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Medication Policy Manual

Policy No: dru688

Topic: Saphnelo, anifrolumab

Date of Origin: November 15, 2021

Committee Approval Date: July 9, 2026

Next Review Date: 2027

Effective Date: September 1, 2026

IMPORTANT REMINDER

This Medication Policy has been developed through consideration of medical necessity, generally accepted standards of medical practice, and review of medical literature and government approval status.

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

The purpose of Medication Policy is to provide a guide to coverage. Medication Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care.

Description

Saphnelo (anifrolumab) is a type I interferon receptor antagonist used for the treatment of patients with systemic lupus erythematosus who are receiving standard therapy.

Policy/Criteria

Most contracts require pre-authorization approval of Saphnelo (anifrolumab) prior to coverage.

I. Continuation of therapy (COT): Saphnelo (anifrolumab) may be considered medically necessary for COT when criteria A and B are met.

A. One of the following (1, 2, or 3) is met:

1. For diagnoses NOT listed in the coverage criteria below, criteria a and b must be met:

a. The patient was established on therapy prior to current health plan membership AND there is documentation that the medication was covered by another health plan. Examples of documentation include the coverage approval letter from the previous health plan or paid claim.

AND

b. There is documentation of clinical benefit, such as disease stability as detailed in the reauthorization criteria.

OR

2. For diagnoses listed in the coverage criteria below, criteria a and b must be met:

a. The patient was established on therapy prior to current health plan membership AND attestation that the medication was covered by another health plan.

AND

b. There is documentation of clinical benefit, such as disease stability as detailed in the reauthorization criteria.

OR

3. The medication was initiated for acute disease management, as part of an acute unscheduled, inpatient hospital admission.

AND

B. Site of care administration requirements are met [refer to Pharmacy Services Medication Policy Manual, Site of Care Review, dru408].

***Please note**: Medications obtained as samples, coupons, or promotions, paying cash for a prescription ("out-of-pocket") as an eligible patient, or any other method of obtaining medications outside of an established health plan benefit (from your insurance) does NOT necessarily establish medical necessity. Medication policy criteria apply for coverage, per the terms of the member contract with the health plan.*

II. New starts (treatment-naïve patients): Saphnelo (anifrolumab) may be considered medically necessary when there is clinical documentation (such as chart notes) that criteria A through D below are met.

A. A diagnosis of active, systemic lupus erythematosus (SLE) established by or in conjunction with a specialist in rheumatology.

AND

B. Treatment with at least one of the following has been ineffective, or all are contraindicated or not tolerated: hydroxychloroquine, methotrexate, azathioprine, or mycophenolate mofetil.

AND

C. Treatment with Benlysta (belimumab) was ineffective, not tolerated, or is contraindicated.

AND

D. **Saphnelo (anifrolumab) IV only**: Site of care administration requirements are met [refer to Pharmacy Services Medication Policy Manual, Site of Care Review, dru408].

III. Administration, Quantity Limitations, and Authorization Period

A. Regence Pharmacy Services considers Saphnelo (anifrolumab) IV coverable only under the medical benefit (as a provider-administered medication).

B. Regence Pharmacy Services considers Saphnelo (anifrolumab) SC (autoinjector pens or prefilled syringes) coverable only under the pharmacy benefit (as a self-administered medication).

C. When pre-authorization is approved, Saphnelo (anifrolumab) will be authorized as follows:

1. IV: Up to 300 mg every 4 weeks.

2. SC: Up to 120 mg once weekly.

D. Authorization **may** be reviewed at least annually. Clinical documentation (such as chart notes) must be provided to confirm that current medical necessity criteria are met, and that the medication is providing clinical benefit, including disease stability or improvement must be provided, relative to baseline symptoms.

IV. Saphnelo (anifrolumab) is considered investigational when used for all other conditions, including but not limited to:

