BlueCross BlueShield
Federal Employee Program

HYFTOR
(sirolimus topical gel)

RATIONALE FOR INCLUSION IN PA PROGRAM

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).

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.

BlueCross BlueShield
Federal Employee Program

HYFTOR
(sirolimus topical gel)

References

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