Sporanox and Onmel

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

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
- Talaromycosis (formerly 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
- Aspergillosis
- Coccidioidomycosis
- Cryptococcosis
- Microsporidiosis
- Talaromycosis (formerly Penicilliosis)
- Sporotrichosis

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 of invasive fungal infections in post-transplant patients

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

II. ***Sporanox capsule (brand and generic)*** may be considered **medically necessary** for the treatment of onychomycosis when the following criteria are met:
- Diagnosis has been confirmed by appropriate laboratory testing (e.g., potassium hydroxide [KOH] preparation, fungal culture, or nail biopsy)
  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. ***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 (e.g., potassium hydroxide [KOH] preparation, fungal culture, or nail biopsy)
  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
  AND
- The patient is unable to take generic Sporanox due to an allergy, intolerance, or contraindication to the excipients

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

IV. ***Sporanox oral solution*** may be considered **medically necessary** 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.**

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

Dosage and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

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

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- Panel on Opportunistic Infections in HIV-Infected Adults and Adolescents. Guidelines for the prevention and treatment of opportunistic infections in HIV-infected adults and adolescents: recommendations from the Centers for Disease Control and Prevention, the National Institutes of Health, and the HIV Medicine Association of the Infectious Diseases Society of America. Available at: https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/Adult_OI.pdf. Accessed February 2022.

POLICY HISTORY

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