

UnitedHealthcare Pharmacy  
Clinical Pharmacy Programs

Program Number	2025 P 1393-4
Program	Prior Authorization/Notification
Medication	Hyftor® (sirolimus topical gel)
P&T Approval Date	9/2022, 9/2023, 9/2024, 9/2025
Effective Date	11/16/2025

**1. Background:**

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

**2. Coverage Criteria<sup>a</sup>:**

**A. Initial Authorization**

1. **Hyftor** will be approved based on **both** of the following criteria:

a. Diagnosis of tuberous sclerosis

**-AND-**

b. Patient has facial angiofibroma associated with tuberous sclerosis

**Authorization will be issued for 12 months.**

**B. Reauthorization**

1. **Hyftor** will be approved based upon the following criterion:

a. Documentation of positive clinical response to therapy (e.g., improvement in skin lesions)

**Authorization will be issued for 12 months.**

<sup>a</sup> State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

**3. Additional Clinical Rules:**

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

#### 4. References:

1. Hyftor [package insert]. Bethesda, MD: Nobelpharma America, LLC; May 2025.

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<b>Change Control</b>	
9/2022	New program.
9/2023	Annual review with no change to coverage criteria.
9/2024	Annual review. Updated initial authorization to 12 months.
9/2025	Annual review. Updated Additional Clinical Rules. Updated reference.