HYFTOR®
(sirolimus topical gel) 0.2%

Appeals Checklist

Understanding the documents and information that may be helpful when seeking an Appeal for HYFTOR®.

ITEMS THAT MAY BE NEEDED TO OBTAIN A PA DECISION FOR HYFTOR®

The items and information listed below may be necessary to obtain a Appeal decision for HYFTOR®. It is important to review the insurer's guidelines for obtaining an Appeal, as these can differ depending on the insurer and other factors.

The checklist is neither medical guidance nor a suggestion that you submit an appeal. The information provided on this checklist is general in nature and is not intended to be conclusive or exhaustive. As the patient's healthcare provider, you are responsible for applying your clinical judgment regarding appropriate care and treatment of each patient.

Here is a checklist of the forms and documents you may need for an appeals package if the insurer denies treatment to your patient.

- ☐ Statement of Medical Necessity
- ☐ Patient Authorization and Notice of Release of Information
- ☐ Copy of patient's health plan or prescription card (front and back)
- ☐ Relevant laboratory/ biopsy results
- ☐ Appeal Letter
- ☐ Denial information including the patients denial letter or Explanation of Benefits letter
- ☐ Patient history and physical findings
- ☐ Additional relevant medical documentation on any medications and or procedures the patient has tried and reasons for any failure regarding the treatment (e.g., laser, dermabrasion, etc.)
- ☐ Documented diagnosis of tuberous sclerosis complex established by ONE of the following
  - Molecular genetic testing (for example, a pathogenic variant in the TSC1 or TSC2 gene)
  - Clinical diagnostic criteria suggest a definitive diagnosis of tuberous sclerosis complex with either TWO major features OR ONE major feature with TWO minor features
  - Three or more facial angiofibromas that are each at least 2 mm in diameter with redness
- ☐ Documentation indicating whether the medication is prescribed by, or in consultation with, a dermatologist or a prescriber who specializes in the management of tuberous sclerosis complex
- ☐ Other supporting documents, including journal articles, abstracts, textbook excerpts, practice guidelines

IT MAY BE NECESSARY TO PROVIDE THE FOLLOWING INFORMATION TO THE PATIENT'S INSURER WHEN MAKING A REQUEST FOR APPEAL

- ☐ Patient information, including name, insurance policy number, and date of birth
- ☐ Physician information, including name, phone and fax number, tax ID number, DEA/NPI and specialty
- ☐ Facility information, including name and tax ID number
- ☐ Date of service
- ☐ Patient diagnosis to relevant ICD Code(s)
- ☐ Drug strength and quantity
- ☐ Relevant procedure and Healthcare Common Procedure Coding System (HCPCS) codes for services/products to be performed/provided
- ☐ Product National Drug Code (NDC)
- ☐ Setting of care
- ☐ Patient clinical notes detailing the relevant diagnosis
- ☐ Proposed treatment plan, including each drug in the regimen

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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.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

HYFTOR® is contraindicated in patients with a history of hypersensitivity to sirolimus or any other component of HYFTOR®.

WARNINGS AND PRECAUTIONS

- **Hypersensitivity Reactions:** Hypersensitivity reactions, including anaphylactic/anaphylactoid reactions, angioedema, exfoliative dermatitis, and hypersensitivity vasculitis, have been associated with the oral administration of sirolimus. The concomitant use of HYFTOR® with other drugs known to cause angioedema, such as angiotensin-converting enzyme (ACE) inhibitors, may increase the risk of developing angioedema. Elevated sirolimus levels may also potentiate angioedema. Discontinue HYFTOR® immediately if symptoms occur.
- **Serious Infection:** Serious infections, including opportunistic infections, have been reported after oral administration of sirolimus. Cases of progressive multifocal leukoencephalopathy (PML), sometimes fatal, have been reported in patients treated with oral sirolimus. Discontinue HYFTOR® immediately if symptoms of infection occur.
- **Malignancy:** Lymphoma and other malignancies, particularly of the skin, have been observed after oral administration of sirolimus. Patients should minimize or avoid exposure to natural or artificial sunlight (tanning beds or UVA/B treatment) while using HYFTOR®. If patients need to be outdoors, they should wear protective clothing and discuss other sun protection measures with their physician.
- **Hyperlipidemia:** Increased serum cholesterol and triglycerides requiring treatment have been observed with oral administration of sirolimus. Monitor for hyperlipidemia during treatment.
- **Interstitial Lung Disease/Non-Infectious Pneumonitis:** Cases of interstitial lung disease (ILD) (including pneumonitis, bronchiolitis obliterans organizing pneumonia [BOOP], and pulmonary fibrosis), some fatal, with no identified infectious etiology have occurred in patients receiving oral sirolimus. Discontinue HYFTOR® immediately if symptoms of ILD occur.
- **Immunizations:** During treatment with HYFTOR®, vaccinations may be less effective. Complete all age-appropriate vaccinations as recommended by current immunization guidelines prior to initiating treatment with HYFTOR®. The use of live vaccines should be avoided during treatment with HYFTOR®.
- **Embryo-Fetal Toxicity:** Based on animal studies and the mechanism of action, oral sirolimus can cause fetal harm when administered to a pregnant woman. In animal studies, oral sirolimus caused embryo-fetal toxicity when administered during the period of organogenesis at maternal exposures that were equal to or less than human exposures at the recommended lowest starting dose. HYFTOR® is systemically absorbed after topical administration and may result in fetal exposure. Advise pregnant women of the potential risk to a fetus. Advise female patients of reproductive potential to avoid becoming pregnant. They should use effective contraception prior to, throughout treatment and for 12 weeks after the final dose of HYFTOR®.
- **Male Infertility:** Azoospermia or oligospermia has been observed after oral administration of sirolimus. Advise males that HYFTOR® may impair fertility.

ADVERSE REACTIONS

The most common adverse reactions (≥ 1%) are dry skin, application site irritation, pruritus, acne, acneiform dermatitis, ocular hyperemia, skin hemorrhage, and skin irritation.

USE IN SPECIFIC POPULATIONS

- **Pregnancy:** Based on animal studies and mechanism of action, 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.
- **Lactation:** Breastfeeding is not recommended during treatment with HYFTOR®.
- **Infertility:** Based on clinical findings and animal studies, male and female fertility may be compromised by the treatment with sirolimus.

Please see additional information at

Full Prescribing Information
hyftorpi.com

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