

Initial Prior Authorization

Daraprim

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Daraprim	pyrimethamine

Indications

FDA-Approved Indications

Treatment of Toxoplasmosis

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

Compendial Uses

- Toxoplasmosis; Prophylaxis^{2,3,4,5}
- Pneumocystis jirovecii pneumonia; Prophylaxis^{2,3,4}
- Cystoisosporiasis; Treatment and secondary prophylaxis ^{2,4,5}

Coverage Criteria

Congenital Toxoplasmosis

Authorization may be granted when the requested drug is being prescribed for the treatment of congenital toxoplasmosis in a pediatric patient.

Cystoisosporiasis

Authorization may be granted when the requested drug is being prescribed for the treatment of cystoisosporiasis when the following criteria is met:

- The patient has experienced an intolerance or has a contraindication to sulfamethoxazole/trimethoprim.

Pneumocystis Jirovecii Pneumonia Prophylaxis, Primary Prophylaxis of Toxoplasmosis

Authorization may be granted when the requested drug is being prescribed for Pneumocystis Jirovecii pneumonia prophylaxis or primary prophylaxis of toxoplasmosis when ALL of the following criteria are met:

- The patient has experienced an intolerance or has a contraindication to sulfamethoxazole/trimethoprim.
- The patient has had a CD4 cell count less than 200 cells/mm³ within the past 3 months.

Secondary Prophylaxis of Cystoisosporiasis

Authorization may be granted when the requested drug is being prescribed for secondary prophylaxis of cystoisosporiasis when ALL of the following criteria are met:

- The patient has experienced an intolerance or has a contraindication to sulfamethoxazole/trimethoprim.
- The patient has had a CD4 cell count less than 200 cells/mm³ within the past 6 months.

Secondary Prophylaxis of Toxoplasmosis

Authorization may be granted when the requested drug is being prescribed for secondary prophylaxis of toxoplasmosis when the following criteria is met:

- The patient has had a CD4 cell count of less than 200 cells/mm³ within the past 6 months.

Toxoplasmosis

Authorization may be granted when the requested drug is being prescribed for the treatment of toxoplasmosis.

Duration of Approval (DOA)

- 1341-A:
 - Congenital toxoplasmosis in a pediatric patient: DOA: 12 months
 - Toxoplasmosis (treatment, primary prophylaxis, secondary prophylaxis): DOA: 3 months
 - Pneumocystis jirovecii Pneumonia (prophylaxis): DOA: 3 months

- Cystoisosporiasis (treatment, secondary prophylaxis): DOA: 6 months

References

1. Daraprim [package insert]. New York, New York: Vyera Pharmaceuticals, LLC; August 2017.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. <https://online.lexi.com>. Accessed November 27, 2024.
3. Micromedex (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 11/27/2024).
4. Panel on Guidelines for the Prevention and Treatment of Opportunistic Infections in Adults and Adolescents with HIV. Guidelines for the Prevention and Treatment of Opportunistic Infections in Adults and Adolescents with HIV. National Institutes of Health, Centers for Disease Control and Prevention, HIV Medicine Association, and Infectious Diseases Society of America. Available at <https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-opportunistic-infection>. Accessed November 29, 2024.
5. Panel on Opportunistic Infections in HIV-Exposed and HIV-Infected Children. Guidelines for the Prevention and Treatment of Opportunistic Infections in HIV-Exposed and HIV-Infected Children. Department of Health and Human Services. Available at <https://clinicalinfo.hiv.gov/en/guidelines/pediatric-opportunistic-infection>. Accessed November 29, 2024.
6. Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV. Department of Health and Human Services. Available at <https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-arv>. Accessed November 29, 2024.