CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Arkansas PASSE

DRUG NAME	Saphnelo (anifrolumab-fnia)
BILLING CODE	J3490/J3590
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Home/Office/Outpatient
STATUS	Prior Authorization Required

Saphnelo is a first in class type 1 interferon (IFN-1) inhibitor, 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. Chart notes document 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 documented moderate to severe SLE or SELENA-SLEDAI score of 6 or greater; AND
5. Member has tried and failed all the following (unless contraindicated):
   a) Hydroxychloroquine (or chloroquine), and
   b) Corticosteroid, and
   c) A non-steroid immunosuppressant (i.e., methotrexate, azathioprine, mycophenolate mofetil) for at least 12 weeks; AND
6. At least one of the above standard therapies will be continued with Saphnelo; AND
7. Saphnelo will not be used with other biologic therapies; AND
8. Member does not have severe active lupus nephritis or severe active central nervous system lupus.
9. **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.

References:

1. Saphnelo. [prescribing information]. AstraZeneca; 2021.
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. Fanouriakis A, Kostopoulou M, Alunno A, et al. 2019 update of the EULAR recommendations for the management of systemic lupus erythematosus. *Ann Rheum Dis*. 2019;78(6):736-745. doi:10.1136/annrheumdis-2019-215089
5. 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
6. 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
7. Kleinmann JF, Tubach F, Le Guern V, et al. International and multidisciplinary expert recommendations for the use of biologics in systemic lupus erythematosus. Autoimmun Rev. 2017;16(6):650-657. doi:10.1016/j.autrev.2017.04.011

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