Commercial/Healthcare Exchange PA Criteria

Effective: November 10, 2022

Prior Authorization: Hyftor

Products Affected: Hyftor (sirolimus) 2% topical gel

Medication Description: HYFTOR is indicated for the treatment of facial angiofibroma associated with tuberous sclerosis in adults and pediatric patients 6 years of age and older.

Covered Uses:

1. Facial angiofibroma associated with tuberous sclerosis

Exclusion Criteria: None

Required Medical Information:

1. Diagnosis

Prescriber Restriction: Medications is prescribed by, or in consultation with, a dermatologist or physician who specializes in the management of patients with tuberous sclerosis complex.

Age Restriction: 6 years of age or older

Coverage Duration: 3 months

Other Criteria:

Initial Approval Criteria

1. Facial Angiofibroma Associated with Tuberous Sclerosis. Approve if the patient meets the following criteria (A, B, **and** C):

A. Patient is ≥ 6 years of age; **AND**

B. Patient has a definitive diagnosis of tuberous sclerosis complex by meeting one of the following (i **or** ii):

i. There is identification of a pathogenic variant in the tuberous sclerosis complex 1 (*TSC1*) gene or tuberous sclerosis complex 2 (*TSC2*) gene by genetic testing; **OR**

ii. According to the prescriber, clinical diagnostic criteria suggest a definitive diagnosis of tuberous sclerosis complex by meeting either two major features or one major feature with two minor features; **AND**

Note: Major feature criteria involve angiofibroma (three or more) or fibrous cephalic plaque; angiomyolipomas (two or more); cardiac rhabdomyoma; hypomelanotic macules (three or more; at least 5 mm in diameter); lymphangiomyomatosis; multiple cortical tubers and/or radial migration lines; multiple retinal hamartomas; Shagreen patch; subependymal giant cell astrocytoma; subependymal nodule (two or more); or ungula fibromas (two or more). Minor feature criteria involve "confetti" skin lesions; dental enamel pits (three or more); intraoral fibromas (two or more); multiple renal cysts; nonrenal hamartomas; retinal achromic patch; and sclerotic bone lesions.

C. Patient has three or more facial angiofibromas that are at least 2 mm in diameter with redness in each

2. Renewal Criteria

1. Patient Currently Receiving Hyftor. Approve for if the patient meets the following criteria (A, B, C, **and** D):
   A. Patient is ≥ 6 years of age; **AND**
   B. Patient has a definitive diagnosis of tuberous sclerosis complex by meeting one of the following (a **or** b):
      i. There is identification of a pathogenic variant in the tuberous sclerosis complex 1 (*TSC1*) gene or tuberous sclerosis complex 2 (*TSC2*) gene by genetic testing; **OR**
      ii. According to the prescriber, clinical diagnostic criteria suggest a definitive diagnosis of tuberous sclerosis complex by meeting either two major features or one major feature with two minor features; **AND**

      Note: Major feature criteria involve angiofibroma (three or more) or fibrous cephalic plaque; angiomyolipomas (two or more); cardiac rhabdomyoma; hypomelanotic macules (three or more; at least 5 mm in diameter); lymphangiomyomatosis; multiple cortical tubers and/or radial migration lines; multiple retinal hamartomas; Shagreen patch; subependymal giant cell astrocytoma; subependymal nodule (two or more); or ungula fibromas (two or more). Minor feature criteria involve "confetti" skin lesions; dental enamel pits (three or more); intraoral fibromas (two or more); multiple renal cysts; nonrenal hamartomas; retinal achromic patch; and sclerotic bone lesions.
   C. Patient has responded to Hyftor as evidenced by a reduction in the size and/or redness of the facial angiofibromas, as determined by the prescriber; **AND**
   D. Medication is prescribed by or in consultation with a dermatologist or a physician who specializes in the management of patients with tuberous sclerosis complex

References:

1. Product Information: HYFTOR™ topical gel, sirolimus topical gel. Nobelpharma America LLC (per FDA), Bethesda, MD, 2022.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	11/10/2022