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# 5.01.038

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<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	April 1, 2025
<b>Subsection:</b>	Anti-Infective Agents	<b>Original Policy Date:</b>	October 16, 2015
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**Last Review Date:** March 7, 2025

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## Daraprim

### Description

#### Daraprim (pyrimethamine)

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#### Background

Daraprim is an orally administered antiparasitic compound. Daraprim is a folic acid antagonist and works together with sulfonamide to block folic acid production in the parasite, which interferes with parasitic reproduction in the body. The action of Daraprim against *Toxoplasma gondii* is greatly enhanced when used in conjunction with sulfonamides (1).

Approved indications that are not supported by the clinical literature have been excluded from prior approval criteria.

#### Regulatory Status

FDA-approved indications: Daraprim is a folic acid antagonist indicated for: (1)

1. Treatment of Toxoplasmosis: Daraprim is indicated for the treatment of toxoplasmosis when used conjointly with a sulfonamide, since synergism exists with this combination.
2. Treatment of Acute Malaria: Daraprim is also indicated for the treatment of acute malaria. It should not be used alone to treat acute malaria. Fast-acting schizonticides such as chloroquine or quinine are indicated and preferable for the treatment of acute malaria. However, conjoint use of Daraprim with a sulfonamide (e.g., sulfadoxine) will initiate transmission control and suppression of susceptible strains of plasmodia.
3. Chemoprophylaxis of Malaria: Daraprim is indicated for the chemoprophylaxis of malaria due to susceptible strains of plasmodia. However, resistance to pyrimethamine is prevalent worldwide. It is not suitable as a prophylactic agent for travelers to most areas.

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Daraprim is contraindicated in patients with documented megaloblastic anemia due to folate deficiency (1).

The Center for Disease Control does not recommend Daraprim for the prevention or the treatment of malaria (2).

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## Related policies

### Policy

*This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.*

Daraprim may be considered **medically necessary** if the conditions indicated below are met.

Daraprim may be considered **investigational** for all other indications.

## Prior-Approval Requirements

### Diagnosis

Patient must have the following:

Toxoplasmosis

**AND ALL** of the following:

1. Used in combination with sulfonamide and folinic acid
2. Monitor complete blood and platelet counts twice a week
3. **NO** megaloblastic anemia due to folate deficiency
4. Patient must test positive for Toxoplasmosis gondii IgG antibodies

**AND ONE** of the following:

1. HIV/AIDS with CD4<100
2. Congenital toxoplasmosis
3. Acute symptomatic toxoplasmosis

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## Prior – Approval *Renewal* Requirements

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Same as above

## Policy Guidelines

### Pre - PA Allowance

None

### Prior - Approval Limits

**Duration** 1 month

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### Prior – Approval *Renewal* Limits

Same as above

## Rationale

### Summary

Daraprim is an orally administered antiparasitic compound. The action of Daraprim against *Toxoplasma gondii* is greatly enhanced when used in conjunction with sulfonamides. The Center for Disease Control does not recommend Daraprim for the prevention or the treatment of malaria (1-2).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Daraprim while maintaining optimal therapeutic outcomes.

### References

1. Daraprim [package insert]. New York, NY: Vyera Pharmaceuticals LLC; August 2017.
2. CDC Website: Malaria Treatment. Accessed on January 29, 2024.

## Policy History

Date	Action
October 2015	Addition to PA
December 2015	Annual editorial review Addition of other causes of toxoplasmosis congenital toxoplasmosis and acute symptomatic toxoplasmosis per PMPC
March 2016	Annual review Policy code changed from 5.03.38 to 5.01.38

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December 2017	Annual editorial review and reference update
November 2018	Annual review and reference update
December 2019	Annual review and reference update
December 2020	Annual review
March 2021	Annual review
September 2021	Annual review and reference update
March 2022	Annual review and reference update
March 2023	Annual review and reference update. Changed policy number to 5.01.038
June 2023	Annual review and reference update
March 2024	Annual review and reference update
June 2024	Annual review
March 2025	Annual review

## [Keywords](#)

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**This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 7, 2025 and is effective on April 1, 2025.**