A. Central nervous system lupus.

B. Lupus nephritis.

C. Use in combination with Benlysta (belimumab).

Position Statement

Summary

- Saphnelo (anifrolumab) is a type 1 interferon antagonist approved for the treatment of patients with moderate to severe systemic lupus erythematosus (SLE) who are receiving standard therapy. [1]
- The intent of this policy is to limit use of Saphnelo (anifrolumab) to patients with a diagnosis of SLE who have had inadequate response to standard therapies.
- Saphnelo (anifrolumab) was evaluated in two phase 3 studies and one phase 2 study. All were 52-week double-blind placebo-controlled trials. All patients had disease activity despite treatment with standard SLE therapy (either one or any combination of oral corticosteroids, hydroxychloroquine, and/or immunosuppressants). Results from two of the three studies showed that Saphnelo (anifrolumab) increased the rate of clinical response as measured by validated indices of disease severity. These trials did not compare Saphnelo (anifrolumab) to Benlysta (belimumab); therefore, the relative safety and efficacy is unknown. [2 3]
- 2023 European League Against Rheumatism (EULAR) Guidelines for SLE recommend that all patients receive hydroxychloroquine. Immunosuppressants such as methotrexate, azathioprine, or mycophenolate should be considered in patients who had an inadequate response to hydroxychloroquine. Glucocorticoids (e.g., prednisone) are recommended for the treatment of flares and to provide symptom relief. The dose of glucocorticoids should be minimized and withdrawn when possible. [4]
    * Benlysta (belimumab) and Saphnelo (anifrolumab) are recommended in patients with inadequate control to hydroxychloroquine with or without immunosuppressants. Guidelines do not recommend one over the other.
- The safety and effectiveness of higher doses or more frequent administration beyond those listed in FDA labeling have not been established for Saphnelo (anifrolumab). [1]
- The safety and effectiveness of Saphnelo (anifrolumab) in conditions other than SLE have not been established. Therefore, Saphnelo (anifrolumab) is not recommended in lupus nephritis (LN) or central nervous system (CNS) lupus. [1]
- Saphnelo (anifrolumab) has not been studied in combination with other biologic therapies, including Benlysta (belimumab). [1]
- New technologies and pharmaceuticals allow therapeutic services, such as infusion therapy, to be administered safely, effectively, and much less costly outside of hospital-based infusion centers (i.e., hospital outpatient settings). Sites of care such as doctor's offices, infusion centers, home infusion, and approved hospital-based infusion centers are well-established, accepted by physicians, and provide the best value to patients to reduce the overall cost of care.

Clinical Efficacy

- Approval for Saphnelo (anifrolumab) was based on two phase 3 trials and one phase 2 trial. [3] [1]
- All studies were 52-weeks in duration included patients with SLE who were receiving standard therapy (HCQ or immunosuppressive therapy) with or without corticosteroids. Patients were maintained on their existing therapies throughout the trial, except for corticosteroids which were tapered off. The studies did not compare Saphnelo (anifrolumab) to Benlysta (belimumab); therefore, the relative safety and efficacy is unknown. [1 3]
- Efficacy was evaluated using Systemic Lupus Erythematosus Responder Index (SRI-4) and BILAG-based Composite Lupus Assessment (BICLA). Both are composite indices of treatment response in SLE though their exact components differ.
- Overall, results showed that treatment with Saphnelo (anifrolumab) increased the rate of response compared to standard therapy alone. However, one phase 3 study (TULIP-1) did not meet its primary endpoint of SRI-4 response.

Investigational Uses

- There are no clinical trials to date supporting the safety or efficacy of Saphnelo (anifrolumab) for the treatment of any condition other than SLE.
- The prescribing information for Saphnelo (anifrolumab) contains a limitation of use stating that it has not been evaluated for the treatment of LN or CNS lupus. Although Saphnelo (anifrolumab) is currently being studied in trials for LN, more data is needed to establish safety and efficacy. Use of Saphnelo (anifrolumab) is therefore not recommended in these settings. [1,5]
- Combination use of Benlysta (belimumab) and Saphnelo (anifrolumab) is considered investigational. Clinical trials of Saphnelo (anifrolumab) did not allow combination use. The safety and efficacy of combined use have not been established.

Cross References
Site of Care Review, Medication Policy Manual, Policy No. dru408
Lupkynis, voclosporin, Medication Policy Manual, Policy No. dru678

Codes	**Number**	**Description**
HCPCS	J0491	Injection, anifrolumab (Saphnelo), intravenous, 1 mg

References

1. Saphnelo [Prescribing Information]. Wilmington, DE: AstraZeneca; Sept 2022.
2. Morand EF, Furie R, Tanaka Y, et al. Trial of Anifrolumab in Active Systemic Lupus Erythematosus. *N Engl J Med*. 2020;382(3):211-21. '31851795:' 31851795
3. Food and Drug Administration, BLA 761123 Multi-disciplinary Review and Evaluation Saphnelo (anifrolumab-fnia) for adults with SLE: https://www.accessdata.fda.gov/drugsatfda_docs/nda/2021/761123Orig1s000MultidisciplineR.pdf. Accessed:
4. Fanouriakis A, Kostopoulou M, Alunno A, et al. 2023 update of the EULAR recommendations for the management of systemic lupus erythematosus. Ann Rheum Dis. England, 2023:01-15.
5. Jayne D, Rovin, B, Mysler, E, et al. Phase II randomised trial of type I interferon inhibitor anifrolumab in patients with active lupus nephritis. *Ann Rheum Dis* 2022;81:496–506.

Revision History

Revision Date	Revision Summary
7/9/2026	• Updated QL section to include new SQ formulations (autoinjector and pre-filled syringe), which were added to policy at parity with IV formulation. • Specified that SOC requirements apply only to IV formulation. • Added IV HCPCS code.
4/2/2026	No criteria changes with this annual review.
4/3/2025	Effective 7/1/25: Added step therapy through Benlysta (belimumab).
3/21/2024	No criteria changes with this annual review.
3/16/2023	No changes to policy criteria with this annual update.
3/18/2022	No changes to policy criteria with this annual update.
11/11/2021	Added SOC requirements to policy to align with dru408 1/1/2022 effective date.
10/15/2021	New policy (effective 11-15-2021). Limits coverage to patients with systemic lupus erythematosus (SLE) in patients with active disease despite standard therapies, the setting in which it was studied and has a labeled indication.

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