

ONMEL (itraconazole, oral)

Diagnosis Considered for Coverage:

- Treatment of onychomycosis of the toenail caused by *Trichophyton rubrum* or *T. mentagrophytes* in non-immunocompromised

Coverage Criteria:

For diagnosis listed above:

Initial Treatment:

- Dosing does not exceed FDA label maximum, **and**
- Intolerance or contraindication to using itraconazole capsule (generic Sporanox) not expected with Onmel, **and**
- One of the following:
 - Inadequate response, intolerable side effect, or has a medical reason for not using oral terbinafine, **or**
 - Positive culture evidence for nail *Candida* is provided.

Retreatment:

- Patient completed a course of Onmel for onychomycosis more than 3 months ago (from the last day the medication was finished), **and**
- Dosing does not exceed FDA label maximum.

Coverage Duration: 12 weeks

Effective: 2/04/2020