Daraprim

Description

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 (2-3).

### 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, used in combination with a sulfonamide and folinic acid; complete blood and platelet counts will be monitored twice a week; no megaloblastic anemia due to folate deficiency; patient must test positive for Toxoplasmosis gondii IgG antibodies; and the patient must have one of the following: the patient must have a diagnosis of HIV/AIDS and CD4 count <100 cells/microL, congenital toxoplasmosis or acute symptomatic toxoplasmosis.

Daraprim is considered **investigational** in patients with 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**

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**Prior – Approval Renewal Limits**

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**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**
**Section:** Prescription Drugs  
**Effective Date:** January 1, 2016  
**Subsection:** Anti-Infective Agents  
**Original Policy Date:** October 16, 2015  
**Subject:** Daraprim  
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3. CDC Website: Malaria Treatment  

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<tr>
<th>Date</th>
<th>Action</th>
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<tr>
<td>October 2015</td>
<td>Addition to PA</td>
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<tr>
<td>December 2015</td>
<td>Annual editorial review</td>
<td>Addition of other causes of toxoplasmosis congenital toxoplasmosis and</td>
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<td>acute symptomatic toxoplasmosis per PMPC</td>
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<td>March 2016</td>
<td>Annual review</td>
<td>Policy code changed from 5.03.38 to 5.01.38</td>
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**Keywords**

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 18, 2016 and is effective April 1, 2016.

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