Saphnelo (anifrolumab-fnia)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	Initial requests: 6 months Continuation requests: 1 year

Medications	Quantity Limit
Saphnelo (anifrolumab-fnia)	May be subject to quantity limit

APPROVAL CRITERIA

Initial requests for Saphnelo (anifrolumab-fnia) may be approved if the following criteria are met:

I. Individual is 18 years of age or older; **AND**
II. Individual has a diagnosis of Systemic Lupus Erythematosus per the American College of Rheumatology (ACR); **AND**
III. Documentation is provided that disease is considered moderate to severe, and is active and documented by a SLEDAI-2K score greater than or equal to 6 while on current treatment regimen for SLE; **AND**
IV. Documentation is provided that diagnosis has been verified by history of positive anti-nuclear antibody (ANA) titer greater than or equal to 1:80 or anti-dsDNA greater than or equal to 30 IU/mL; **AND**
V. Individual's SLE disease remains active while on corticosteroids, antimalarials, or immunosuppressants (alone or as combination therapy) for at least the last 30 days; **AND**
VI. Individual is using in combination with standard therapy (for example, corticosteroids, antimalarials, and/or immunosuppressants [but not other biologics]).

Continuation requests for Saphnelo (anifrolumab-fnia) may be approved if all of the following criteria are met:

I. Documentation is provided showing improvement in disease activity following treatment with Saphnelo (anifrolumab-fnia) indicating a therapeutic response; **AND**
II. Individual has no evidence of severe active central nervous system lupus (such as psychosis or seizures); **AND**
III. Individual has no evidence of severe active lupus nephritis (defined as proteinuria greater than 6 gm/d, serum creatinine greater than 2.5 mg/dl, or requiring dialysis); **AND**
IV. Individual is using in combination with standard therapy (for example, corticosteroids, antimalarials, and/or immunosuppressants [but not other biologics]).

Saphnelo (anifrolumab-fnia) may not be approved for the following:

I. Individual has evidence of severe active central nervous system lupus (such as psychosis or seizures); **OR**
II. Individual has evidence of severe active lupus nephritis (defined as proteinuria greater than 6 gm/d, serum creatinine greater than 2.5 mg/dl, or requiring dialysis); **OR**
III. Individual is using in combination with another biologic (including, but not limited to, B-cell targeted therapies or belimumab) or voclosporin; **OR**
IV. Individual has human immunodeficiency virus (HIV) infection, hepatitis B virus infection, or hepatitis C virus infection (NCT01438489, NCT02446912, NCT02446899).

Key References:

1. American College of Rheumatology (ACR). Guidelines for referral and management of systemic lupus erythematosus in adults. Arthritis & Rheumatism. 1999; 42(9): 1785-1796.
2. American College of Rheumatology (ACR). Guidelines for the Treatment of Systemic Lupus Erythematosus (SLE). May 7, 2025. Available at sle-guideline-summary-2025.pdf. Accessed July 8, 2025.
3. Aringer M, Costenbader KH, Daikh DI, et. al. 2019 EULAR/ACR Classification Criteria for Systemic Lupus Erythematosus. Arthritis Rheumatol. 2019 Sep; 71(9): 1400-1412. Doi: 10.1002/art.40930. Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6827566/. Accessed July 8, 2025.
4. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: July 8, 2025.
5. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
6. 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 Feb;69(2):376-386. doi: 10.1002/art.39962.
7. Furie R, Morand E, Bruce I, et. al. Type I interferon inhibitor anifrolumab in active systemic lupus erythematosus (TULIP-1): a randomised, controlled, phase 3 trial. The Lancet. Rheumatology. 2019 Nov;1(4):E208-E219. Available at: https://www.thelancet.com/journals/lanrhe/article/PIIS2665-9913(19)30076-1/fulltext#%20.
8. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; Updated periodically.
9. Morand EF, Furie R, Tanaka Y, et. al; TULIP-2 Trial Investigators. Trial of Anifrolumab in Active Systemic Lupus Erythematosus. N Engl J Med. 2020 Jan 16;382(3):211-221. doi: 10.1056/NEJMoa1912196. Epub 2019 Dec 18.
10. NCT01438489. U.S. National Library of Medicine, ClinicalTrials.gov website. https://clinicaltrials.gov/ct2/show/NCT01438489?term=NCT01438489&draw=2&rank=1.
11. NCT02446899. U.S. National Library of Medicine, ClinicalTrials.gov website. https://clinicaltrials.gov/ct2/show/NCT02446899?term=NCT02446899&draw=1&rank=1.
12. NCT02446912. U.S. National Library of Medicine, ClinicalTrials.gov website. https://clinicaltrials.gov/ct2/show/NCT02446912?term=NCT02446912&draw=2&rank=1.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.