

Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	May 2, 2023

## HYFTOR™ (sirolimus topical gel)

**LENGTH OF AUTHORIZATION:** Initial Therapy – 3 months  
Continuation of Therapy – Up to 1 year

**INITIAL REVIEW:**

- Patient must be  $\geq 6$  years of age.
- Patient must have a documented diagnosis of facial angiofibroma associated with tuberous sclerosis evidenced by the following:
  - The presence of three (3) or more facial angiofibromas that are at least 2 mm in diameter with redness in each.
- Must be prescribed by or in consultation with a dermatologist OR a physician who specializes in the management of individuals with tuberous sclerosis complex.

**CONTINUATION OF THERAPY:**

- Documentation of improved clinical response (e.g., reduction in size and improvement in redness of facial angiofibromas compared to baseline assessment); AND
- Patient has not experienced any treatment-restricting adverse effects; AND
- Dosing is appropriate as per labeling or is supported by compendia.

**DOSING AND ADMINISTRATION:**

- Refer to product labeling at <https://www.accessdata.fda.gov/scripts/cder/daf/>
- Available as a 0.2% topical gel.