TOPICAL ANTFUNGALS
Jublia (efinonazole), Kerydin (tavaborole)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background
Onychomycosis is a common nail infection caused predominantly by dermatophyte fungi that occurs under the toenail. Jublia and Kerydin are both antifungal solutions used topically to treat onychomycosis of the toenails caused by Trichophyton rubrum and Trichophyton mentagrophytes. Oral treatment of onychomycosis is the standard of care, however, drug interactions and risk of acute liver injury can limit their use (1-3).

Regulatory Status
FDA-approved indications:
Jublia is an azole antifungal indicated for the topical treatment of onychomycosis of the toenails 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 Jublia in pediatric patients have not been established. Safety and effectiveness of Kerydin in pediatric patients below 6 years of age have not been established (1-2).

Summary
Jublia and Kerydin are both antifungal solutions used to topical treat onychomycosis of the toenails due to Trichophyton rubrum and Trichophyton mentagrophytes. Safety and effectiveness of Jublia in pediatric patients have not been established. Safety and effectiveness of Kerydin in pediatric patients below 6 years of age have not been established (1-2).

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

References