Daraprim (pyrimethamine)

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.

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).

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* for the treatment of Toxoplasmosis and if the conditions indicated below are met.

Daraprim is 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

Prior - Approval *Renewal* Requirements

Same as above

**Policy Guidelines**

**Pre - PA Allowance**

None

**Prior - Approval Limits**

**Duration** 1 month

**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**

2. CDC Website: Malaria Treatment. Accessed on October 9, 2019.

**Policy History**

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<td>October 2015</td>
<td>Addition to PA</td>
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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  

December 2017  Annual editorial review and reference update  

November 2018  Annual review and reference update  

December 2019  Annual review and reference update  

**Keywords**

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 6, 2019 and is effective January 1, 2020.