Pharmacy Medical Necessity Guidelines
Oral Antifungal Agents
Flucytosine (Ancobon); Posaconazole (Noxafil); Terbinafine (Lamisil) Granules; Voriconazole (Vfend)
Effective: 1/19/15

Clinical Documentation and Prior Authorization Required | Yes
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Not Covered | Type of Review – Clinical Review
Fax: 617-673-0956

Pharmacy (RX) or Medical (MED) Benefit | RX
Department to Review | RxUM

OVERVIEW
FDA-APPROVED INDICATIONS
Flucytosine is indicated only in the treatment of serious infections caused by susceptible strains of Candida and/or Cryptococcus.
- Candida: Septicemia, endocarditis and urinary system infections have been effectively treated with flucytosine. Limited trials in pulmonary infections justify the use of flucytosine.
- Cryptococcus: Meningitis and pulmonary infections have been treated effectively. Studies in septicemias and urinary tract infections are limited, but good responses have been reported.
- Flucytosine should be used in combination with amphotericin B for the treatment of systemic candidiasis and cryptococcosis because of the emergence of resistance.

Posaconazole suspension is indicated for the treatment of oropharyngeal candidiasis including oropharyngeal candidiasis refractory to itraconazole and/or fluconazole in patients 13 years and older.
Posaconazole suspension and tablets are indicated as prophylaxis of invasive Aspergillus and Candida infections in patients 13 years and older who are at high risk of developing these infections because of being severely immunocompromised, such as hematopoietic stem cell transplant (HSCT) recipients with graft-vs-host disease (GVHD) or patients with hematologic malignancies with prolonged neutropenia from chemotherapy.

Terbinafine granules are indicated for the treatment of tinea capitis in patients 4 years and older.

Voriconazole is indicated for:
- Treatment of candidemia in nonneutropenic patients 12 years and older and the following Candida infections: disseminated infections in the skin and infections in the abdomen, bladder wall, kidney, and wounds.
- Treatment of esophageal candidiasis in patients 12 years and older.
- Treatment of invasive aspergillosis in patients 12 years and older.
- Treatment of serious fungal infections caused by Scedosporium apiospermum and Fusarium spp., including Fusarium solani, in patients 12 years and older intolerant of, or refractory to, other therapy

PHARMACY COVERAGE GUIDELINES
Tufts Health Plan – Network Health may authorize coverage of a non-preferred oral antifungal agent for members when the following criteria for a particular regimen are met and limitations do not apply:

Flucytosine
- The member meets criteria for one of the following conditions:
  - Diagnosis of cryptococcal menigitis
  - Diagnosis of a cryptococcal pulmonary infection and provider documentation of clinical inappropriateness of treatment with first line agents:
    - Fluconazole
    - Itraconazole
- Voriconazole
  - Diagnosis of candida endocarditis
  - Diagnosis of candida septicemia and provider documentation of clinical inappropriateness of treatment with first line agents:
    - Fluconazole
    - Voriconazole
    - An echinocandin
    - Amphotericin B
  - Diagnosis of candiduria and provider documentation of clinical inappropriateness of treatment with fluconazole and amphotericin monotherapy

Posaconazole
- The member is 13 years of age or older and
- The member meets criteria for one of the following conditions:
  - Zygomycosis (mucormycosis)
  - Prevention of invasive aspergillus and candida fungal infections for a member with one of the following conditions:
    - hematologic malignancy with neutropenia,
    - hematopoietic stem cell transplant, or
    - graft-versus-host disease
  - Diagnosis of esophageal or oropharyngeal candidiasis and
    - The request is for the oral suspension
    - The member tried and failed therapy with, or the provider documented clinical inappropriateness of therapy with, at least two of the following: oral fluconazole, itraconazole, and voriconazole

Terbinafine Granules
- The member is 4 years of age or older and is diagnosed with tinea capitis OR
- The member is diagnosed with onychomycosis and is unable to swallow terbinafine tablets

Voriconazole
- The member is 12 years of age or older and meets criteria for one of the following conditions:
  - Diagnosis of esophageal candidiasis and
    - The member tried and failed therapy with, or the provider documented clinical inappropriateness of therapy with both oral fluconazole and itraconazole
  - Diagnosis of candidemia and disseminated candidiasis infections and
    - The member tried and failed therapy with, or the provider documented clinical inappropriateness of therapy with oral fluconazole
  - Prevention of invasive aspergillus and candida fungal infections for a member with one of the following conditions:
    - hematologic malignancy with neutropenia,
    - hematopoietic stem cell transplant, or
    - graft-versus-host disease
  - Diagnosis of an invasive aspergillus infection
  - Diagnosis of a serious infection caused scedosporium and fusarium species

LIMITATIONS
Approval will be limited to one complete course of therapy.

CODES
None

REFERENCES
APPROVAL HISTORY

- 1/13/15: Reviewed by the Pharmacy and Therapeutics Committee; added flucytosine and posaconazole criteria

BACKGROUND, PRODUCT, AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for Tufts Health Plan – Network Health benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. They are used in conjunction with the applicable Member Handbook and in coordination with the member’s physician(s). 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 Tufts Health Plan – Network Health service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. Tufts Health Plan – Network Health reviews Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

Pharmacy Medical Necessity Guidelines apply to all fully insured Tufts Health Plan – Network Health offerings unless otherwise noted in this policy or the applicable Member Handbook. Check the applicable product formulary in the Pharmacy section of our website to determine if the drug requires you to get prior authorization.

For Tufts Health Unify (Medicare-Medicaid One Care for people ages 21 – 64), please refer to Tufts Health Unify Prior Authorization Medical Necessity Guidelines.

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.