BOSTON MEDICAL CENTER HEALTHNet PLAN

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Pharmacy Policy

Antifungal Agents

Policy Number: 9.406
Version Number: 2.0
Version Effective Date: 6/1/2021

Product Applicability	☐ **All Plan[+] Products**
Well Sense Health Plan ☐ New Hampshire Medicaid	**Boston Medical Center HealthNet Plan** ☒ MassHealth - MCO ☒ MassHealth - ACO ☐ Qualified Health Plans/ConnectorCare/Employer Choice Direct ☐ Senior Care Options

Note: Disclaimer and audit information is located at the end of this document.

Prior Authorization Policy

Products Affected:

- **voriconazole tablet and suspension**
- **itraconazole capsule and solution**
- **Noxafil suspension and injection**
- **posaconazole tablet**
- **Cresemba capsule and injection**
- **Ciclopirox 8% solution**

The Plan may authorize coverage of the above products for members meeting the following criteria:

Covered Use	All FDA approved indications not otherwise excluded
Exclusion Criteria	None
Required Medical Information	**itraconazole capsule and solution:** 1. Laboratory findings (KOH preparation, fungal culture, or nail biopsy) that confirm the diagnosis of onychomycosis within the previous 6 months; ***AND***

[+] *Plan* refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.

2. Evidence of medically significant onychomycosis due to *any* of the following conditions:

    - Paronychia (involvement of the skin around the border of the nail).
    - Medically significant pain caused by the affected nail/s.
    - Immunodeficiency due to disease or immunosuppressant drug therapy
    - Diabetes mellitus with additional risk factors for cellulitis (i.e. prior cellulitis , venous insufficiency, edema)
    - History of cellulitis of the lower extremity with infection of the ipsilateral toenail; ***AND***

3. An inadequate response, intolerance or contraindication to a full course of oral terbinafine; ***OR***
4. A diagnosis of tinea infection not responding to a trial of topical antifungal therapy and oral terbinafine; ***OR***
5. A diagnosis of a serious/invasive systemic fungal infection requiring systemic antifungal therapy

Ciclopirox 8% solution:

1. Laboratory findings (KOH preparation, fungal culture, or nail biopsy) that confirm the diagnosis of onychomycosis (not involving the lunula) within the previous 6 months; ***AND***
2. Evidence of medically significant onychomycosis due to any of the following conditions:

    - Paronychia (involvement of the skin around the border of the nail).
    - Medically significant pain caused by the affected nail/s.
    - Immunodeficiency due to disease or immunosuppressant drug therapy
    - Diabetes mellitus with additional risk factors for cellulitis (i.e. prior cellulitis , venous insufficiency, edema)
    - History of cellulitis of the lower extremity with infection of the ipsilateral toenail; ***AND***

3. A contraindication to using oral formulations of terbinafine such as:

    - Abnormal liver function tests
    - History of hepatitis or other liver disease
    - Allergy to oral antifungal agents
    - Concurrent drug therapy with significant hepatotoxic potential
    - Significant drug-drug interactions
    - Age under 12 years

Note: Coverage of ciclopirox solution will not be approved for treatment of onychomycosis with lunula involvement

