

PRIOR AUTHORIZATION POLICY

POLICY: Infectious Disease – Daraprim Prior Authorization Policy

- Daraprim® (pyrimethamine tablets – Vyera Pharmaceuticals)

REVIEW DATE: 10/28/2020

OVERVIEW

Daraprim is indicated for the treatment of **toxoplasmosis** when used conjointly with a sulfonamide, since synergism exists with this combination.¹

Toxoplasmosis is an infection caused by the protozoan parasite, *Toxoplasma gondii*.² In the US, it is estimated that 11% of the population ≥ 6 years of age have been infected with *Toxoplasma*. The incidence is $> 60\%$ in some areas of the world. The parasite can be transmitted by food (e.g., by eating undercooked, contaminated meat or shellfish), through infected cats (cats become infected by eating infected rodents, birds, or other small animals), or by mother-to-child (congenital) transmission.

Pyrimethamine, a folic acid antagonist, is considered to be the most effective drug against toxoplasmosis and is a standard component of therapy.² Leucovorin, a folinic acid, protects the bone marrow from the toxic effects of pyrimethamine and is often prescribed in conjunction with pyrimethamine.

Guidelines

The guidelines for the prevention and treatment of opportunistic infections in adults and adolescents with human immunodeficiency (HIV) [2020] recommend pyrimethamine as the drug of choice for treatment and chronic maintenance treatment (secondary prophylaxis) of *Toxoplasma gondii* encephalitis.³ Pyrimethamine is recommended as an option for: primary prophylaxis of *Toxoplasma gondii* encephalitis; primary prophylaxis and chronic maintenance treatment (secondary prophylaxis) of *Pneumocystis pneumonia*; and chronic maintenance treatment (secondary prophylaxis) and treatment of cystoisosporiasis (formerly isosporiasis).³ The drug of choice for these conditions is trimethoprim-sulfamethoxazole.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Daraprim. All approvals are provided for 1 year in duration unless otherwise noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Daraprim is recommended in those who meet one of the following criteria:

FDA-Approved Indications

1. **Treatment of Toxoplasmosis.** Approve for 1 year.

Other Uses with Supportive Evidence

2. **Cystoisosporiasis (formerly known as isosporiasis) – Chronic Maintenance Treatment (Secondary Prophylaxis).** Approve for 1 year if the patient has tried one other therapy for this condition.
Note: Other therapies used for this condition include trimethoprim-sulfamethoxazole and ciprofloxacin.
3. **Cystoisosporiasis (formerly known as isosporiasis) – Treatment.** Approve for 1 year if the patient has tried one other therapy for this condition.
Note: Other therapies used for this condition include trimethoprim-sulfamethoxazole and ciprofloxacin.
4. ***Pneumocystis* Pneumonia – Chronic Maintenance Therapy (Secondary Prophylaxis).** Approve for 1 year if the patient has tried one other therapy for this condition.
Note: Other therapies used for this condition include trimethoprim-sulfamethoxazole, dapsone, aerosolized pentamidine (via Respigard II™ nebulizer), and atovaquone.
5. ***Pneumocystis* Pneumonia – Primary Prophylaxis.** Approve for 1 year if the patient has tried one other therapy for this condition.
Note: Other therapies used for this condition include trimethoprim-sulfamethoxazole, dapsone, aerosolized pentamidine (via Respigard II™ nebulizer), and atovaquone.
6. ***Toxoplasma gondii* Encephalitis – Chronic Maintenance Therapy (Secondary Prophylaxis).** Approve for 1 year.
7. ***Toxoplasma gondii* Encephalitis – Primary Prophylaxis.** Approve for 1 year if the patient has tried one other therapy for this condition.
Note: Other therapies used for this condition include trimethoprim-sulfamethoxazole and atovaquone.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Daraprim is not recommended in the following situations:

1. **Malaria – Chemoprophylaxis or Treatment.** Daraprim is no longer indicated for the treatment of acute malaria or for chemoprophylaxis of malaria.¹ Even when malaria was an approved indication, the Centers for Disease Control and Prevention (CDC) did not include Daraprim as a recommended therapy for malaria (due to widespread resistance).
2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Daraprim® [prescribing information]. New York, NY: Viera Pharmaceuticals LLC.; August 2017.
2. Centers for Disease Control and Prevention – Toxoplasmosis. Available at: <https://www.cdc.gov/parasites/toxoplasmosis/index.html>. Accessed on October 26, 2020.
3. Guidelines for the prevention and treatment of opportunistic infections in adults and adolescents with HIV: recommendations from the Centers for Disease Control and Prevention, the National Institutes of Health, and the HIV Medicine Association of the Infectious Diseases Society of America. Available at: <https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-opportunistic-infection/whats-new-guidelines>. Accessed on October 26, 2020.