CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Georgia Medicaid

DRUG NAME	Saphnelo (anifrolumab-fnia)
BENEFIT TYPE	Medical
STATUS	Prior Authorization Required

Saphnelo, approved by the FDA in 2021, is a first in class type I interferon (IFN) receptor antagonist , and the first drug to target IFN-1 for the treatment of Systemic Lupus Erythematosus (SLE). Saphnelo is indicated for adults with moderate to severe SLE, in combination with standard therapy.
SLE is the most common type of lupus. It is a chronic autoimmune disease with periods of flares and remissions that causes inflammation and damage throughout the body. Up to 60-80% of adult SLE patients have increased type 1 IFN signaling, which is associated with higher disease activity/severity. Pooled clinical trial data for Saphnelo demonstrates improved overall disease activity.

Saphnelo (anifrolumab-fnia) will be considered for coverage when the following criteria are met:

Systemic Lupus Erythematosus (SLE)

For **initial** authorization:

1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with a rheumatologist; AND
3. Member has a documented diagnosis of active, autoantibody-positive SLE as confirmed by documentation of at least one of the following:
   a) Positive anti-nuclear antibody (ANA) titer ≥1:80
   b) Elevated (above normal) anti-double-stranded DNA (anti-dsDNA)
   c) Elevated (above normal) anti-Smith (anti-Sm) antibody; AND
4. Member has tried and failed hydroxychloroquine OR is unable to reduce steroid to an acceptable dose for chronic use (5 mg prednisone per day or less); AND
5. Standard therapy (e.g., hydroxychloroquine) will be continued unless contraindicated; AND
6. Saphnelo will not be used with other biologic therapies; AND
7. Member does not have severe active lupus nephritis or severe active central nervous system lupus.
8. **Dosage allowed/Quantity limit:** 300 mg IV infusion every 4 weeks (1 vial per 28 days)

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:

1. Chart notes must document improved disease activity such as reduced number of flares, reduced severity of skin disease, or ability to taper glucocorticoid use.

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Saphnelo (anifrolumab-fnia) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
09/15/2021	New policy for Saphnelo created.
08/23/2022	Updated billing code. Removed SELENA-SLEDAI score.
01/09/2024	Updated references. Removed requirement for non-steroid immunosuppressant trial, changed to only require HCQ or steroid instead of both, removed "moderate to severe" (EULAR 2023).

References:

1. Saphnelo. [prescribing information]. AstraZeneca; 2023.
2. Furie R, Khamashta M, Merrill JT, et al. Anifrolumab, an Anti-Interferon-α Receptor Monoclonal Antibody, in Moderate-to-Severe Systemic Lupus Erythematosus. *Arthritis Rheumatol*. 2017;69(2):376-386. doi:10.1002/art.39962
3. Morand EF, Furie R, Tanaka Y, et al. Trial of Anifrolumab in Active Systemic Lupus Erythematosus. *N Engl J Med*. 2020;382(3):211-221. doi:10.1056/NEJMoa1912196
4. Gordon C, Amissah-Arthur MB, Gayed M, et al. The British Society for Rheumatology guideline for the management of systemic lupus erythematosus in adults: Executive Summary. *Rheumatology (Oxford)*. 2018;57(1):14-18. doi:10.1093/rheumatology/kex291
5. Fanouriakis A, Tziolos N, Bertsias G, Boumpas DT. Update on the diagnosis and management of systemic lupus erythematosus. *Ann Rheum Dis*. 2021;80(1):14-25. doi:10.1136/annrheumdis-2020-218272
6. 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. Published 2024 Jan 2. doi:10.1136/ard-2023-224762

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