

Federal Employee Program. **TOPICAL ANTIFUNGALS Jublia** (efinazonazole), **Kerydin** (tavaborole)

#### RATIONALE FOR INCLUSION IN PA PROGRAM

### **Background**

Onychomycosis is a fungal infection of the nails caused predominantly by dermatophytes of the genus *Trichophyton*. Jublia (efinaconazole) and Kerydin (tavaborole) are both antifungal solutions used topically to treat onychomycosis of the toenails caused by *Trichophyton rubrum* and *Trichophyton mentagrophytes*. Accurate diagnosis is crucial for successful treatment and requires identification of physical changes and positive laboratory analysis. Only half of all nail problems are caused by onychomycosis, and diagnosis by physical examination alone can be inaccurate. Treatment varies depending on the severity of the condition, as well as the causative organism and concerns about adverse effect and drug interactions(1-3).

# **Regulatory Status**

FDA-approved indications:

**Jublia** is an azole antifungal indicated for the topical treatment of onychomycosis of the toenail(s) due to *Trichophyton rubrum* and *Trichophyton mentagrophytes* (1).

**Kerydin** is an oxaborole antifungal indicated for the topical treatment of onychomycosis of the toenails due to *Trichophyton rubrum* or *Trichophyton mentagrophytes* (2).

Safety and effectiveness of daily use of Jublia or Kerydin for longer than 48 weeks have not been established (1-2).

Safety and effectiveness of Jublia and Kerydin in pediatric less than 6 years of age have not been established (1-2).

# Summary

Jublia (efinaconazole) and Kerydin (tavaborole) are both antifungal topical solutions used for the treatment of onychomycosis of the toenails due to *Trichophyton rubrum* and *Trichophyton mentagrophytes*. Safety and effectiveness of daily use of Jublia or Kerydin for longer than 48 weeks have not been established. Safety and effectiveness of Jublia and Kerydin in pediatric patients below 6 years of age have not been established (1-2).



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# **TOPICAL ANTIFUNGALS**

Jublia (efinazonazole), Kerydin (tavaborole)

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Jublia and Kerydin while maintaining optimal therapeutic outcomes.

### References

- 1. Jublia [package Insert]. Bridgewater, NJ: Bausch Health US, LLC; March 2022.
- 2. Kerydin [package Insert]. Melville, NY: Anacor Pharmaceuticals, Inc.; August 2018.
- 3. Westerberg, D & Voyack, M. Bassler M. Onychomycosis: Current Trends in Diagnosis and Treatment. American Family Physician 2013 Dec 1;88 (11):762-770.