Louisiana Medicaid
Sirolimus (Hyftor™)

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request clinical authorization for sirolimus (Hyftor™).

Additional Point-of-Sale edits may apply.

*This agent may have a **Black Box Warning** and may be subject to **Risk Evaluation and Mitigation Strategy (REMS)** under FDA safety regulations. Please refer to individual prescribing information for details.*

Approval Criteria

- The recipient is 6 years of age or older on the date of the request; **AND**
- The recipient has a documented diagnosis of facial angiofibroma associated with tuberous sclerosis; **AND**
- The medication is prescribed by, or the request states that this medication is being prescribed in consultation with, a dermatologist or a provider experienced in the treatment of tuberous sclerosis; **AND**
- If request is for a non-preferred agent - **ONE** of the following is required: (See Dermatology – Topical Immunomodulators on the PDL/NPDL for list of preferred agents)
    - The recipient has had a *treatment failure* with at least one preferred product; **OR**
    - The recipient has had an *intolerable side effect* to at least one preferred product; **OR**
    - The recipient has *documented contraindication(s)* to all of the preferred products that are appropriate to use for the condition being treated; **OR**
    - There is *no preferred product that is appropriate* to use for the condition being treated; **AND**
- By submitting the authorization request, the prescriber attests to the following:
    - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
    - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
    - The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not receive the requested medication in combination with any medication that is contraindicated or not recommended per FDA labeling.

Duration of initial approval: 3 months

Reauthorization Criteria

- The recipient continues to meet initial approval criteria; **AND**
- The prescriber **states on the request** that the recipient is established on the medication with evidence of a positive response to therapy.

Duration of initial and reauthorization approval: 6 months

Reference

Hyftor (sirolimus) [package insert]. Bethesda, MD: Nobelpharma America, LLC; March 2022. https://hcp.hyftor.com/wp-content/uploads/2022/04/Approved-PI.pdf

Revision / Date	Implementation Date
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