

PRIOR AUTHORIZATION POLICY

POLICY: Lupus – Saphnelo Prior Authorization Policy

- Saphnelo® (anifrolumab-fnia intravenous infusion – AstraZeneca)

REVIEW DATE: 03/19/2025

OVERVIEW

Saphnelo, a type 1 interferon (IFN) 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

Guidelines

European League Against Rheumatism (EULAR) guidelines for SLE (2023 update) recommend hydroxychloroquine for all patients, unless contraindicated.² Depending on the type and severity of organ involvement, glucocorticoids can be used but dosing should be minimized or withdrawn. Methotrexate, azathioprine, mycophenolate, and/or biologic agents (Benlysta® [belimumab intravenous or subcutaneous infusion], Saphnelo) should be considered in patients who do not respond to hydroxychloroquine ± glucocorticoids. EULAR also states biologic agents (Benlysta, Saphnelo) should be considered as second-line therapy for the treatment of active skin disease. Patient with active proliferative lupus nephritis should also consider combination therapy with biologic agents (Benlysta, Lupkynis™ [voclosporin capsules]). In general, the pharmacological interventions are directed by patient characteristics and the type/severity of organ involvement.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Saphnelo. 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 as well as the monitoring required for adverse events and long-term efficacy, approval requires Saphnelo 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 is recommended in those who meet the following:

FDA-Approved Indication

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

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- II. Patient has autoantibody-positive 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; OR
Note: Examples of standard therapies include an antimalarial (e.g., hydroxychloroquine), systemic corticosteroid (e.g., prednisone), and other immunosuppressants (e.g., azathioprine, mycophenolate mofetil, methotrexate).
 - B) Patient is determined to be intolerant to standard therapy due to a significant toxicity, as determined by the prescriber; 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. 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; OR
Note: Examples of standard therapies include an antimalarial (e.g., hydroxychloroquine), systemic corticosteroid (e.g., prednisone), and other immunosuppressants (e.g., azathioprine, mycophenolate mofetil, methotrexate).
 - B) Patient is determined to be intolerant to standard therapy due to a significant toxicity, as determined by the prescriber; AND
 - II. Patient responded to Saphnelo, as determined by the prescriber; 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.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Saphnelo is not recommended in the following situations:

1. **Concurrent Use with Other Biologics.** Saphnelo has not been studied and is not recommended in combination with other biologics (e.g., Benlysta [belimumab intravenous infusion or subcutaneous injection], rituximab).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[®] injection, for intravenous use [prescribing information]. Wilmington DE: AstraZeneca; August 2024.
2. 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 |
|-----------------------|----------------------------------------|-------------|
| Annual Revision | No criteria changes. | 08/23/2023 |
| Early Annual Revision | No criteria changes. | 03/13/2024 |
| Annual Revision | No criteria changes. Updated Appendix. | 03/19/2025 |

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, JIA, PsO, PsA, RA, UC |
| Cimzia[®] (certolizumab pegol SC injection) | Inhibition of TNF | AS, CD, 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, golimumab IV infusion) | Inhibition of TNF | SC formulation: AS, PsA, RA, UC IV formulation: AS, PJIA, PsA, RA |
| Tocilizumab Products (Actemra [®] IV, biosimilar; Actemra SC, biosimilar) | Inhibition of IL-6 | SC formulation: PJIA, RA, SJIA IV formulation: PJIA, RA, SJIA |
| Kevzara[®] (sarilumab SC injection) | Inhibition of IL-6 | RA |
| Orencia[®] (abatacept IV infusion, abatacept SC injection) | T-cell costimulation modulator | SC formulation: JIA, PSA, RA IV formulation: JIA, PsA, RA |
| Rituximab IV Products (Rituxan [®] , biosimilars) | CD20-directed cytolytic antibody | RA |
| Kineret[®] (anakinra SC injection) | Inhibition of IL-1 | JIA [^] , RA |
| Omvoh[®] (mirikizumab IV infusion, SC injection) | Inhibition of IL-23 | UC |
| Stelara[®] (ustekinumab SC injection, ustekinumab IV infusion) | Inhibition of IL-12/23 | SC formulation: CD, PsO, PsA, UC IV formulation: CD, UC |
| Siliq[®] (brodalumab SC injection) | Inhibition of IL-17 | PsO |
| Cosentyx[®] (secukinumab SC injection; secukinumab IV infusion) | Inhibition of IL-17A | SC formulation: AS, ERA, nr-axSpA, PsO, PsA 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 | PsO |
| Ilumya[®] (tildrakizumab-asmn SC injection) | Inhibition of IL-23 | PsO |
| Skyrizi[®] (risankizumab-rzaa SC injection, risankizumab-rzaa IV infusion) | Inhibition of IL-23 | SC formulation: CD, PSA, PsO, UC IV formulation: CD, UC |
| Tremfya[®] (guselkumab SC injection, guselkumab IV infusion) | Inhibition of IL-23 | SC formulation: PsA, PsO, UC IV formulation: UC |
| Entyvio[®] (vedolizumab IV infusion, vedolizumab SC injection) | Integrin receptor antagonist | CD, UC |

* 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.

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