Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines
Medical Benefit Drugs

Saphnelo (anifrolumab-fnia)

Effective: October 13, 2026

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

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax 617-673-0988

☒ Tufts Health Plan Commercial products; Fax 617-673-0988

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax 617-673-0988

☐ Tufts Health Together – MassHealth Accountable Care Partnership Plans; Fax 617-673-0939

☒ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax 617-673-0939

☐ 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

Food and Drug Administration - Approved Indications

Saphnelo (anifrolumab-fnia) 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 of Saphnelo (anifrolumab-fnia) for Members when **ALL** of the following 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. 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: Codes

Codes	Description
J0491	Injection, anifrolumab-fnia, 1 mg

References

1. American College of Rheumatology Ad Hoc Committee on Systemic Lupus Erythematosus Guidelines. Guidelines for referral and management of systemic lupus erythematosus in adults. Arthritis Rheum. 1999 Sep;42(9):1785–96.
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.
3. 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.
4. 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.
5. Saphnelo (anifrolumab) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; April 2026.

Approval And Revision History

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

Subsequent endorsement date(s) and changes made:

- September 21, 2022, year: Reviewed by the Medical Policy Approval Committee (MPAC)
- November 14, 2023: Administrative update to remove Tufts Health Together from Medical Necessity Guideline (see Unified Medical Policies). Expanded provider specialty requirements to “prescribed by or in consultation with a rheumatologist or nephrologist.” Updated prerequisite wording. Added “Documentation the requested medication will not be used in combination with other biologic therapies. Removed the Limitation For the treatment of systemic lupus erythematosus, Saphnelo (anifrolumab) will not be approved in the following instances: For Members with severe active central nervous system lupus, For Member with severe active lupus nephritis, For use in combination with other biologic immunosuppressant therapies such as belimumab (Benlysta) or rituximab (Rituxan, Truxima) (effective 2/1/24).
- November 2023: Administrative update to rebrand Tufts Health Unify to Tufts Health One Care for 2024.
- October 8, 2024: No changes
- July 2025: Administrative update to remove Harvard Pilgrim Health Care Stride Medicare Advantage from the Medical Necessity Guideline template.
- October 14, 2025: No changes.
- October 13, 2026: Administrative updates: Template updated to remove CareLink from the Medical Necessity Guideline template. Template updated from “Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans” to “Tufts Health Together- MassHealth Accountable Care Partnership Plans.

Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member’s benefit document, and in coordination with the Member’s physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members

under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is 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.