

Saphnelo™ (anifrolumab-fnia)

When requesting Saphnelo (anifrolumab-fnia), the individual requiring treatment must be diagnosed with the following FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

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.

Coverage Guidelines

Systemic lupus erythematosus (SLE)

The individual must meet **all** of the following criteria for initial authorization:

- Has autoantibody-positive SLE, defined as positive for at least one of the following:
 - o antinuclear antibodies (ANA)
 - o anti-double-stranded DNA (anti-dsDNA) antibodies
 - o anti-Smith (anti-Sm) antibodies
- Is 18 years of age or older;
- Will be using Saphnelo concurrently with at least one other standard therapy (e.g., an antimalarial [e.g., hydroxychloroquine], a systemic corticosteroid [e.g., prednisone], or other immunosuppressant [e.g., azathioprine, mycophenolate mofetil, methotrexate]) OR is intolerant to standard therapy due to a significant toxicity;
- Saphnelo is prescribed by or in consultation with a rheumatologist, clinical immunologist, nephrologist, neurologist, or dermatologist.

For reauthorization, the individual must meet **all** of the following criteria:

- Is using Saphnelo concurrently with at least one other standard therapy (e.g., an antimalarial [e.g., hydroxychloroquine], a systemic corticosteroid [e.g., prednisone], or other immunosuppressant [e.g., azathioprine, mycophenolate mofetil, methotrexate]) OR is intolerant to standard therapy due to a significant toxicity;
- Has responded to Saphnelo (e.g., 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]);
- Saphnelo is prescribed by or in consultation with a rheumatologist, clinical immunologist, nephrologist, neurologist, or dermatologist.

Approval duration (initial and renewal): 12 months

Dosing Recommendation

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

References

1. Saphnelo™ injection, for intravenous use [prescribing information]. Wilmington DE: AstraZeneca; December 2023.
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.

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