UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2026 P 2071-11
Program	Prior Authorization/Medical Necessity
Medication	Daraprim® (pyrimethamine)
P&T Approval Date	10/2015, 10/2016, 3/2018, 5/2019, 5/2020, 5/2021, 5/2022, 5/2023, 5/2024, 5/2025, 5/2026
Effective Date	8/1/2026

1. Background:

Daraprim® (pyrimethamine) is indicated for the treatment of toxoplasmosis when used conjointly with a sulfonamide, since synergism exists with this combination.

The use of pyrimethamine for the treatment or prophylaxis of malaria is no longer recommended in the CDC Guidelines for the Treatment of Malaria in the United States. For the treatment of malaria, contact the CDC Malaria Hotline: (770) 488-7788 or (855) 856-4713 toll-free Monday-Friday 9 am to 5 pm EST - (770) 488-7100 after hours, weekends and federal holidays.

Limitations of Use:
Outpatient medication access to Daraprim is available exclusively through the Daraprim Direct program in partnership with Optime Care, Inc.

Members will be required to meet the coverage criteria below.

2. Coverage Criteria[a]:

A. Daraprim (pyrimethamine) will be approved based on submission of medical records (e.g., chart notes) documenting **one** of the following criteria:

1. Treatment of severe acquired toxoplasmosis, including **toxoplasmic encephalitis**

-OR-

2. Treatment of congenital toxoplasmosis

-OR-

3. Secondary prophylaxis of toxoplasmic encephalitis

-OR-

4. **All** of the following:

   a. Primary Pneumocystis pneumonia (PCP) prophylaxis in HIV-infected patients or as secondary prophylaxis in HIV-infected patients who have been treated for an acute episode of Pneumocystis pneumonia

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b. Patient has experienced intolerance to prior prophylaxis with trimethoprim-sulfamethoxazole (TMP-SMX)
c. **One** of the following:

(1) Patient has been re-challenged with trimethoprim-sulfamethoxazole (TMP-SMX) using a desensitization protocol and is still unable to tolerate
(2) Evidence of moderately severe or life threatening-reaction to trimethoprim-sulfamethoxazole (TMP-SMX) in the past (e.g., toxic epidermal necrolysis (TEN), Stevens-Johnson syndrome)

-OR-

5. **All** of the following:

a. Primary prophylaxis of toxoplasmic encephalitis
b. Toxoplasma IgG positive
c. CD4 count ≤ 100 cells/mm^3 if initiating prophylaxis or CD4 count < 100-200 cells/mm^3 if reinstituting prophylaxis
d. Will be used in combination with dapsone or atovaquone
e. Patient has experienced intolerance to prior prophylaxis with trimethoprim-sulfamethoxazole (TMP-SMX)
f. **One** of the following:

(1) Patient has been re-challenged with trimethoprim-sulfamethoxazole (TMP-SMX) using a desensitization protocol and is still unable to tolerate
(2) Evidence of moderately severe or life threatening-reaction to trimethoprim-sulfamethoxazole (TMP-SMX) in the past (e.g., toxic epidermal necrolysis (TEN), Stevens-Johnson syndrome)

Authorization will be issued for 12 months*

*** Consider discontinuation of primary prophylaxis if CD4 count > 200 cells/mm^3 for > 3 months after institution of combination antiretroviral therapy.**

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

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4. References:

1. Daraprim [Package Insert]. Jersey City, NJ: Tilde Sciences LLC; October 2023.
2. Centers for Disease Control and Prevention. Treatment of Malaria (Guidelines For Clinicians). Accessed April 10, 2025: Clinical Guidance: Malaria Diagnosis & Treatment in the U.S.
3. Centers for Disease Control and Prevention. CDC Yellow Book: Health Information for International Travel 2024. New York: Oxford University Press; 2024. Accessed April 10, 2025: https://wwwnc.cdc.gov/travel/yellowbook/2024/infections-diseases/malaria
4. Daraprim Accessing Daraprim. Accessed April 10, 2025: https://www.daraprimdirect.com/home/hcp#PO
5. Department of Health and Human Services. Guidelines for the Prevention and Treatment of Opportunistic Infections in HIV-Infected Adults and Adolescents. Accessed April 10, 2025: Guidelines for the Prevention and Treatment of Opportunistic Infections in Adults and Adolescents With HIV
6. Department of Health and Human Services. Guidelines for the Prevention and Treatment of Opportunistic Infections in HIV-Exposed and HIV-Infected Children. Accessed April 10, 2025: Toxoplasmosis | Pediatric Opportunistic Infection | ClinicalInfo (hiv.gov)

Program	Prior Authorization/Medical Necessity – Daraprim® (pyrimethamine)
Change Control	
10/2015	New Program
10/2016	Annual review. Updates to references.
3/2018	Annual review. Updates to references, added criteria for PCP prophylaxis and clarified existing criteria.
5/2019	Annual review. Updated background information without change to coverage criteria. Updated references.
5/2020	Annual review without change to coverage criteria. Updated references.
5/2021	Annual review without change to coverage criteria. Updated references.
5/2022	Annual review without change to coverage criteria. Updated references.
5/2023	Annual review without change to clinical coverage criteria. Clarified documentation requirement. Updated references.
5/2024	Annual review without change to coverage criteria. Updated references.
5/2025	Annual review without change to coverage criteria. Updated references.
5/2026	Annual review without change to coverage criteria. Updated references.

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