Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines:
Hyftor (sirolimus gel)

Effective: March 1, 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

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

Hyftor (sirolimus topical gel) is an mTOR inhibitor immunosuppressant indicated for the treatment of facial angiofibroma associated with tuberous sclerosis in adults and pediatric patients 6 years of age and older.

Clinical Guideline Coverage Criteria

The plan may authorize coverage of Hyftor (sirolimus topical gel) for patients when **ALL** of the following criteria are met:

Initial therapy:

1. Documented diagnosis of facial angiofibroma associated with tuberous sclerosis

AND

2. Patient is 6 years of age or older

AND

3. Prescribed by or in consultation with a dermatologist

Reauthorization:

1. Documentation that the patient has shown improvement on the requested medication

Limitations

1. Initial approval will be authorized for 4 months. Reauthorization will be provided in 12-month intervals.
2. Samples, free goods, or similar offerings of the requested medication do not qualify for an established clinical response and will not be considered for prior authorization.

Codes

None

References

1. Hyftor (sirolimus topical gel) [prescribing information]. Bethesda, MD: Nobelpharma America, LLC; 2022 March.

Approval And Revision History

February 14, 2023: Reviewed by the Pharmacy & Therapeutics Committee. Medical Necessity Guideline effective 4.1.23.
Subsequent endorsement date(s) and changes made:

- February 13, 2024: No changes
- February 11, 2025: No changes
- February 10, 2026: No changes
- February 2026: Administrative update to remove CareLink from Medical Necessity Guideline template.

Background, Product and Disclaimer Information

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be 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 the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy 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 Pharmacy Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern.

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