Medical Policy:
Saphnelo (anifrolumab-fnia) intravenous infusion

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.345	January 8, 2024	December 9, 2021

Definitions

Saphnelo, a type 1 interferon (IFN) receptor antagonist, is indicated for the treatment of adults with moderate to severe systemic lupus erythematosus (SLE) who are receiving standard therapy. Efficacy has not been evaluated and is not recommended in patients with severe active lupus nephritis or severe active central nervous system lupus.

Length of Authorization

Coverage will be provided for 6 months for initial therapy, and 1 year for continuation of treatment.

Dosing Limits [Medical Benefit]

Approve a single dose vial (300 mg/2ml) every 4 weeks. (300 billable units (300 mg) every 4 weeks)

Guideline

I. Initial Approval Criteria

1. **Systemic Lupus Erythematosus (SLE)**

Approve if the patient meets all of the following criteria (A, B, C, D, AND E):

A. Patient is ≥ 18 years of age **AND**
B. 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**
C. Patient meets **ONE** of the following (i or ii) **AND**
    i. The medication is being used concurrently with at least one other standard therapy; **OR**
    ii. Patient is determined to be intolerant to standard therapy due to a significant toxicity, as determined by the prescriber.
    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).
D. The medication is prescribed by or in consultation with a rheumatologist, clinical immunologist, nephrologist, neurologist, or dermatologist; **AND**
E. Will not be used concurrently with other biologics (e.g., Benlysta [belimumab intravenous infusion or subcutaneous injection], rituximab)

II. Continuation Criteria:

1. **Systemic Lupus Erythematosus (SLE)**

Approve if the patient meets ALL of the following criteria (A, B, C, **AND** D):

A. Patient meets ONE of the following (i or ii) **AND**
    i. The medication is being used concurrently with at least one other standard therapy **OR**
    ii. Patient is determined to be intolerant to standard therapy due to a significant toxicity, as determined by the prescriber.
B. 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).
C. The medication is prescribed by or in consultation with a rheumatologist, clinical immunologist, nephrologist, neurologist, or dermatologist **AND**
D. Will not be used concurrently with other biologics. (e.g., Benlysta [belimumab intravenous infusion or subcutaneous injection], rituximab)

Dosing/Administration

The recommended dosage is 300 mg as an intravenous infusion over a 30-minute period every 4 weeks.

Applicable Procedure Codes

Code	Description
J0491	Saphnelo 300MG/2ML Solution J0491 Injection, anifrolumab-fnia, 1 mg

Applicable NDCs

Code	Description
00310-3040-00	Solution, 300 mg/2ml, one single dose vial

ICD-10 Diagnoses

Code	Description
M32.10	Systemic lupus erythematosus, organ or system involvement unspecified
M32.11	Endocarditis in systemic lupus erythematosus
M32.12	Pericarditis in systemic lupus erythematosus
M32.13	Lung involvement in systemic lupus erythematosus
M32.14	Glomerular disease in systemic lupus erythematosus
M32.15	Tubulo-interstitial nephropathy in systemic lupus erythematosus
M32.19	Other organ or system involvement in systemic lupus erythematosus
M32.8	Other forms of systemic lupus erythematosus
M32.9	Systemic lupus erythematosus, unspecified

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	1/8/2024	Annual Review: No criteria changes
EmblemHealth & ConnectiCare	5/9/2023	Annual Review: No criteria updates
EmblemHealth & ConnectiCare	1/12/2023	Transfer to new template. Removed codes C9086 and J3590. Added J0491
EmblemHealth & ConnectiCare	12/9/2021	New Policy

Appendix

	Mechanism of Action	Examples of Inflammatory Indications*
Biologics		
Benlysta® (belimumab SC injection, IV infusion)	BLyS inhibitor	SLE, lupus nephritis
Adalimumab SC Products (Humira®, biosimilars)	Inhibition of TNF	AS, CD, JIA, HS, PsO, PsA, RA, UC, UV
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
Simponi®, Simponi® Aria™ (golimumab SC injection, golimumab IV infusion)	Inhibition of TNF	SC formulation: AS, PsA, RA, UC
		IV formulation: AS, PJIA, PsA, RA
Actemra® (tocilizumab IV infusion, tocilizumab SC injection)	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

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)	Inhibition of IL-17A	AS, nr-axSpA, PsO, PsA
Taltz® (ixekizumab SC injection)	Inhibition of IL-17A	AS, nr-axSpA, PsO, PsA
Ilumya™ (tildrakizumab-asmn SC injection)	Inhibition of IL-23	PsO
Skyrizi™ (risankizumab-rzaa SC injection)	Inhibition of IL-23	PsO
Tremfya™ (guselkumab SC injection)	Inhibition of IL-23	PsA, PsO
Entyvio™ (vedolizumab IV infusion)	Integrin receptor antagonist	CD, UC

* Not an all-inclusive list of indications (e.g., oncology indications and less common 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; TNF – Tumor necrosis factor; AS – Ankylosing spondylitis; CD – Crohn's disease; JIA – Juvenile idiopathic arthritis; HS – Hidradenitis suppurativa; PsO – Plaque psoriasis; PsA – Psoriatic arthritis; RA – Rheumatoid arthritis; UC – Ulcerative colitis; UV – Uveitis; nr-axSpA – Non-radiographic axial spondyloarthritis; IL – Interleukin; ^ Off-label use of Kineret in JIA supported in guidelines.

References

1. Saphnelo™ intravenous infusion [package insert]. Wilmington DE, AstraZeneca; July 2021. Updated July 2021. Accessed Sep 16, 2021.
2. Saphnelo™ intravenous infusion. IBM Micromedex® [database online]. Greenwood Village, CO. Truven Health Analytics. Available at: https://www.micromedexsolutions.com. Updated Sep 2, 2021. Accessed Sep 16, 2021.
3. 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;78(6):736-745.