

## Pharmacy Policy Bulletin

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**Title:** Sirolimus topical gel (Hyftor™)

**Policy #:** Rx.01.274

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**Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, quantity, or formulary restrictions (ie limits on non-preferred drugs). Individual member benefits must be verified.**

**This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.**

**Members are advised to use participating pharmacies in order to receive the highest level of benefits.**

### **Intent:**

The intent of this policy is to communicate the medical necessity criteria for **Sirolimus topical gel (Hyftor™)** as provided under the member's prescription drug benefit.

### **Description:**

Tuberous sclerosis complex (TSC) is an inherited neurocutaneous disorder that involve many organ systems, including developmental delay and multiple benign hamartomas of the brain, eyes, heart, lung, liver, kidney, and skin. The expression of the disease varies substantially among individuals and within families. Some individuals with TSC may demonstrate only dermatologic features of the disease while others may develop more serious neurologic or systemic manifestations. Nearly all patients with TSC have one or more of the skin lesions characteristic of the disorder.

The mechanism of action of sirolimus in the treatment of angiofibroma associated with tuberous sclerosis is unknown. Tuberous sclerosis is associated with genetic defects in TSC1 and TSC2 which leads to the constitutive activation of mammalian target of rapamycin (mTOR). Sirolimus inhibits mTOR activation.

Hyftor™ is indicated for the treatment of facial angiofibroma associated with tuberous sclerosis in adults and pediatric patients 6 years of age and older.

### **Policy:**

**INITIAL CRITERIA:** Sirolimus (Hyftor™) is approved when ALL of the following are met:

1. Diagnosis of facial angiofibroma associated with tuberous sclerosis complex; and
2. Member is 6 years of age or older; and
3. Member is not a candidate for laser therapy or surgical treatments; and
4. Prescribed by or in consultation with a dermatologist

Initial authorization duration: 6 months

**REAUTHORIZATION CRITERIA:** Sirolimus (Hyftor™) is re-approved with documentation of positive clinical response to therapy (e.g., improvement in size or redness of facial angiofibroma)

Reauthorization duration: 2 years

### **Black Box Warning as shown in the drug Prescribing Information:**

N/A

### **Guidelines:**

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

## BENEFIT APPLICATION

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the prescription drug benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

### References:

Randle S. Tuberos sclerosus complex: Management and prognosis. UpToDate. Available from: uptodate.com. Accessed February 24, 2023.

Hyftor™ (sirolimus) [package insert]. Bethesda, MD: Nobelpharma America, LLC; March 2022. Available at <https://www.hyftor.com/wp-content/uploads/2022/04/Approved-PI.pdf>. Accessed February 24, 2023.

### Applicable Drugs:

Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

Brand Name	Generic Name
Hyftor™	sirolimus

### Cross References:

Rx.01.33 Off Label Use

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<b>Policy Version Number:</b>	1.00
<b>P&amp;T Approval Date:</b>	December 08, 2022
<b>Policy Effective Date:</b>	April 01, 2023
<b>Next Required Review Date:</b>	December 08, 2023

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The Policy Bulletins on this web site were developed to assist the Company in administering the provisions of the respective benefit programs, and do not constitute a contract. If you have coverage through the Company, please refer to your specific benefit program for the terms, conditions, limitations and exclusions of your coverage. Company does not provide health care services, medical advice or treatment, or guarantee the outcome or results of any medical services/treatments. The facility and professional providers are responsible for providing medical advice and treatment. Facility and professional providers are independent contractors and are not employees or agents of the Company. If you have a specific medical condition, please consult with your doctor. The Company reserves the right at any time to change or update its Policy Bulletins.

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