PRIOR AUTHORIZATION CRITERIA

BRAND NAME
(generic)

DARAPRIM
(pyrimethamine)

Status: CVS Caremark® Criteria
Type: Initial Prior Authorization

POLICY

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 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 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.; 2023. https://online.lexi.com. Accessed December 11, 2023.
3. Micromedex (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 12/11/2023).
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 December 11,2023.
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 December 11, 2023.
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 December 11, 2023.