Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines
Medical Benefit Drugs

Saphnelo™ (anifrolumab-fnia)

Effective: January 1, 2026

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Public Plans Products

☒ Tufts Health One Care* – A Medicare-Medicaid Plan (a dual-eligible product); Fax 617-673-0956

*The MNG applies to Tufts Health One Care members unless a less restrictive LCD or NCD exists.

Senior Products

☒ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); Fax 617-673-0956

☒ Tufts Medicare Preferred HMO, (a Medicare Advantage product); Fax 617-673-0956

☒ Tufts Medicare Preferred PPO, (a Medicare Advantage product); Fax 617-673-0956

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Approval of Saphnelo was based on combined data from 3 randomized, placebo-controlled trials, TULIP-1, TULIP-2, and MUSE. Patients had moderate to severe SLE based on American College of Rheumatology classification criteria, were at least 18 years of age and who were receiving standard therapy (at least one of the following: oral corticosteroids, antimalarials and immunosuppressants). Results from the trials were inconsistent but combined composite end point data were used to evaluate efficacy and demonstrated benefits of overall disease activity in Saphnelo-treated patients compared to placebo-treated patients.

Benlysta and Saphnelo have different mechanisms of actions. Benlysta inhibits B-cell stimulating factor and Saphnelo binds to subunit 1 of the type I IFN receptor, blocking the activity of type I IFNs involved in regulating the inflammatory pathways implicated in SLE.

Food and Drug Administration - Approved Indications

Saphnelo (anifrolumab) is a type 1 interferon (IFN) receptor antagonist indicted for the treatment of adult patients with moderate to severe systemic lupus erythematosus (SLE), who are receiving standard therapy.

The efficacy of Saphnelo (anifrolumab) has not been evaluated in patients with severe active lupus nephritis or severe active central nervous system lupus. Use of Saphnelo (anifrolumab) is not recommended in these situations.

Clinical Guideline Coverage Criteria

The plan may authorize coverage for Saphnelo (anifrolumab-fnia) when **BOTH** the following clinical criteria are met:

1. Documented diagnosis of systemic lupus erythematosus

AND

2. Prescribed by or in consultation with a rheumatologist or nephrologist

AND

3. Patient is 18 years of age or older

AND

4. Documentation of **one (1)** of the following:
   a. Use in combination with at least one agent from the following standard of care therapeutic categories: Antimalarials (e.g., hydroxychloroquine), corticosteroids (e.g., prednisone), or immunosuppressants (e.g., methotrexate)
   b. b. Clinical inappropriateness of use of all of the following standard of care therapeutic categories: Antimalarials, corticosteroids, and immunosuppressants

AND

5. Documentation the requested medication will not be used in combination with other biologic therapies

Limitations

- None

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J0491	Injection anifrolumab-fnia, 1 mg

References

1. Fanouriakis A, et al. 2019 update of the EULAR recommendations for the management of systemic lupus erythematosus. Ann Rheum Dis. 2019;78:736-45.
2. Furie R, et al. Anifrolumab, an anti-interferon-α receptor monoclonal antibody, in moderate-to-severe systemic lupus erythematosus. Arthritis Rheumatol. 2017;69(2):376-
3. 386.
4. Furie R, et al. Anifrolumab reduces flare rates in patients with moderate to severe systemic lupus erythematosus. Lupus. 2021;30(8):1254-1263.
5. Furie R, et al. Type I interferon inhibitor anifrolumab in active systemic lupus erythematosus (TULIP-1): a randomised, controlled, phase 3 trial. Lancet Rheum. 2019; 1(4): e208–e219.
6. Jayne D, et al. POS0690: Randomized, controlled, Phase 2 trial of type 1 IFN inhibitor anifrolumab in patients with active proliferative lupus nephritis. Ann Rheum Dis.2021;80:592.
7. Morand EF, et al. Trial of anifrolumab in active systemic lupus erythematosus. N Engl J Med.2020;382(3):211-221.
8. Saphnelo (anifrolumab) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; August 2024.

Approval And Revision History

September 13, 2022: Reviewed by Pharmacy and Therapeutics Committee (P&T).

September 21, 2022: Reviewed by the Medical Policy Approval Committee (MPAC).

Subsequent endorsement date(s) and changes made:

- November 14, 2023: Added provider specialty requirements. Added standard therapy prerequisite criterion. Added “Documentation the requested medication will not be used in combination with other biologic therapies. Removed the Limitation The health plan may authorize coverage of Saphnelo for up to 12 months if coverage criteria are met and Any indications other than those listed are considered experimental or investigational and will not be approved by the health plan (effective 2/1/24).
- November 2023: Administrative Update in support of calendar year 2024 Medicare Advantage and PDP Final Rule.
- October 8, 2024: No changes.
- October 2024: Administrative Update: Rebranded Tufts Health Unify to Tufts Health One Care.
- December 2024: Joint Medical Policy and Health Care Services UM Committee review (eff 1/1/25)
- July 2025: Administrative update to remove Harvard Pilgrim Health Care Stride Medicare Advantage from the Medical Necessity Guideline template.
- December 9, 2025: No changes (eff 1/1/26)
- December 2025: Joint Medical Policy and Health Care Services UM Committee review (effective 1/1/26)

Background, Product and Disclaimer Information

Point32Health prior authorization criteria to be applied to Medicare Advantage plan members is based on guidance from Medicare laws, National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs). When no guidance is provided, Point32Health uses clinical practice guidance published by relevant medical societies, relevant medical literature, Food and Drug Administration (FDA)-approved package labeling, and drug compendia to develop prior authorization criteria to apply to Medicare Advantage plan members. Medications that require prior authorization generally meet one or more of the following criteria: Drug product has the potential to be used for cosmetic purposes; drug product is not considered as first-line treatment by medically accepted practice guidelines, evidence to support the safety and efficacy of a drug product is poor, or drug product has the potential to be used for indications outside of the indications approved by the FDA. Prior authorization and use of the coverage criteria within this Medical Necessity Guideline will ensure drug therapy is medically necessary, clinically appropriate, and aligns with evidence-based guidelines. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests revisions.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guidelines not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.