Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review. Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: 11/01/2022**
Policy Number: PA.CP.PHAR.551	**Effective Date: 10/2021** **Revision Date: 10/2022**
Policy Name: Anifrolumab-fnia (Saphnelo)	

Type of Submission – Check all that apply:

- ☐ **New Policy**
- ✓ **Revised Policy***
- ☐ **Annual Review - No Revisions**
- ☐ **Statewide PDL** - *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

4Q 2022 annual review: no significant changes; references reviewed and updated.

Name of Authorized Individual (Please type or print): **Venkateswara R. Davuluri, MD**	**Signature of Authorized Individual:**

Clinical Policy: Anifrolumab-fnia (Saphnelo)

Reference Number: PA.CP.PHAR.551
Effective Date: 10/2021
Last Review Date: 10/2022

Coding Implications
Revision Log

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. Dose does not exceed 300 mg every 4 weeks.

Approval duration: 6 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.LTSS.PHAR.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. If request is for a dose increase, new dose does not exceed 300 mg every 4 weeks.

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.LTSS.PHAR.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
SLE: systemic lupus erythematosus

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
glucocorticoids (e.g., prednisone)	Varies	Varies
antimalarial agents (e.g., hydroxychloroquine, chloroquine)	Varies	Varies
non-biologic immunosuppressants (e.g., azathioprine, methotrexate, mycophenolate)*	Varies	Varies

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.
** For LN, cyclophosphamide is also an acceptable immunosuppressant.*

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	See dosing regimen

VI. Product Availability

Single-dose vial: 300 mg/2 mL

VII. References

1. Saphnelo Prescribing Information. Wilmington, DE: AstraZeneca Pharmaceuticals LP; July 2021. Available at www.saphnelo.com. Accessed August 10, 2022.
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. 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.
4. 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. doi:10.1093/rheumatology/kex286.
5. Morand EF, Furie R, Tanaka Y, et al. Trial of Anifrolumab in Active Systemic Lupus Erythematosus. N Engl J Med 2020;382:211-21.
6. 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.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	10/2021	
4Q 2022 annual review: no significant changes; references reviewed and updated.	10/2022	