Pharmacy Medical Necessity Guidelines:
Itraconazole capsules (Sporanox®) and tablets (Onmel™)

Effective: November 15, 2016

Prior Authorization Required ✓ Type of Review – Care Management
Not Covered Type of Review – Clinical Review ✓
Pharmacy (RX) or Medical (MED) Benefit RX Department to Review RXUM

This pharmacy medical necessity guideline applies to the following:

Tufts Health Plan Commercial Plans
☒ Tufts Health Plan Commercial Plans – large group plans
☒ Tufts Health Plan Commercial Plans – small group and individual plans

Tufts Health Public Plans
☒ Tufts Health Direct – Health Connector
☐ Tufts Health Together – A MassHealth Plan
☐ Tufts Health RITogether – A Rite Care + Rhody Health Partners Plan

Tufts Health Freedom Plan products
☒ Tufts Health Freedom Plan - large group plans
☒ Tufts Health Freedom Plan - small group plans

Fax Numbers:
RXUM: 617.673.0988

Note: For Tufts Health Plan Medicare Preferred members, please refer to the Tufts Health Plan Medicare Preferred Step Therapy Criteria. Background, applicable product and disclaimer information can be found on the last page.

OVERVIEW

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

Sporanox (itraconazole) capsules
Indicated for the treatment of the following fungal infections:
- In immunocompromised and non-immunocompromised patients:
  - Blastomycosis, pulmonary and extrapulmonary
  - Histoplasmosis, including chronic cavitary pulmonary disease and disseminated, nonmeningeal histoplasmosis, and
  - Aspergillosis, pulmonary and extrapulmonary, in patients who are intolerant of or who are refractory to amphotericin B therapy.
- In non-immunocompromised patients:
  - Onychomycosis of the toenail, with or without fingernail involvement, due to dermatophytes (tinea unguium), and
  - Onychomycosis of the fingernail due to dermatophytes (tinea unguium).

Onmel (itraconazole) tablets
Indicated for the treatment of onychomycosis of the toenail caused by Trichophyton rubrum or T. mentagrophytes.

*Please note that terbinafine tablets are Tufts Health Plan’s preferred antifungal agent in the treatment of medically significant (non-cosmetic) cases of onychomycosis (nail fungus).

COVERAGE GUIDELINES

The plan may authorize coverage of itraconazole capsules, Sporanox (itraconazole) capsules, or Onmel (itraconazole) tablets for immunocompromised and non-immunocompromised Members when the following criteria are met:

1. The requesting physician has documented that the Member has had a treatment failure of, or is unable to tolerate, an adequate trial of the formulary alternative terbinafine tablets
   OR
2. The requesting physician has documented that the Member has a diagnosis of one of the following fungal infections:
   a) Blastomycosis
      OR
   b) Histoplasmosis
      OR
   c) Cryptococcus neoformans
d) Aspergillosis

OR

e) Tinea (pedis, corporis) resistant to aggressive topical therapy

LIMITATIONS
1. Onmel (itraconazole) is limited to 28 tablets per 28 days.
2. Brand Sporanox (itraconazole) capsules are not covered for the Small Group and Individual formularies.
3. The initial authorization will be limited to 12 weeks any subsequent authorization will require more information.

CODES
None

REFERENCES

APPROVAL HISTORY
January 2004: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:
- October, 2004: No changes.
- September 13, 2005: No changes.
- August 8, 2006: No changes.
- July 10, 2007: No changes.
- July 8, 2008: No changes.
- July 14, 2009: No changes.
- September 8, 2009: No changes.
- January 1, 2010: Removal of Tufts Health Plan Medicare Preferred language (separate criteria have been created specifically for Tufts Health Plan Medicare Preferred).
- March 9, 2010: Moved Sporanox (itraconazole) Capsules from Medical Necessity Guidelines for Non-covered Drugs with Suggested Alternatives to the Prior Authorization program.
- March 8, 2011: No changes.
- February 14, 2012: No changes.
- February 12, 2013: Removed criteria #1: The Member has met the clinical coverage criteria for the oral antifungal agent terbinafine tablets (See Medical Necessity Guidelines for Lamisil® (terbinafine) tablets). Due to removal of the MNG for Lamisil (terbinafine)
- January 14, 2014: No changes.
- December 9, 2014: Combined the criteria for itraconazole capsules (Sporanox) and Onmel (itraconazole) tablets into one document.
- November 10, 2015: Added the limitation that the brand Sporanox capsules is not covered for the Small Group and Individual formularies.
- January 1, 2016: Administrative change to rebranded template applicable to Tufts Health Direct.
- November 15, 2016: No changes.
- April 11, 2017: Administrative update, Adding Tufts Health RITogether to the template.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION
Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage
decisions are made. They are used in conjunction with a member’s benefit document and in coordination with the member’s physician(s). The plan makes coverage decisions on a case-by-case basis considering the individual member’s health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

This Pharmacy Medical Necessity Guideline does not apply to Uniformed Services Family Health Plan members or to certain delegated service arrangements. Unless otherwise noted in the member’s benefit document or applicable Pharmacy Medical Necessity Guideline, Pharmacy Medical Necessity Guidelines do not apply to CareLinkSM members. For self-insured plans, drug coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a coverage guideline and a self-insured member’s benefit document, the provisions of the benefit document will govern. Applicable state or federal mandates will take precedence.

For Tufts Health Plan Medicare Preferred, please refer to Tufts Health Plan Medicare Preferred Prior Authorization Criteria.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.