Pharmacy Medical Necessity Guidelines:
Hyftor (sirolimus)

Effective: January 13, 2026

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM
These pharmacy medical necessity guidelines apply to the following: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RXUM: 617.673.0939	

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

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

COVERAGE GUIDELINES

The plan may authorize coverage of Hyftor (sirolimus) gel for Members when the following criteria are met:

Initial

1. Documented diagnosis of facial angiofibroma associated with tuberous sclerosis

AND

2. Member is 6 years of age or older

AND

3. Hyftor is prescribed by or in consultation with a dermatologist

Reauthorization

1. Documentation of improvement with Hyftor therapy

LIMITATIONS

1. Initial approval will be granted for 4 months.
2. Reauthorization will be granted for 12 months.

CODES

None

REFERENCES

1. Hyftor (sirolimus) [prescribing information]. Bethesda, MD: Nobelpharma America, LLC; January 2024.

APPROVAL HISTORY

February 14, 2023: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. January 9, 2024: Effective February 1, 2024, updated fax number for RxUM.
2. January 14, 2025: No changes
3. January 13, 2026: No changes.

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.

Provider Services