Pharmacy Drug Policy & Procedure

Policy Name:	Hyftor (topical sirolimus)	Policy#:	3178P

Purpose of the Policy

The purpose of this policy is to define coverage criteria for Hyftor (topical sirolimus).

Statement of the Policy

Health Alliance Medical Plans will approve the use of Hyftor (topical sirolimus) under the pharmacy benefit if the following criteria are met.

Criteria

1. Coverage Criteria for Facial Angiofibroma

1.1 Documented diagnosis of facial angiofibroma associated with tuberous sclerosis (TSC)
1.2 Age 6 years or older
1.3 Prescribed by or in consultation with a dermatologist (skin doctor)
1.4 3 or more papules of angiofibroma (≥2 mm in diameter with redness) on the face
1.5 Patient has previously tried or is not a candidate for laser therapy or surgery

2. Approval Period

2.1 Initial: 12 months
2.2 Reapproval: 12 months with documentation of improvement from baseline in size and redness of facial angiofibroma

CPT Codes	

HCPCS Codes	

References

1. Hyftor (sirolimus topical) [prescribing information]. Bethesda, MD: Nobelpharma America LLC; March 2022.
2. Koenig MK, Bell CS, Hebert AA, et al. Efficacy and Safety of Topical Rapamycin in Patients With Facial Angiofibromas Secondary to Tuberous Sclerosis Complex: The TREATMENT Randomized Clinical Trial. JAMA Dermatol. 2018 Jul 1;154(7):773-780.
3. Wataya-Kaneda M, Ohno Y, Fujita Y, et al. Sirolimus gel treatment vs placebo for facial angiofibromas in patients with tuberous sclerosis complex: a randomized clinical trial. JAMA Dermatol. 2018;154(7):781-788.
4. Northrup H, Aronow ME, Bebin EM et al; International Tuberous Sclerosis Complex Consensus Group. Updated International Tuberous Sclerosis Complex Diagnostic Criteria and Surveillance and Management Recommendations. Pediatr Neurol. 2021 Oct;123:50-66.

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DISCLAIMER

This Medical Policy has been developed as a guide for determining medical necessity. The process of medical necessity review also entails review of the most recent literature and physician review. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care. Health Alliance encourages input from providers when developing and implementing medical policies. Benefit determinations are based on applicable contract language in the member's Policy/ Subscription Certificate/ Summary Plan Description. This Medical Policy does not guarantee coverage. There may be a delay between the revision of this policy and the posting on the web. Please contact the Health Alliance Customer Service Department at 1-800-851-3379 for verification of coverage.