Antifungal Topical Solutions

WA.PHAR.36 Antifungal Topical Solutions

Background:

Onychomycosis is a fungal infection of the nail bed (skin beneath the nail plate) with secondary involvement of the nail plate (visible part of the nail on fingers and toes). It is a relatively common and relapsing condition in the adult population. The main pathogens responsible for onychomycosis are dermatophytes, yeasts, and molds. More common in toenails than fingernails, they often cause the end of the nail to separate from the nail bed. Additionally, debris (white, green, yellow, or black) may build up under the nail plate and discolor the nail bed.

Medical necessity

Drug	Medical Necessity
efinaconazole 10% (JUBLIA®) tavaborole 5% (KERYDIN®)	*Jublia*, or *Kerydin* may be considered medically necessary when: used for the treatment of onychomycosis due to *Trichophyton rubrum* and *Trichophyton mentagrophytes*

Clinical policy:

Drug	Clinical Criteria (Initial Approval)
efinaconazole (JUBLIA®) tavaborole (KERYDIN®)	*Jublia*, or *Kerydin* may be covered when **ALL** of the following are met: 1. Diagnosis of onychomycosis of the toenail due to **ONE** of the following: *a. Trichophyton rubrum* *b. Trichophyton mentagrophytes* 2. Diagnosis confirmed by **ONE** of the following: a. Potassium hydroxide (KOH) test b. Fungal culture c. Nail biopsy 3. Documentation of medical necessity for **ONE** of the following: a. Client has a history of cellulitis of the lower extremity secondary to onychomycosis and has required systemic antibiotic therapy b. Client is diabetic and has additional risk factors for cellulitis c. Client has a history of peripheral vascular disease d. Client is immunocompromised (i.e. receiving chemotherapy, taking long term oral corticosteroids, taking anti-rejection medications) e. Client is experiencing pain/discomfort associated with the infected nail 4. History of failure of **TWO** or contraindication to **ALL** of the following: a. Minimum 12-week treatment with oral terbinafine (generic Lamisil)

	b. Minimum 12-week treatment with oral itraconazole (generic Sporanox) c. Minimum 48-week treatment with topical ciclopirox (generic PENLAC) **Approve for 48 weeks**

Dosage and quantity limits

Drug Name	Dose and Quantity Limits
efinaconazole (JUBLIA®)	4mL (1 bottle) per 30-day up to 48-weeks
tavaborole (KERYDIN®)	4mL or 10mL (1 bottle) per 30-days up to 48-weeks

References

1. Jublia Prescribing Information. Valeant Pharmaceuticals North America, LLC. Bridgewater, NJ. September 2016.
2. Lamisil Prescribing Information. Novartis Pharmaceuticals Corporation. East Hanover, NJ. January 2017.
3. Kerydin Prescribing Information. Anacor Pharmaceuticals, Inc., Palo Alto, CA. March 2015.
4. Treating Onychomycosis. Am Fam Physician. 2001 Feb 15; 63(4):663-72, 677-8.
5. Sporanox Prescribing Information. Janssen Pharmaceuticals. Titusville, NJ. October 2016.
6. Goldstein AO. Onychomycosis. In: UpToDate, Post TW (Ed) UpToDate, Waltham, MA. (Accessed on March 17, 2017.)
5. Penlac prescribing Information. Valeant Pharmaceuticals North America LLC. Bridgewater, NJ. June 2016.
6. Grag J, Tilak R, Sanjay S, et al. Evaluation of Pan-Dermatophyte Nested PCR in Diagnosis of Onychomycosis. 2007. J Clin Microbiology. 45:3443-3445.