CARECONTINUUM™

UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Lupus – Saphnelo Intravenous Utilization Management Medical Policy
- Saphnelo® (anifrolumab-fnia intravenous infusion – AstraZeneca)

REVIEW DATE: 03/11/2026; selected revision 05/13/2026

OVERVIEW

Saphnelo intravenous, a type 1 interferon receptor antagonist, is indicated for the treatment of moderate to severe **systemic lupus erythematosus (SLE)** in adults who are receiving standard therapy.[1]

Limitations of Use: Saphnelo efficacy has not been evaluated and is not recommended in patients with severe active lupus nephritis or severe active central nervous system lupus.[1]

Of note, subcutaneous Saphnelo is not targeted in this policy.

Guidelines

American College of Rheumatology (ACR) guidelines for treatment of SLE (2025) recommend hydroxychloroquine (HCQ) for all patients (unless contraindicated), minimization of glucocorticoid exposure, and early introduction of conventional and/or biologic immunosuppressive therapies.[2] Treatment strategies should be stratified based on organ-specific manifestations such as hematologic, neuropsychiatric, cutaneous/mucocutaneous, serositis, musculoskeletal, systemic vasculitis, and/or cardiopulmonary. The following ACR recommendations are specific to Benlysta® (belimumab intravenous infusion and subcutaneous injection) and Saphnelo: (1) Cutaneous lupus: For ongoing moderate to severe cutaneous lupus refractory to topical and antimalarial therapies, and/or oral glucocorticoid necessitating escalation of therapy, ACR conditionally recommends the addition of methotrexate (MTX), mycophenolic acid analog (MPAA), Saphnelo, and/or Benlysta (level of evidence [LOE]: very low to moderate). (2) SLE arthritis: For a patient with persistent or recurrent active SLE arthritis on HCQ, regardless of prior/current nonsteroidal anti-inflammatory drugs or short-term glucocorticoid therapy, ACR conditionally recommends initial therapy with MTX, MPAA, or azathioprine (AZA), with a low threshold to add or substitute with Benlysta or Saphnelo for inadequate response over initial biologic therapy (LOE: very low to low). (3) Systemic vasculitis: For vasculitis attributed to active SLE, ACR conditionally recommends initial therapy with pulse/high-dose glucocorticoid taper and conventional (e.g., intravenous cyclosporine, MPAA, AZA) or biologic (e.g., anti-CD20 therapy, Benlysta, Saphnelo) immunosuppressive therapy over glucocorticoid monotherapy alone (LOE: very low to low). The guidelines do not express a preference between Benlysta and Saphnelo; selection should be individualized based on mechanism of action and patient-specific clinical characteristics.

European League Against Rheumatism (EULAR) guidelines for SLE (2023 update) also recommend HCQ for all patients, unless contraindicated.[3] Depending on the type and severity of organ involvement, glucocorticoids may be used but dosing should be minimized or withdrawn. In general, pharmacological interventions are directed by patient characteristics and the type/severity of organ involvement. The following EULAR recommendations are specific to Benlysta and Saphnelo: (1) In patients who do not respond to HCQ ± glucocorticoids, the addition of immunomodulating/immunosuppressive agents should be considered (e.g., MTX, AZA, MPAA, and/or biologic agents [e.g., Benlysta, Saphnelo]). (2) For patients with active skin disease, treatment should include topical agents (e.g., glucocorticoids, calcineurin inhibitors), antimalarials (e.g., HCQ, chloroquine), and/or systemic glucocorticoids as needed, with MTX, MPAA, Saphnelo, or Benlysta considered as second-line.

