathioprine, methotrexate, mycophenolate);
4. Member is not receiving Saphnelo in combination with Lupkynis or a biologic agent (e.g., Benlysta);
5. Member does not have severe active central nervous system lupus or severe active lupus nephritis;
6. If request is for a dose increase, new dose does not exceed one of the following (a or b):
   a. IV: 300 mg (1 vial) every 4 weeks;
   b. SC: 120 mg per week, and one of the following (i or ii):
      i. 1 syringe per week;
      ii. 1 autoinjector per week.

Approval duration: 12 months

B. Other diagnoses/indications (1 or 2)**:**
1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.PHARM.01) applies.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – PA.CP.PMN.53

B. Autoantibody negative SLE.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

ANA: anti-nuclear antibody
Anti-dsDNA: anti-double-stranded DNA
Anti-Sm: anti-Smith
DNA: deoxyribonucleic acid
FDA: Food and Drug Administration
LN: lupus nephritis
RNP: ribonucleoprotein
SLE: systemic lupus erythematosus

Appendix B: Therapeutic Alternatives
Not applicable

Appendix C: Contraindications/Boxed Warnings
- Contraindication(s): previous anaphylaxis with anifrolumab-fnia
- Boxed warning(s): none reported

Appendix D: Autoantibody Positive Versus Negative SLE
The pivotal clinical trials for Saphnelo enrolled patients with at least one of the following:
- Positive antinuclear antibody test at screening by immunofluorescent assay (IFA) at the central laboratory with titer ≥1:80;
- Anti-dsDNA antibodies at screening elevated to above normal (including indeterminate), as per the central laboratory;
- Anti-Smith antibody at screening elevated to above normal as per the central laboratory

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
SLE	300 mg IV every 4 weeks or 120 mg SC every week	See dosing regimen

VI. Product Availability
- Single-dose vial for IV infustion: 300 mg/2 mL
- Single-dose prefilled syringe for SC injection: 120 mg/0.8 mL
- Single-dose autoinjector (Saphnelo Pen) for SC injection: 120 mg/0.8 mL

VII. References

1. Saphnelo Prescribing Information. Wilmington, DE: AstraZeneca Pharmaceuticals LP; April 2026. Available at www.saphnelo.com. Accessed April 30, 2026.
2. Fanouriakis A, Kostopoulou M, Alunno A, et al. 2019 update of the EULAR recommendations for the management of systemic lupus erythematosus. *Ann Rheum Dis.* 2019;0:1–10. doi:10.1136/annrheumdis-2019-215089.
3. Fanouriakis A, Kostopoulou M, Andersen J, et al. EULAR recommendations for the management of systemic lupus erythematosus: 2023 update. Ann Rheum Dis. 2024;83(1):15-29.
4. Petri M, Orbai AM, Alarcón GS, et al. Derivation and validation of the Systemic Lupus International Collaborating Clinics classification criteria for systemic lupus erythematosus. *Arthritis Rheum.* 2012; 64:2677.
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.* 2018;57:e1-e45.
6. Morand EF, Furie R, Tanaka Y, et al. Trial of Anifrolumab in Active Systemic Lupus Erythematosus. N Engl J Med 2020;382:211-21.
7. Furie R, Khamashta M, Merrill JT, et al. Anifrolumab, an Anti–Interferon-a Receptor Monoclonal Antibody, in Moderate-to-Severe Systemic Lupus Erythematosus. Arthritis & Rheumatology 2017; 69(2): 376-386.

Coding Implications
Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J0491	Injection, anifrolumab-fnia, 1 mg

Reviews, Revisions, and Approvals	Date
Policy created.	10/2021
4Q 2022 annual review: no significant changes; references reviewed and updated.	10/2022
4Q 2023 annual review: added exclusion for concurrent biologic per Warning in the Prescribing Information; references reviewed and updated.	10/2023
4Q 2024 annual review: added exclusions for concurrent treatment with Lupkynis and diagnoses of severe active central nervous system lupus or severe active lupus nephritis; references reviewed and updated.	10/2024
4Q 2025 annual review: revised initial approval durations to 12 months; added coding implications section; references reviewed and updated.	10/2025
RT4: added new subcutaneous formulations of prefilled syringe and autoinjector.	05/2026