RATIONALE FOR INCLUSION IN PA PROGRAM

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).

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.