Corporate Medical Policy: Anifrolumab-fnia (Saphnelo™)

Restricted Product(s):

- anifrolumab-fnia (Saphnelo™) intravenous infusion for administration by a healthcare professional

FDA Approved Use:

- For treatment of adults with moderate to severe systemic lupus erythematosus (SLE) who are receiving standard therapy
- Limitations of use: Efficacy has not been evaluated for severe active lupus nephritis or severe active central nervous system lupus. Use in these situations is not recommended.

Criteria for Medical Necessity:

The restricted product(s) may be considered medically necessary when the following criteria are met:

Initial Criteria for Approval:

1. The patient is 18 years of age or older; **AND**
2. The patient has a clinical diagnosis of moderate to severe systemic lupus erythematosus (SLE) according to American College of Rheumatology classification criteria **[medical record documentation required]**; **AND**
3. The patient is autoantibody positive with ONE of the following **[medical record documentation required]**:
    a. ANA (anti-nuclear antibody) above the laboratory reference range; **OR**
    b. Anti-dsDNA (double stranded DNA antibody) above the laboratory reference range, or greater than two-fold the reference range if tested by ELISA; **OR**
    c. Anti-Sm (anti-Smith antibody) above the laboratory reference range, or greater than two-fold the reference range if tested by ELISA; **AND**
4. SLE is active with a score of 6 or greater (as documented by SLEDAI-2K or as scored by a comparable standardized rating scale that reliably measures SLE disease activity) while on treatment with standard therapy (e.g., corticosteroids, anti-malarials [hydroxychloroquine, chloroquine], non-steroidal anti-inflammatory drugs [NSAIDs], non-biologic immunosuppressants [azathioprine, methotrexate, cyclosporine, oral cyclophosphamide]) alone or as combination therapy **[medical record documentation required]**; **AND**
5. The patient does NOT have severe active central nervous system lupus or severe active lupus nephritis; **AND**
6. The patient will NOT be using anifrolumab (Saphnelo™) in combination with another biologic immunomodulator agent; **AND**
7. The requested quantity does NOT exceed the maximum units allowed for the duration of approval (see table below); **AND**
8. For requests for injection or infusion administration of the requested medication in an **inpatient or outpatient hospital setting,** Site of Care Criteria applies (outlined below)*

Duration of Approval: 365 days (1 year)

Continuation Criteria for Approval:

1. The patient was approved through Blue Cross NC initial criteria for approval; **OR**
2. The patient would have met initial criteria for approval at the time they started therapy; **AND**
3. The patient has a diagnosis of moderate to severe systemic lupus erythematosus (SLE) **[medical record documentation required]**; **AND**
4. The patient has experienced a reduction ≥ 4 points in SLEDAI-2K score from baseline (or similar improvement from baseline as scored by a comparable standardized rating scale that reliably measures SLE disease activity) following treatment with anifrolumab (Saphnelo™) indicating a therapeutic response **[medical record documentation required]**; **AND**
5. The patient does NOT have severe active central nervous system lupus or severe active lupus nephritis; **AND**
6. The patient will NOT be using anifrolumab (Saphnelo™) in combination with another biologic immunomodulator agent; **AND**
7. The requested quantity does NOT exceed the maximum units allowed for the duration of approval (see table below); **AND**
9. For requests for injection or infusion administration of the requested medication in an **inpatient or outpatient hospital setting,** Site of Care Criteria applies (outlined below)*

Duration of Approval: 365 days (1 year)

FDA Label Reference				
Medication	**Indication*,^**	**Dosing**	**HCPCS**	**Maximum Units***
anifrolumab (Saphnelo™) intravenous (IV) infusion	Moderate to severe systemic lupus erythematosus (SLE) in adults who are receiving standard therapy	IV: 300 mg every 4 weeks	C9086 J3490** J3590**	3900

*Anifrolumab has not been studied for use in severe active central nervous system lupus

^Anifrolumab has not been studied for use in severe active lupus nephritis

***Maximum units allowed for duration of approval**

****Non-specific assigned HCPCS codes, must submit requested product NDC**

***Site of Care Medical Necessity Criteria**

1. For requests for injection or infusion administration in an **inpatient setting**, the injection or infusion may be given if the above medical necessity criteria are met AND the inpatient admission is NOT for the sole purpose of administering the injection or infusion; **OR**
2. For requests for injection or infusion administration in an **outpatient hospital setting**, the injection or infusion may be given if the above medical necessity criteria are met AND ONE of the following must be met:
    a. History of mild adverse events that have not been successfully managed through mild pre-medication (e.g., diphenhydramine, acetaminophen, steroids, fluids, etc.); **OR**
    b. Inability to physically and cognitively adhere to the treatment schedule and regimen complexity; **OR**
    c. New to therapy, defined as initial injection or infusion OR less than 3 months since initial injection or infusion; **OR**
    d. Re-initiation of therapy, defined as ONE of the following:
        i. First injection or infusion after 6 months of no injections or infusions for drugs with an approved dosing interval less than 6 months duration; **OR**
        ii. First injection or infusion after at least a 1-month gap in therapy outside of the approved dosing interval for drugs requiring every 6 months dosing duration; **OR**
    e. Requirement of a change in the requested restricted product formulation; **AND**
3. If the Site of Care Medical Necessity Criteria in #1 or #2 above are not met, the injection or infusion will be administered in a **home-based infusion** or physician office setting with or without supervision by a certified healthcare professional.

References: all information referenced is from FDA package insert unless otherwise noted below.

1. Mikdashi J, Nived O. Measuring disease activity in adults with systemic lupus erythematosus: the challenges of administrative burden and responsiveness to patient concerns in clinical research. *Arthritis Res Ther*. 2015;17(1):183.
2. Aringer M, Costenbader K, Daikh D, et al. 2019 European League Against Rheumatism/American College of Rheumatology classification criteria for systemic lupus erythematosus. *Arthritis Rheumatol*. 2019;71(9):1400-1412.

Policy Implementation/Update Information:

January 2022: Coding update: Added HCPCS code C9086 to dosing reference table effective 1/1/2022, deleted C9399 termed 12/31/2021. Blue Cross NC Pharmacy and Therapeutics Committee 12/21/2021.
November 2021: Original medical policy criteria issued.

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    - Information written in other languages
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- You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, Civil Rights Coordinator - Privacy, Ethics & Corporate Policy Office is available to help you.

- You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at *https://ocrportal.hhs.gov/ocr/portal/lobby.jsf,* or by mail or phone at: U.S. Department of Health and Human Services 200 Independence Avenue, SW Room 509F, HHH Building Washington, D.C. 20201 **1-800-368-1019, 800-537-7697** (TDD). Complaint forms are available at *http://www.hhs.gov/ocr/office/file/index.html.*

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LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 1-888-206-4697 (TTY: 1-800-442-7028).

ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Звоните 1-888-206-4697 (телетайп: 1-800-442-7028).

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