	Noxafil injection, posaconazole suspension and tablet: 1. A diagnosis of Oropharyngeal candidiasis (for suspension only); ***AND*** o An inadequate response, intolerance, resistance or contraindication to fluconazole and itraconazole; ***OR*** 2. A requirement of prophylaxis for invasive aspergillus or candida infections; ***AND*** o Severe immunodeficiency such as hematopoietic stem cell transplant with graft vs host disease, high risk solid organ transplant recipient, or prolonged neutropenia secondary to chemotherapy; ***OR*** 3. A diagnosis of a zygomycosis infection; ***OR*** 4. A diagnosis of a posiconazole sensitive invasive fungal infection with documented resistance to other oral antifungal therapy (culture studies must be included); ***AND*** 5. Clinical rationale why the injectable formulation is preferred over the oral formulations (for injection only) **voriconazole tablet and suspension:** 1. A diagnosis of invasive aspergillus, Fusarium spp or Scedosporium apiospermum infections ; ***AND*** o An inadequate response, intolerance or contraindication to an alternative antifungal therapy appropriate for the fungal infection ; ***OR*** 2. A diagnosis of candidemia, or esophageal candidiasis; ***AND*** o An inadequate response, intolerance, resistance or contraindication to fluconazole and itraconazole. **Cresemba capsule and injection:** 1. A diagnosis of invasive mucormycosis (zygomycosis) confirmed by fungal culture; ***OR*** 2. A diagnosis of invasive aspergillus; ***AND*** o An inadequate response, intolerance, resistance, or contraindication to voriconazole; ***AND*** 3. A clinical rationale for use of the injectable formulation over the oral formulation (injection only)
Age Restriction	Noxafil suspension and posaconazole tablet : 13 years and older Noxafil injection: 18 years or older Cresemba: 18 years or older
Prescriber Restriction	None
Coverage Duration	Initial: Itraconazole 100mg capsule , solution: • Onychomycosis: Maximum of 6 weeks for fingernail infection or 12 weeks for toenail infection. Only one course of therapy will be approved over a period of one year from the approval date. • Tinea infection: Maximum of 2 weeks

	• Other systemic infections: up to recommended treatment durations specific to type of infection Ciclopirox 8% solution: • Onychomycosis: maximum of 48 weeks Noxafil (posaconazole): • Prophylaxis therapy: maximum of 1 year • Treatment: up to recommended treatment durations specific to type of infection voriconazole: • Treatment: up to recommended treatment durations specific to type of infection Cresemba capsule and injection Initial : 12 weeks Reauthorization: 12 weeks
Other criteria	Reauthorization: Cresemba: 1. Member is responding to treatment and tolerating it well; ***AND*** 2. Treatment with Cresemba is still medically necessary

Clinical Background Information and References

1. Gupta, AK, Ryder, JE, Johnson, AM. Cumulative meta-analysis of systemic antifungal agents for the treatment of onychomycosis. Br J Dermatol 2004; 150:537
2. Goldstein, AO, Goldstein, BG. Onychomycosis. UptoDate®, accessed October 2014; available from http://www.uptodate.com
3. Gupta, AK, Fleckman, P, Baran, R. ciclopirox nail lacquer solution 8% in the treatment of toenail onychomycosis. J Am Acad Dermatol 1997; 37:740
4. Kauffman CA. Treatment of oropharyngeal and esophageal candidiasis. UptoDate®, accessed Feb 2012. Available from http://www.uptodate.com.
5. Owens JN, Skelley JW, Kyle JA. The Fungus Among Us: An Antifungal Review. US Pharm. 2010; 35(8):44-56.
6. Vusion® [package insert]. Newtown, PA. Prestium Pharma, Inc; October 2013.
7. Julia® [package insert]. Bridgewater, NJ. Valeant Pharmaceuticals North America LLC; June 2014
8. Kerydin™ [package insert]. Palo Alto, CA. Anacor Pharmaceuticals, Inc; July 2014
9. Noxafil® injection [package insert]. Whitehouse Station, NJ. Merck & Co., Inc; July 2015.

   CRESEMBA® [package insert]. Northbrook, IL. Astellas Pharma; April 2015.

Applicable coding:

Code	Medication
J1833	**Cresemba (Isavuconazonium injection)**

Original Approval Date	Original Effective Date	Policy Owner	Approved by
12/1/2020	1/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee

Policy Revisions History			
Review Date	**Summary of Revisions**	**Revision Effective Date**	**Approved by**
12/1/2020	9.142 Antifungal Agents Policy retired, new policy created. No criteria changes	1/1/2021	P&T Committee
2/11/2021	P&T Annual Review: reflected generic availability of posaconazole tablet; moved brand Noxafil tablet to non-formulary	6/1/2021	P&T Committee

Next Review Date

2/2022

Other Applicable Policies

Reference to Applicable Laws and Regulations, If Any

Disclaimer Information

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over

these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.