UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 1393-3
Program	Prior Authorization/Notification
Medication	Hyftor® (sirolimus topical gel)
P&T Approval Date	9/2022, 9/2023, 9/2024
Effective Date	12/1/2024

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.[1]

2. Coverage Criteria[a]:

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.

[a] 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, Medical Necessity, and/or Step Therapy may be in place.

4. References:

1. Hyftor [package insert]. Bethesda, MD: Nobelpharma America, LLC; March 2022.

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Change Control	
9/2022	New program.
9/2023	Annual review with no change to coverage criteria.
9/2024	Annual review. Updated initial authorization to 12 months.