

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 individual has a 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 or cyclophosphamide]).

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 or cyclophosphamide]).

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), voclosporin, or cyclophosphamide; **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. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2021. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
3. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: August 3, 2021.
4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
5. 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.
6. 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](https://www.thelancet.com/journals/lanrhe/article/PIIS2665-9913(19)30076-1/fulltext#%20).
7. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2021; Updated periodically.
8. 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.
9. NCT01438489. U.S. National Library of Medicine, ClinicalTrials.gov website. <https://clinicaltrials.gov/ct2/show/NCT01438489?term=NCT01438489&draw=2&rank=1>.
10. NCT02446899. U.S. National Library of Medicine, ClinicalTrials.gov website. <https://clinicaltrials.gov/ct2/show/NCT02446899?term=NCT02446899&draw=1&rank=1>.
11. 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.

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