

**Pharmacy Policy**

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**Pyrimethamine (Daraprim)**

**Policy Number:** 9.401

**Version Number:** 2.0

**Version Effective Date:** 6/1/2021

<p>Product Applicability <input type="checkbox"/> All Plan+ Products</p>	
<p><b>Well Sense Health Plan</b></p> <p><input type="checkbox"/> New Hampshire Medicaid</p>	<p><b>Boston Medical Center HealthNet Plan</b></p> <p><input checked="" type="checkbox"/> MassHealth - MCO</p> <p><input checked="" type="checkbox"/> MassHealth - ACO</p> <p><input type="checkbox"/> Qualified Health Plans/ConnectorCare/Employer Choice Direct</p> <p><input type="checkbox"/> Senior Care Options</p>

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

**Prior Authorization Policy**

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**Products Affected:**

- **Pyrimethamine (Daraprim)**

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

<b>Covered Use</b>	All FDA approved indications not otherwise excluded
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	<b>For Toxoplasmosis (Primary prophylaxis)</b>

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	<ol style="list-style-type: none"> <li>1. Diagnosis of HIV; <b>AND</b></li> <li>2. CD4 counts &lt; 100 cells/microL; <b>AND</b></li> <li>3. Seropositive for anti-toxoplasma immunoglobulin G (IgG); <b>AND</b></li> <li>4. Being used in conjunction with leucovorin; <b>AND</b></li> <li>5. Member is on antiretroviral treatment; <b>AND</b></li> <li>6. One of the following: <ol style="list-style-type: none"> <li>a. Member has a history of trimethoprim-sulfamethoxazole (TMP-SMX) allergy and TMP-SMX desensitization has been attempted and is still unable to tolerate, <b>OR</b></li> <li>b. Member had life threatening-reaction to trimethoprim-sulfamethoxazole (TMP-SMX) in the past (e.g. toxic epidermal necrolysis, Stevens-Johnson syndrome)</li> </ol> </li> </ol> <p><b>For treatment of AIDS-associated Toxoplasmic Encephalitis</b></p> <ol style="list-style-type: none"> <li>1. CD4 counts&lt;100 cells/microL; <b>AND</b></li> <li>2. Seropositive for anti-toxoplasma immunoglobulin G (IgG); <b>AND</b></li> <li>3. Presence of clinical syndrome like headache, fever and neurological symptoms; <b>AND</b></li> <li>4. Presence of lesions as demonstrated by brain imaging (CT or MRI); <b>AND</b></li> <li>5. Member is on antiretroviral treatment; <b>AND</b></li> <li>6. Being used in conjunction with leucovorin.</li> </ol> <p><b>For treatment of Congenital Toxoplasmosis.</b></p> <ol style="list-style-type: none"> <li>1. Being used in conjunction with a Sulfonamide; <b>AND</b></li> <li>2. Being used in conjunction with leucovorin</li> </ol>
<b>Age Restriction</b>	None
<b>Prescriber Restriction</b>	Infectious disease specialist, neurologist or HIV specialist
<b>Coverage Duration</b>	Up to 6 months
<b>Other criteria</b>	<p>Reauthorization:</p> <p><b>For toxoplasmosis (primary prophylaxis):</b></p> <ol style="list-style-type: none"> <li>1. Member is compliant to anti-retroviral treatment regimen</li> </ol> <p><b>For treatment of AIDS-associated toxoplasmosis encephalitis:</b></p> <ol style="list-style-type: none"> <li>1. Member is compliant to anti-retroviral treatment regimen; <b>AND</b></li> <li>2. Improvement on brain imaging (CT or MRI); <b>AND</b></li> <li>3. Improvement of clinical symptoms</li> </ol> <p><b>For treatment of congenital toxoplasmosis:</b></p>

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	1. Improvement of clinical symptoms
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**Applicable Coding:**

**Clinical Background Information and References**

1. Daraprim<sup>®</sup> [prescribing information]. Horsham (PA): Amedra Pharmaceuticals LLC; 2014 Oct.
2. Gandhi RT. Toxoplasmosis in HIV-infected patients. UptoDate<sup>®</sup>. Last updated Nov 4, 2015. Accessed Dec 24, 2015. [www.uptodate.com](http://www.uptodate.com).
3. Guerina NG, Lee J, Lynfield R. Congenital toxoplasmosis: Treatment, outcome, and prevention. UptoDate<sup>®</sup>. Last updated Jun 8, 2015. Accessed Dec 29, 2015. [www.uptodate.com](http://www.uptodate.com).
4. Centers for Disease Control and Prevention. Yellow Book Infectious Diseases Related to Travel. Accessed Dec 28, 2015: <http://wwwnc.cdc.gov/travel/yellowbook/2016/infectious-diseases-related-to-travel/malaria#4904>
5. Centers for Disease Control and Prevention. Treatment of Malaria (Guidelines For Clinicians). Accessed Dec 28, 2015: <http://www.cdc.gov/malaria/resources/pdf/treatmenttable.pdf>
6. Department of Health and Human Services. Guidelines for the Prevention and Treatment of Opportunistic Infections in HIV-Infected Adults and Adolescents. Accessed Dec 28, 2015: <https://aidsinfo.nih.gov/guidelines/html/4/adult-and-adolescent-oi-prevention-and-treatment-guidelines/322/toxo>
7. Department of Health and Human Services. Guidelines for the Prevention and Treatment of Opportunistic Infections in HIV-Exposed and HIV-Infected Children. Accessed Dec 28, 2015: <https://aidsinfo.nih.gov/guidelines/html/5/pediatric-oi-prevention-and-treatmentguidelines/418/toxoplasmosis>

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	9.061 Daraprim Policy retired, new policy created	1/1/2021	P&T Committee
2/11/2021	P&T Review: No changes	6/1/2021	P&T Committee

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## Next Review Date

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2/2022

## Other Applicable Policies

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## Reference to Applicable Laws and Regulations, If Any

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### 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.

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