| Division: Pharmacy Policy | Subject: Prior Authorization Criteria |
|---|---|
| Original Development Date:<br>Original Effective Date:<br>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 ≥ 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.