PRIOR AUTHORIZATION CRITERIA

BRAND NAME*
(generic)

KERYDIN
(tavaborole topical solution)

Status: CVS Caremark Criteria ***MDC-1***
Type: Initial Prior Authorization ***Ref # 1169-A***

** Drugs that are listed in the target drug box include both brand and generic and all dosage forms and strengths unless otherwise stated*

FDA-APPROVED INDICATIONS
Kerydin (tavaborole) topical solution, 5% is an oxaborole antifungal indicated for the treatment of onychomycosis of the toenails due to Trichophyton rubrum or Trichophyton mentagrophytes.

COVERAGE CRITERIA
The requested drug will be covered with prior authorization when the following criteria are met:

- The requested drug is being prescribed for onychomycosis of the toenail(s) due to Trichophyton rubrum or Trichophyton mentagrophytes, which has been confirmed with a fungal diagnostic test (e.g., potassium hydroxide [KOH] preparation, fungal culture, or nail biopsy)
  AND
- The patient has experienced an inadequate treatment response, intolerance, or contraindication to an oral antifungal therapy (e.g., terbinafine, itraconazole)

RATIONALE
These criteria meet the Medicare Part D definition of a medically accepted indication. This definition includes uses which are approved by the FDA or supported by a citation included, or approved for inclusion, in one of the Medicare approved compendia.

The intent of the criteria is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. Kerydin (tavaborole) topical solution, 5% is an oxaborole antifungal indicated for the treatment of onychomycosis of the toenails due to Trichophyton rubrum or Trichophyton mentagrophytes. Kerydin is to be applied to affected toenails once daily for 48 weeks. Kerydin should be applied to the entire toenail surface and under the tip of each toenail being treated. Kerydin is for topical use only and not for oral, ophthalmic, or intravaginal use.[1]

Accurate diagnosis of onychomycosis involves physical and microscopic examination and culture. Only 50% of nail problems are caused by onychomycosis, and clinical diagnosis by physical examination alone can be inaccurate. When onychomycosis is suspected, samples should be taken to conduct diagnostic tests. Samples are then prepared with potassium hydroxide (KOH) solution to be viewed under a microscope to look for the presence of a fungal infection. Once infection is confirmed, cultures should then be performed to identify the organism causing the infection to help select the appropriate treatment regimen.[5]

Systemic antifungals are the most effective treatment for onychomycosis. Antifungals from the azole and allylamine classes are the most widely used oral medications for the treatment of onychomycosis. Terbinafine (Lamisil) is the most effective systemic agent available.[5] Oral treatment of onychomycosis is the standard of care, however, drug interactions and risk of acute liver injury can limit their use.[4] Difficulties in formulating topical treatment to penetrate the nail and reach the site of infection in the nail bed has hampered the development and the use of topical agents.[4] In 2 randomized trials, complete cure rate, defined as no evidence of fungal infection at week 52, was demonstrated in 6.5% and 9.1% of patients receiving tavaborole compared with 0.5% and 1.5% receiving placebo for the treatment of onychomycosis of the toenail.[1]

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REFERENCES

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4. Elewski BE, Rich,P, Pollak R, et al. Efinaconazole 10% solution in the treatment of toenail onychomycosis: Two phase III multicenter randomized, double-blind studies. *J Am Acad Dermatol* 2013;68:600-8.
5. Westerberg, DP, Voyack MJ. Onychomycosis: Current Trends in Diagnosis and Treatment. *American Family Physician* 2013;88(11):762-70.

Written by: UM Development (PL/WW)
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CRITERIA FOR APPROVAL

1	Is the requested drug being prescribed for onychomycosis of the toenail(s) due to Trichophyton rubrum or Trichophyton mentagrophytes, which has been confirmed with a fungal diagnostic test (e.g., potassium hydroxide [KOH] preparation, fungal culture, or nail biopsy)?	Yes	No
2	Has the patient experienced an inadequate treatment response, intolerance, or contraindication to an oral antifungal therapy (e.g., terbinafine, itraconazole)?	Yes	No

Guidelines for Approval	
Duration of Approval	**12 Months**
Set 1	
Yes to question(s)	**No to question(s)**
1	None
2	

Mapping Instructions			
	Yes	**No**	**DENIAL REASONS – DO NOT USE FOR MEDICARE PART D**
1.	Go to 2	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you meet all of these conditions: - You have a fungal infection of the toenail(s) - You had a test to confirm your toenail fungus Your request has been denied based on the information we have. [Short Description: No approvable diagnosis, no confirmation of diagnosis]
2.	Approve,12 months	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you have tried at least one oral medicine first and it did not work for you or you cannot use it. Your request has been denied based on the information we have. [Short Description: No inadequate response, intolerance, or contraindication to an oral antifungal]