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Saphnelo intravenous. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indication. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. Because of the specialized skills required for evaluation and diagnosis of patients treated with Saphnelo intravenous as well as the monitoring required for adverse events and long-term efficacy, approval requires Saphnelo intravenous to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Saphnelo intravenous is recommended in those who meet the following:

FDA-Approved Indication

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1. **Systemic Lupus Erythematosus.** Approve for the duration noted if the patient meets ONE of the following (A or B):
   - **A)** Initial Therapy. Approve for 6 months if the patient meets ALL of the following (i, ii, iii, and iv):
     - **i.** Patient is ≥ 18 years of age; AND
     - **ii.** Patient has autoantibody-positive systemic lupus erythematosus (SLE), defined as positive for at least one of the following: antinuclear antibodies (ANA), anti-double-stranded DNA (anti-dsDNA) antibodies, anti-Smith (anti-Sm) antibodies; AND
       Note: Not all patients with SLE are positive for anti-dsDNA, but most will be positive for ANA.
     - **iii.** Patient meets ONE of the following (a or b):
       - **a)** The medication is being used concurrently with at least one other standard therapy for SLE; OR
         Note: Examples of standard therapies for SLE include an antimalarial (e.g., hydroxychloroquine), systemic corticosteroid (e.g., prednisone), and other immunosuppressants (e.g., azathioprine, mycophenolate mofetil, methotrexate).
       - **b)** According to the prescriber, patient is determined to be intolerant to standard therapy due to a significant toxicity; AND
     - **iv.** The medication is prescribed by or in consultation with a rheumatologist, clinical immunologist, nephrologist, neurologist, or dermatologist; OR
   - **B)** Patient is Currently Receiving Saphnelo Intravenous or Subcutaneous. Approve for 1 year if the patient meets ALL of the following (i, ii, and iii):
     - **i.** Patient meets ONE of the following (a or b):
       - **a)** The medication is being used concurrently with at least one other standard therapy for SLE; OR
         Note: Examples of standard therapies for SLE include an antimalarial (e.g., hydroxychloroquine), systemic corticosteroid (e.g., prednisone), and other immunosuppressants (e.g., azathioprine, mycophenolate mofetil, methotrexate).
       - **b)** According to the prescriber, patient is determined to be intolerant to standard therapy due to a significant toxicity; AND
     - **ii.** According to the prescriber, patient responded to Saphnelo; AND

Note: Examples of a response include reduction in flares, reduction in corticosteroid dose, decrease of anti-dsDNA titer, improvement in complement levels (i.e., C3, C4), or improvement in specific organ dysfunction (e.g., musculoskeletal, blood, hematologic, vascular, others).

iii. The medication is prescribed by or in consultation with a rheumatologist, clinical immunologist, nephrologist, neurologist, or dermatologist.

Dosing. Approve 300 mg given as an intravenous infusion administered not more frequently than once every 4 weeks.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Saphnelo intravenous is not recommended in the following situations:

1. **Concurrent Use with Other Biologics.** Saphnelo has not been studied in combination with other biologics.[1] Safety and efficacy have not been established with these combinations. See APPENDIX for examples of other biologics that should not be taken in combination with Saphnelo.

2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Saphnelo® intravenous and subcutaneous injection [prescribing information]. Wilmington DE: AstraZeneca; April 2026.
2. Sammaritano LR, Askanase A, Bermas BL, et al. 2025 American College of Rheumatology (ACR) Guideline for the Treatment of Systemic Lupus Erythematosus. *Arthritis Rheumatol*. Published online November 4, 2025.
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.

HISTORY

Type of Revision	Summary of Changes	Review Date
Early Annual Revision	No criteria changes.	03/13/2024
Annual Revision	No criteria changes. Updated Appendix.	03/19/2025
Annual Revision	The term "standard therapy" was clarified to "standard therapy for systemic lupus erythematosus (SLE)". The requirement "as determined by the prescriber" was updated to "according to the prescriber".	03/11/2026
Selected Revision	**Title**: The policy name was updated to add Intravenous. Throughout the policy, it was clarified the target is Saphnelo intravenous.	05/13/2026

