Effective Date **2/15/2024**
Next Review Date **2/15/2025**
Coverage Policy Number **IP0280**

Anifrolumab-fnia

Table of Contents

Related Coverage Resources

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This policy supports medical necessity review for anifrolumab-fnia (**Saphnelo**®).

Additional criteria that support the review for medical necessity exceptions of non-covered products are located in the Non-Covered Product Table by the respective plan type and drug list where applicable.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Medical Necessity Criteria

Anifrolumab-fnia (Saphnelo) is considered medically necessary when the following are met:

Systemic Lupus Erythematosus (SLE). Individual meets **ALL** of the following criteria:
A. Age 18 years or older

B. Documentation of positive autoantibody test (for example, anti-nuclear antibody [ANA] greater than or equal to 1:80, anti-double-stranded DNA [anti-dsDNA] greater than or equal to 30 IU/ml, anti-Smith (anti-Sm) antibodies)
C. **ONE** of the following:
    i. The medication is being used concurrently with at least **ONE** other standard therapy (for example, an antimalarial, systemic corticosteroid, other immunosuppressants)
    ii. Intolerance to standard therapy due to a significant toxicity, as determined by the prescriber
D. Medication is prescribed by, or in consultation with, a rheumatologist, clinical immunologist, nephrologist, neurologist, or dermatologist
E. Non-Covered Product Criteria is met, refer to below table(s)

Dosing. Up to 300 mg given intravenously every 4 weeks.

Employer Group Non-Covered Products and Criteria:

Non-Covered Product	Criteria
Saphnelo (anifrolumab-fnia)	Documentation of **ONE** of the following: 1. Failure, contraindication, or intolerance to Benlysta (belimumab) [may require prior authorization] intravenous infusion or subcutaneous injection 2. Depression or suicidality, according to the prescriber 3. Treatment with Saphnelo therapy has been started

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Reauthorization Criteria

Continuation of anifrolumab-fnia (Saphnelo) is considered medically necessary for Systemic Lupus Erythematosus when the above medical necessity criteria are met AND there is documentation of beneficial response.

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).

Authorization Duration

Initial approval duration: up to 6 months
Reauthorization approval duration: up to 12 months

Conditions Not Covered

Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive):

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. **Severe active lupus nephritis.** Saphnelo has not been studied and is not recommended in individuals with severe active lupus nephritis.[1] Safety and efficacy have not been established for this indication.

3. **Severe active central nervous system lupus.** Saphnelo has not been studied and is not recommended in individuals with severe active central nervous system lupus.[1] Safety and efficacy have not been established for this indication.

Coding Information

1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPCS Codes	Description
J0491	Injection, anifrolumab-fnia, 1 mg

Background

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. Efficacy has not been evaluated and is not recommended in patients with severe active lupus nephritis or severe active central nervous system lupus.

Guidelines
Saphnelo is not addressed in current guidelines. European League Against Rheumatism guidelines for SLE (2019) 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, or mycophenolate should be considered in patients who do not respond to hydroxychloroquine ± glucocorticoids. Cyclophosphamide can be used for severe organ- or life-threatening disease or as rescue therapy in patients not responding to other immunosuppressive therapies. Add on treatment with Benlysta® (belimumab intravenous infusion or subcutaneous injection) should be considered for those who do not respond to standard of care with hydroxychloroquine + glucocorticoids ± immunosuppressive therapies. Rituximab can also be considered for organ-threatening disease or for those with intolerance or contraindications to standard immunosuppressives.

APPENDIX

	Mechanism of Action	Examples of Inflammatory Indications*
Biologics		
Saphnelo™ (anifrolumab-fnia IV infusion)	IFN receptor antagonist	SLE
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
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, ERA, 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, risankizumab-rzaa IV infusion)	Inhibition of IL-23	SC formulation: CD, PsA, PsO
		IV formulation: CD
Tremfya™ (guselkumab SC injection)	Inhibition of IL-23	PsO, PsA
Entyvio™ (vedolizumab IV infusion)	Integrin receptor antagonist	CD, UC

* Not an all-inclusive list of indications (e.g., oncology indications and rare inflammatory conditions are not listed). Refer to the prescribing information for the respective agent for FDA-approved indications; IFN – Interferon; SLE – Systemic lupus erythematosus; SC – Subcutaneous; 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; IV – Intravenous, 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.

References

1. Saphnelo injection, for intravenous use [prescribing information]. Wilmington DE: AstraZeneca; September 2022.
2. 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.