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Section:	Prescription Drugs	**Effective Date:**	October 1, 2024
Subsection:	Topical Products	**Original Policy Date:**	September 2, 2022
Subject:	Hyftor	**Page:**	1 of 4

Last Review Date: September 6, 2024

Hyftor

Description

Hyftor (sirolimus) topical gel

Background
Hyftor (sirolimus) is an inhibitor of mammalian target of rapamycin (mTOR). Tuberous sclerosis is associated with genetic defects in TSC1 and TSC2 which leads to the constitutive activation of mTOR. The mechanism of action of Hyftor in the treatment of angiofibroma associated with tuberous sclerosis is unknown (1).

Regulatory Status
FDA-approved indication: Hyftor is an mTOR inhibitor immunosuppressant indicated for the treatment of facial angiofibroma associated with tuberous sclerosis in adults and pediatric patients 6 years of age and older (1).

All age-appropriate vaccinations as recommended by current immunization guidelines should be completed prior to Hyftor initiation (1).

Oral sirolimus can cause fetal harm when administered to a pregnant woman. Hyftor is systemically absorbed after topical administration and may result in fetal exposure. Pregnant women should be advised of the potential risk to a fetus. Female patients of reproductive potential should be advised to use effective contraception prior to, throughout treatment, and for 12 weeks after the final dose of Hyftor (1).

The safety and effectiveness of Hyftor in pediatric patients less than 6 years of age have not been established (1).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Hyftor may be considered **medically necessary** if the conditions indicated below are met.

Hyftor may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 6 years of age or older

Diagnosis

Patient must have the following:

Facial angiofibroma associated with tuberous sclerosis

AND ALL of the following:

a. Patient's lesions are considered not appropriate for laser therapy or surgery
b. Prescribed by or recommended by a dermatologist
c. Females of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Hyftor and for 12 weeks after the last dose

Prior – Approval *Renewal* Requirements

Age 6 years of age or older

Diagnosis

Patient must have the following:

Facial angiofibroma associated with tuberous sclerosis

AND ALL of the following:

a. Patient has had clinical benefit from therapy
b. Prescribed by or recommended by a dermatologist
c. Females of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Hyftor and for 12 weeks after the last dose

Policy Guidelines

Pre – PA Allowance

None

Prior - Approval Limits

Quantity 8 tubes per 90 days

Duration 6 months

Prior – Approval *Renewal* Limits

Quantity 8 tubes per 90 days

Duration 12 months

Rationale

Summary

Hyftor (sirolimus) is an inhibitor of mammalian target of rapamycin (mTOR). Tuberous sclerosis is associated with constitutive activation of mTOR. Hyftor is indicated for the treatment of facial angiofibroma associated with tuberous sclerosis. The safety and effectiveness of Hyftor in pediatric patients less than 6 years of age have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Hyftor while maintaining optimal therapeutic outcomes.

References

1. Hyftor [package insert]. Bethesda, MD: Nobelpharma America,LLC; March 2022.

Policy History

Date	Action
September 2022	Addition to PA
December 2022	Annual review. Per SME, added initiation requirement that the patient's lesions be considered not appropriate for laser therapy or surgery. Per FEP, added requirement for medication to be prescribed by or recommended by a dermatologist
June 2023	Annual review
September 2023	Annual review
June 2024	Annual review
September 2024	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 6, 2024 and is effective on October 1, 2024.