APPENDIX

	Mechanism of Action	Examples of Indications*
Biologics		
Benlysta® (belimumab SC injection, IV infusion)	BLyS inhibitor	SLE, lupus nephritis
Adalimumab SC Products (Humira®, biosimilars)	Inhibition of TNF	AS, CD, HS, JIA, PsO, PsA, RA, UC
Cimzia® (certolizumab pegol SC injection)	Inhibition of TNF	AS, CD, JIA, nr-axSpA, PsO, PsA, RA
Etanercept SC Products (Enbrel®, biosimilars)	Inhibition of TNF	AS, JIA, PsO, PsA, RA
Infliximab IV Products (Remicade®, biosimilars)	Inhibition of TNF	AS, CD, PsO, PsA, RA, UC
Zymfentra® (infliximab-dyyb SC injection)	Inhibition of TNF	CD, UC
Simponi®, Simponi Aria® (golimumab SC injection, IV infusion)	Inhibition of TNF	SC formulation: AS, PsA, RA, UC
		IV formulation: AS, PJIA, PsA, RA
Kineret® (anakinra SC injection)	Inhibition of IL-1	RA
Tocilizumab Products (Actemra® IV, biosimilars; Actemra SC, biosimilars)	Inhibition of IL-6	SC formulation: PJIA, RA, SJIA
Kevzara® (sarilumab SC injection)	Inhibition of IL-6	IV formulation: PJIA, RA, SJIA
Kevzara® (sarilumab SC injection)	Inhibition of IL-6	PJIA, RA
Siliq® (brodalumab SC injection)	Inhibition of IL-17	PsO
Cosentyx® (secukinumab SC injection; IV infusion)	Inhibition of IL-17A	SC formulation: AS, ERA, HS, nr-axSpA, PsO, PsA
Kineret® (anakinra SC injection)	Inhibition of IL-1	IV formulation: AS, nr-axSpA, PsA
Taltz® (ixekizumab SC injection)	Inhibition of IL-17A	AS, nr-axSpA, PsO, PsA
Bimzelx® (bimekizumab-bkzx SC injection)	Inhibition of IL-17A/17F	AS, HS, nr-axSpA, PsO, PsA
Ustekinumab Products (Stelara® IV, biosimilars; Stelara SC, biosimilars)	Inhibition of IL-12/23	SC formulation: CD, PsO, PsA, UC
Siliq® (brodalumab SC injection)	Inhibition of IL-17	IV formulation: CD, UC
Ilumya® (tildrakizumab-asmn SC injection)	Inhibition of IL-23	PsO
Omvoh® (mirikizumab IV infusion, SC injection)	Inhibition of IL-23	CD, UC
Skyrizi® (risankizumab-rzaa SC injection, IV infusion)	Inhibition of IL-23	SC formulation: CD, PsO, PsA, UC
Bimzelx® (bimekizumab-bkzx SC injection)	Inhibition of IL-17A/17F	IV formulation: CD, UC
Tremfya® (guselkumab SC injection, IV infusion)	Inhibition of IL-23	SC formulation: CD, PsO, PsA, UC
Skyrizi® (risankizumab-rzaa SC injection, risankizumab-rzaa IV infusion)	Inhibition of IL-23	IV formulation: CD, UC
Entyvio® (vedolizumab IV infusion, SC injection)	Integrin receptor antagonist	CD, UC
Orencia® (abatacept IV infusion, SC injection)	T-cell costimulation modulator	SC formulation: JIA, PsA, RA
		IV formulation: JIA, PsA, RA
Rituximab IV Products (Rituxan®, biosimilars)	CD20-directed antibody	RA

* Not an all-inclusive list of indication (e.g., oncology indications and rare inflammatory conditions are not listed). Refer to the prescribing information for the respective agent for FDA-approved indications; SC – Subcutaneous; IV – Intravenous; BLyS – B-lymphocyte stimulator-specific inhibitor; SLE – Systemic lupus erythematosus; IFN – Interferon; TNF – Tumor necrosis factor; AS – Ankylosing spondylitis; CD – Crohn's disease; JIA – Juvenile idiopathic arthritis; PsO – Plaque psoriasis; PsA – Psoriatic arthritis; RA – Rheumatoid arthritis; UC – Ulcerative colitis; nr-axSpA – Non-radiographic axial spondyloarthritis; PJIA – Polyarticular juvenile idiopathic arthritis; IL – Interleukin; SJIA – Systemic juvenile idiopathic arthritis; ^ Off-label use of Kineret in JIA supported in guidelines; ERA – Enthesitis-related arthritis.