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5.01.38

Section:	Prescription Drugs	**Effective Date:**	January 1, 2019
Subsection:	Anti-Infective Agents	**Original Policy Date:**	October 16, 2015
Subject:	Daraprim	**Page:**	1 of 4

Last Review Date: November 30, 2018

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).

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

Duration 1 month

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 October 9, 2018.

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
December 2017	Annual editorial review and reference update
November 2018	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on November 30, 2018 and is effective January 1, 2019.