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