Sporanox and Onmel

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the Sporanox® and Onmel™ prior authorization program is to ensure appropriate selection of patients based on product labeling and/or clinical guidelines and/or clinical studies, and to encourage the use of more cost-effective agents prior to the use of Sporanox or Onmel for the treatment of onychomycosis.

The Food and Drug Administration (FDA) has approved the use of Sporanox® (itraconazole) capsules for treatment of the following fungal infections:
- Blastomycosis, pulmonary and extrapulmonary
- Histoplasmosis, including chronic cavitary pulmonary disease and disseminated, non-meningeal histoplasmosis, and
- Aspergillosis, pulmonary and extrapulmonary, in patients who are intolerant of or who are refractory to amphotericin B therapy.

Sporanox® (itraconazole) capsules are also approved for the following onychomycosis diagnoses:
- Onychomycosis of the toenail, with or without fingernail involvement, due to dermatophytes (tinea unguium)
- Onychomycosis of the fingernail due to dermatophytes (tinea unguium).

Compendial uses for Sporanox® (itraconazole) capsules
- Coccidioidomycosis
- Cryptococcosis
- Microsporidiosis
- Penicilliosis
- Sporotrichosis

The FDA has approved the use of Sporanox® (itraconazole) oral solution for the treatment oropharyngeal and esophageal candidiasis.

Compendial uses for Sporanox® (itraconazole) solution
- Blastomycosis
- Histoplasmosis
Onmel™ (itraconazole) tablets are FDA approved for the treatment of onychomycosis of the toenail caused by *Trichophyton rubrum* or *Trichophyton mentagrophytes*.

### POLICY

I. **Sporanox capsule (brand and generic)** therapy may be considered medically necessary for the treatment of systemic fungal infections or for prophylaxis in post-transplant patients.

   **Approval** will be for up to **12 months**.

II. **Sporanox capsule (brand and generic) and Onmel** may be considered medically necessary for the treatment of onychomycosis when the following criteria are met:

   - Diagnosis has been confirmed by appropriate laboratory testing; AND
   - Treatment is considered medically necessary (e.g., not for cosmetic purposes only); AND
   - Patient has experienced an inadequate response, adverse event, intolerance, or contraindication to terbinafine therapy

   **Approval** will be for **12 weeks**. (Only 1 approval allowed in a 12 month period.)

III. **Sporanox oral solution** may be considered medically necessary for the when the following criteria are met:

   - Those who have a diagnosis of oropharyngeal and/or esophageal candidiasis AND have experienced an inadequate response, adverse event, intolerance, or contraindication to fluconazole therapy; OR
   - Those with a diagnosis of a systemic fungal infection who cannot physically swallow itraconazole capsules or unable to achieve therapeutic levels with itraconazole capsules; OR
   - Patient has a life-threatening or serious infection

   **Approval** will be for up to **12 months**.

IV. The aforementioned drugs are considered not medically necessary for patients who do not meet the criteria set forth above.

Prior approval is required. **Submit a prior approval/treatment request now**.

### PROCEDURES AND BILLING CODES

To report provider services, use appropriate **CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes**.

- Code(s), if applicable.

### REFERENCES
• Elewski BE. Large-scale epidemiological study of the causal agents of onychomycosis: mycological findings from the multicenter onychomycosis study of terbinafine. Arch Dermatology. 1997; 133:1317-1318.

POLICY HISTORY

Policy #: 05.01.76
Policy Creation: April 2006
Reviewed: July 2016
Revised: August 2016
Current Effective Date: September 6, 2016

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