Hyftor (sirolimus) topical gel

Override(s)	Approval Duration
Prior Authorization Quantity Limit	Initial requests: 3 months Continued Therapy requests: 1 year

Medications	Quantity Limit
Hyftor (sirolimus) topical gel 0.2%	May be subject to quantity limit

APPROVAL CRITERIA

Initial requests for Hyftor (sirolimus) topical gel may be approved if the following criteria are met:

I. Individual is six (6) years of age or older; **AND**
II. Individual has a diagnosis of facial angiofibroma associated with tuberous sclerosis; **AND**
III. Individual has 3 or more papules of angiofibroma that are at least 2 mm in diameter with redness in each; (Wataya-Kaneda, 2018) **AND**
IV. Individual is unwilling or not a candidate for laser therapy or surgery (Wataya-Kaneda, 2018).

Continuation requests for Hyftor (sirolimus) topical gel may be approved if the following criteria are met:

I. Treatment with Hyftor (sirolimus) has resulted in significant improvement or stabilization in clinical signs and symptoms of disease (including but not limited to reduction in size or color of angiofibromas).

Key References:

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Updated periodically.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc. Updated periodically.
4. 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 Jul 1;154(7):781-788. PMID: 29800026; Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6128500/ Accessed on June 8, 2023.