Pharmacy Policy

**Daraprim®**

Policy Number: 9.061  
Version Number: 2.0  
Version Effective Date: 05/02/2017

### Product Applicability

<table>
<thead>
<tr>
<th>All Plan Products</th>
<th>Well Sense Health Plan</th>
<th>Boston Medical Center HealthNet Plan</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>☑️ New Hampshire Medicaid</td>
<td>☑️ MassHealth</td>
</tr>
<tr>
<td></td>
<td>☑️ NH Health Protection Program</td>
<td>☑️ Qualified Health Plans/ConnectorCare/Employer Choice Direct</td>
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<td></td>
<td></td>
<td>☑️ Senior Care Options</td>
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Note: Disclaimer and audit information is located at the end of this document.

### Policy Summary

The Plan will authorize coverage of Daraprim® when appropriate criteria are met.

### Description of Item or Service

Daraprim® (pyrimethamine) is an oral antiparasitic with an FDA-approved indication for the treatment of toxoplasmosis, when used in conjunction with sulfonamide. It is also approved for the treatment and prevention of acute malaria. However, its routine use for malaria is no longer recommended by the CDC due to widespread resistance.

Toxoplasmosis is the most common central nervous system infection in patients in HIV-infected patients who are not receiving appropriate prophylaxis. HIV-infected patients with CD4 counts less than 50 cells/microL are at the greatest risk for toxoplasmic encephalitis (TE). TE is rare in patients with CD4 counts above 200 cells/microL. Primary prophylaxis against TE should be initiated with trimethoprim-sulfamethoxazole (TMP-SMX) double strength when CD4 counts are less than 100 cells/microL. The alternative regimen of atorvastatine or dapsone-pyrimethamine plus leucovorin can be considered for patients who cannot tolerate...
TMP-SMX. Primary prophylaxis of TE should be discontinued in patient receiving antiretroviral therapy (ART) whose CD4 counts increase to > 200 cells/microL for more than 3 months. Reinitiating primary prophylaxis is recommended when CD4 count decreases to less than 100 to 200 cells/microL.

Daraprim®, when given in combination with sulfadiazine and leucovorin, is the preferred regimen for initial treatment and chronic maintenance therapy of TE. For primary prophylaxis in patients with a CD4 count < 100 cells/microL, the preferred regimen is trimethoprim-sulfamethoxazole, however, pyrimethamine is considered an alternative recommendation when given with either dapsone and leucovorin or atovaquone and leucovorin. Of note, these patients are typically already on prophylaxis with trimethoprim-sulfamethoxazole for PCP prophylaxis once their CD4 count is less than 200 cells/microL. When Daraprim® is unavailable; trimethoprim-sulfamethoxazole should be utilized in place of Daraprim® combination regimens. For patients with a sulfa allergy, sulfa desensitization should be attempted, unless patients have life threatening reactions to TMP-SMX.

**Policy**

The Plan may authorize coverage of Daraprim* for members meeting the following criteria:

**Prior Authorization – (Initial Duration of Approval – 6 months)**

A prior authorization request will be required for all prescriptions for Daraprim*. Requests will be approved when the following criteria are met:

Documentation of the following:

| Toxoplasmosis (Primary prophylaxis) | a) Diagnosis of HIV; **AND**  
b) CD4 counts < 100 cells/microL; **AND**  
c) Seropositive for anti-toxoplasma immunoglobulin G (IgG); **AND**  
d) Documentation stating why atovaquone 1500 mg is not acceptable for primary prophylaxis; **AND**  
e) One of the following:  
a. Member has a history of trimethoprim-sulfamethoxazole (TMP-SMX) allergy and TMP-SMX desensitization has been attempted and is still unable to tolerate, **or**  
b. Member had life threatening reaction to trimethoprim-sulfamethoxazole (TMP-SMX) in the past (e.g. toxic epidermal necrolysis, Stevens-Johnson syndrome) |
| Treatment of AIDS-associated Toxoplastic Encephalitis | a. Diagnosis made by infectious disease specialist, neurologist or HIV specialist; **AND**  
b. CD4 counts<100 cells/microL; **AND**  
c. Seropositive for anti-toxoplasma immunoglobulin G (IgG); **AND**  
d. Presence of clinical syndrome like headache, fever and neurological symptoms; **AND**  
e. Presence of lesions as demonstrated by brain imaging (CT or MRI); **AND**  

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| Treatment of Congenital Toxoplasmosis. | a. Diagnosis made by infectious disease specialist; **AND**  
b. Being used in conjunction with a Sulfonamide. |

**CONTINUATION OF THERAPY – (Duration of Approval – Maximum of 6 months)**
Documentation of all of the following:

- Compliance to prescribed medication
- If HIV related, member compliant to anti-retroviral treatment regimen
- Improvement on brain imaging (CT or MRI)
- Improvement of clinical symptoms

*Quantity Limitations Apply – See Appendix A*

**Limitations**
The Plan will **not** approve coverage of Daraprim® in the following instances:

- When the above criteria are not met.

**Clinical Background Information and References**


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Daraprim®
Appendix A – Quantity Limitations for Daraprim®

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dosing Regimen</th>
<th>Maximum Quantity</th>
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</thead>
<tbody>
<tr>
<td>Initial treatment</td>
<td>200mg once, followed by:</td>
<td>90 tablets per 30 days</td>
</tr>
<tr>
<td></td>
<td>&lt;60kg: 50mg daily</td>
<td></td>
</tr>
<tr>
<td></td>
<td>&gt;60kg: 75mg daily</td>
<td></td>
</tr>
<tr>
<td>Primary Prophylaxis</td>
<td>50mg weekly</td>
<td></td>
</tr>
<tr>
<td>Secondary Prophylaxis</td>
<td>25-50mg daily</td>
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Original Approval Date | Original Effective Date | Policy Owner | Approved by                     |
-----------------------|-------------------------|--------------|---------------------------------|
01/14/2016             | 05/03/2016              | Pharmacy Services | Pharmacy & Therapeutics (P&T) Committee NH DHHS |

Policy Revisions History

<table>
<thead>
<tr>
<th>Review Date</th>
<th>Summary of Revisions</th>
<th>Revision Effective Date</th>
<th>Approved by</th>
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<tbody>
<tr>
<td>1/12/2017</td>
<td>P&amp;T Annual Review, updated criteria to include trail of sulfonamides and continuation of therapy criteria added. Revised the initial description to reflect the current guidelines for treatment.</td>
<td>05/01/2017</td>
<td>P&amp;T Committee</td>
</tr>
</tbody>
</table>

Next Review Date

01/11/2018

Other Applicable Policies

9.002 Mandatory Generic Substitution Policy
9.015 Quantity Limitation Policy

Reference to Applicable Laws and Regulations, If Any

Disclaimer Information

* 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.
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.

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