OVERVIEW
Ciclodan 8% Kit, CNL 8 Nail Kit, Pedipirox-4 Nail Kit, and Penlac (generics) contain the same active ingredient, ciclopirox topical solution 8%. Ciclopirox topical solution 8%, Jublia, and Kerydin are topical antifungals indicated for the treatment of onychomycosis. Onychomycosis is a general term that refers to nail infections caused by any fungus, including yeasts and nondermatophyte molds. While onychomycosis can affect both the toenails and the fingernails, it is approximately 4- to 25-times more widespread in toenails than in fingernails. Toenail onychomycosis is most commonly caused by dermatophytes, namely *Trichophyton rubrum* and *T. mentagrophytes*; these organisms account for up to 90% of all cases. Fingernail onychomycosis is more likely to be caused by yeast (*Candida albicans*). Nondermatophyte molds cause < 10% of cases of toenail onychomycosis and rarely cause fingernail onychomycosis. Accurate diagnosis is very important since the physical changes associated with onychomycosis may also be associated with other conditions (e.g., psoriasis, chronic nail trauma). A microscopy test using potassium hydroxide (KOH) is typically done to confirm infection; a fungal culture may also be used to identify the specific causative organism.

Treatment choice is dependent on several factors, including: infecting organism, clinical presentation, severity of the infection, comorbidities, and concerns about adverse events (AEs) and drug-drug interactions. Oral antifungals (e.g., azoles [itraconazole] and allylamines [terbinafine]) are the gold standard for the treatment of onychomycosis. They have been shown to be significantly more effective than topical antifungals for this condition, but they may be associated with systemic AEs (e.g., hepatotoxicity) and risk of drug-drug interactions. Thus, oral antifungals may not be appropriate for certain patient populations. Topical antifungals, although not as effective, generally do not cause systemic AEs or drug-drug interactions.

POLICY STATEMENT
A step therapy program has been developed to encourage the use of a generic Step 1 product prior to the use of a Step 2 product. If the step therapy rule is not met for a Step 2 agent at the point of service, coverage will be determined by the step therapy criteria below. All approvals are provided for 12 months in duration.

**Automation:** Patients with a history of one Step 1 drug within the 130-day look-back period are excluded from step therapy.

**Step 1:** Ciclodan 8% topical solution (branded generic), ciclopirox topical solution 8%, ciclopirox 8% treatment kit

**Step 2:** Ciclodan 8% Kit, CNL 8 Nail Kit, Jublia, Kerydin, Pedipirox-4 Nail Kit, Penlac
CRITERIA

1. If a patient has used one Step 1 product, then authorization for a Step 2 product may be given.

2. No other exceptions are recommended.

References