AETNA BETTER HEALTH®
Coverage Policy/Guideline

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Effective Date:	8/28/2026	Last Review Date:	7/2026

Applies to:	☒Illinois	☒Florida Kids	☐Michigan
	☒New Jersey	☒Maryland	☐Texas
	☒Pennsylvania Kids	☐Virginia	☐Kentucky PRMD

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Saphnelo under the patient's prescription drug benefit.

Description:

FDA-approved Indications[1]

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

Limitations 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.

All other indications are considered experimental/investigational and not medically necessary.

Applicable Drug List:

Saphnelo

Policy/Guideline:

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

Initial requests

- Medical records (e.g., chart notes, laboratory reports) documenting the presence of autoantibodies relevant to SLE (e.g., antinuclear antibodies [ANA] by immunofluorescence [IFA] 1:80 or higher, anti-double-stranded DNA [anti-ds DNA], anti-Smith [anti-Sm], antiphospholipid antibodies, low complement proteins).

Continuation requests

- Medical records (e.g., chart notes, lab reports) documenting disease stability or improvement.

Prescriber Specialties

This medication must be prescribed by or in consultation with a rheumatologist or a specialist in the treatment of systemic lupus erythematosus.

Exclusions

Coverage will not be provided for members with any of the following exclusions:

- Severe active lupus nephritis in a member initiating therapy with Saphnelo.
- Severe active central nervous system (CNS) lupus (including seizures that are attributed to CNS lupus, psychosis, organic brain syndrome, cerebritis, or CNS vasculitis requiring therapeutic intervention before initiation of anifrolumab) in a member initiating therapy with Saphnelo.
- Member is using Saphnelo in combination with other biologics.

Coverage Criteria

Systemic Lupus Erythematosus (SLE)[1-6]

Authorization of 12 months may be granted for treatment of active SLE in members 18 years of age or older when all of the following criteria are met:

- Prior to initiating therapy, the member is positive for autoantibodies relevant to SLE (e.g., ANA by IFA 1:80 or higher, anti-ds DNA, anti-Sm, antiphospholipid antibodies, low complement proteins).
- The member is receiving standard treatment for SLE with any of the following (alone or in combination):
    - Glucocorticoids (e.g., prednisone, methylprednisolone, dexamethasone)
    - Antimalarials (e.g., hydroxychloroquine)
    - Immunosuppressants (e.g., azathioprine, methotrexate, mycophenolate, cyclosporine, cyclophosphamide)

Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition.

Approval Duration and Quantity Restrictions:

Initial and Renewal Approval Duration: 12 months

Quantity Level Limit:

- Saphnelo 300 mg/2mL: 1 vial per 30 days
- Saphnelo 120 mg/0.8mL: 4 syringes/autoinjectors per 30 days

References:

1. Saphnelo [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; August 2024.
2. Fanouriakis A, Kostopoulou M, Alunno A, et al. 2023 Update of the EULAR Recommendations for the Management of Systemic Lupus Erythematosus. Ann Rheum Dis. 2024;83:15-29.
3. Aringer M, Costenbader K, Daikh D, et al. 2019 European League Against Rheumatism/American College of Rheumatology classification criteria for systemic lupus erythematosus. Ann Rheum Dis. 2019;78:1151-1159.
4. Gordon C, Amissah-Arthru MB, Gayed M, et al. The British Society for Rheumatology guideline for the management of systemic lupus erythematosus in adults. Rheumatology (Oxford). 2018;57(1):e1-e45.
5. Petri M, Orbai A-M, Alarcon GS, et al. Derivation and Validation of Systemic Lupus International Collaborating Clinics (SLICC) Classification Criteria for Systemic Lupus Erythematosus. Arthritis Rheum. 2012; 64:2677-2686. URL: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3409311/. Accessed January 6, 2026.
6. Sammaritano LR, Askanase A, Bermas BL, et al. 2025 American College of Rheumatology (ACR) Guideline for the treatment of systemic lupus erythematosus. Arthritis Care Res. November 2025. URL: https://rheumatology.org/lupus-guideline. Accessed March 14, 2026.