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Section:	Prescription Drugs	**Effective Date:**	April 1, 2025
Subsection:	Miscellaneous Products	**Original Policy Date:**	August 20, 2021
Subject:	Saphnelo	**Page:**	1 of 5

Last Review Date: March 7, 2025

Saphnelo

Description

Saphnelo (anifrolumab-fnia)

Background
Saphnelo (anifrolumab-fnia) is a human IgG1κ monoclonal antibody that binds to subunit 1 of the type I interferon receptor (IFNAR) with high specificity and affinity. The binding inhibits type I IFN signaling, thereby blocking the biologic activity of type I INFs. Saphnelo also induces the internalization of IFNAR1, thereby redcing the levels of cell surface IFNAR1 available for receptor assembly. This inhibits IFN responsive gene expression as well as downstream inflammatory and immunological processes. Type I IFNs play a role in the pathogenesis of systemic lupus erythematosus (SLE) (1).

Regulatory Status
FDA-approved indication: Saphnelo is a type I interferon (IFN) receptor antagonist indicated for the treatment of adult patients with moderate to severe systemic lupus erythematosus (SLE), who are receiving standard therapy (1).

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 (1).

Saphnelo has warnings for the following: serious infections, hypersensitivity reactions including anaphylaxis, and malignancy. Saphnelo patients should have updated immunizations according to immunization guidelines prior to initiation therapy. Concurrent use of live or live-attenuated

vaccines should be avoided in patients treated with Saphnelo. Saphnelo is also not studied in combination with other biologic therapies, including B-cell targeted therapies (1).

The safety and effectiveness of Saphnelo in pediatric patients less than 18 years of age have not been established (1).

Related policies
Benlysta

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Saphnelo may be considered **medically necessary** if the conditions indicated below are met.

Saphnelo may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Systemic lupus erythematosus (SLE)

AND ALL of the following:

1. Must have moderate to severe SLE
2. Must be receiving standard therapy [e.g., corticosteroids, NSAID, azathioprine, leflunomide, methotrexate, mycophenolate, tacrolimus, and antimalarials (e.g., hydroxychloroquine, chloroquine, quinine, quinidine, mefloquine)]

AND NONE of the following:

1. Chronic infection, including, but not limited to Hepatitis B, Hepatitis C, HIV, TB

2. Severe active lupus nephritis
3. Severe active central nervous system lupus
4. Concurrent therapy with other biologic therapies
5. Given concurrently with live vaccines

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Systemic lupus erythematosus (SLE)

AND ALL of the following:

1. Must be receiving standard therapy [e.g., corticosteroids, NSAID, azathioprine, leflunomide, methotrexate, mycophenolate, tacrolimus, and antimalarials (e.g., hydroxychloroquine, chloroquine, quinine, quinidine, mefloquine)]
2. Documented clinical benefit from therapy (e.g., improvement in functional impairment, decrease of corticosteroid dose, decrease in pain medications, decrease in the number of exacerbations since prior to the start of Saphnelo)

AND NONE of the following:

1. Chronic infection, including, but not limited to Hepatitis B, Hepatitis C, HIV, TB
2. Severe active lupus nephritis
3. Severe active central nervous system lupus
4. Concurrent therapy with other biologic therapies
5. Given concurrently with live vaccines

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity 3 vials per 84 days

Duration 6 months

Prior – Approval *Renewal* Limits

Quantity 3 vials per 84 days

Duration 12 months

Rationale

Summary
Most patients with active systemic lupus erythematosus (SLE) express elevated levels of type I IFN inducible genes. Saphnelo is a type I interferon (IFN) receptor antagonist indicated for the treatment of SLE. Patients on Saphnelo should not receive live vaccines or use Saphnelo in combination with biologic medications. The safety and effectiveness of Saphnelo in pediatric patients less than 18 years of age have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Saphnelo while maintaining optimal therapeutic outcomes.

References
1. Saphnelo [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; August 2024.

Policy History

Date	Action
August 2021	Addition to PA
December 2021	Annual review
September 2022	Annual review
September 2023	Annual review and reference update
March 2024	Annual review and reference update
March 2025	Annual review and reference update

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Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 7, 2025 and is effective on April 1, 2025.