Pharmacy Medical Necessity Guidelines:
Itraconazole capsules (Sporanox®)

Effective: April 14, 2020

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

These pharmacy medical necessity guidelines apply to the following:	**Fax Numbers:**
Commercial Products ☒ Tufts Health Plan Commercial products – large group plans ☒ Tufts Health Plan Commercial products – small group and individual plans ☒ Tufts Health Freedom Plan products – large group plans ☒ Tufts Health Freedom Plan products – small group plans • CareLink^{SM} – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization **Tufts Health Public Plans Products** ☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product) ☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans ☐ Tufts Health RITogether – A Rhode Island Medicaid Plan	RXUM: 617.673.0988

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

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, non-meningeal 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).

*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** 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:
   Blastomycosis

    OR

    a. Histoplasmosis

    OR

    b. Cryptococcus neoformans

    OR

    c. Aspergillosis

    OR

d. Tinea (pedis, corporis) resistant to aggressive topical therapy

LIMITATIONS

1. Brand Sporanox (itraconazole) capsules are not covered for all Commercial formularies. Refer to the Pharmacy Medical Necessity Guidelines for Noncovered Drugs with Suggested Alternatives.
2. The initial authorization will be limited to 12 weeks any subsequent authorization will require more information.

CODES

None

REFERENCES

1. Gupta AK, Gregurek-Novak T. Efficacy of Itraconazole, Terbinafine, Fluconazole, Griseofulvin and Ketoconazole in the Treatment of *Scopulariopsis brevicaulis* Causing Onychomycosis of the Toes. *Dermatology* 2001; 202:235-238
2. Krob AH, Fleischer AB Jr, D'Agostino R Jr, Feldman SR. Terbinafine is more effective than itraconazole in treating toenail onychomycosis: results from a meta-analysis of randomized controlled trials. *J Cutan Med Surg*. 2003; 7:306–311.
3. Mishra M, Panda P, Tripathy S et al. An open randomized comparative study of oral itraconazole pulse and terbinafine pulse in the treatment of onychomycosis. *Indian J Dermatol Venereol Leprol* 2005; 71:262-6
4. Sporanox (itraconazole) capsules [package insert]. Titusville, NJ; Janssen Pharmaceuticals, Inc.; May 2018.

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.
- November 14, 2017: No changes
- December 11, 2018: No changes
- August 13, 2019: Administrative update to add itraconazole capsules to criteria, as it was inadvertently removed. Updated limitations section to note Sporanox capsules are non-covered for all Commercial lines of business. No changes to criteria itself.
- April 14, 2020: Administrative update to remove itraconazole tablets (Onmel) from the MNG, as the drug is no longer available on the market. MNG retitled: Itraconazole capsules (Sporanox®).

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. 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.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

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.

Provider Services