UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2026 P 1529-1
Program	Prior Authorization/Notification
Medication	Saphnelo® (anifrolumab-fnia)* *This program applies to the subcutaneous formulation of anifrolumab-fnia
P&T Approval Date	9/2026
Effective Date	11/1/2026

1. Background:

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.

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.

2. Coverage Criteria[a]:

A. Systemic Lupus Erythematosus

1. **Initial Authorization**

a. **Saphnelo** will be approved based on **all** of the following criteria:

(1) Diagnosis of moderate to severe systemic lupus erythematosus

-AND-

(2) Patient is currently receiving standard immunosuppressive therapy [e.g., hydroxychloroquine, chloroquine, prednisone, azathioprine, methotrexate]

-AND-

(3) Patient does **not** have severe active lupus nephritis or severe active central nervous system lupus

-AND-

(4) Patient is not receiving Saphnelo in combination with Benlysta (belimumab) for treatment of the same indication

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Saphnelo** will be approved based on **both** of the following criteria:

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(1) Documentation of positive clinical response to Saphnelo therapy

-AND-

(2) Patient is not receiving Saphnelo in combination with Benlysta (belimumab) for treatment of the same indication

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.
- The intravenous infusion is typically covered under the medical benefit. Please refer to the UnitedHealthcare Drug Policy for Saphnelo.

4. References:

1. Saphnelo [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; April 2026.

Program	Prior Authorization/Notification - Saphnelo (anifrolumab-fnia)
Change Control	
9/2026	New program.

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