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 jiroveci pneumonia; Prophylaxis^{2,3,4} Cystoisosporiasis: treatment and secondary prophylaxis ^{2,4,5}

COVERAGE CRITERIA

The requested drug will be covered with prior authorization when the following criteria are met:

- The requested drug is being prescribed for the treatment of congenital toxoplasmosis in a pediatric patient **OR**
- The requested drug is being prescribed for the treatment of toxoplasmosis
- OR
- The requested drug is being prescribed for secondary prophylaxis of toxoplasmosis
- o The patient has had a CD4 cell count of less than 200/mm3 within the past 6 months

OR

• The requested drug is being prescribed for any of the following: A) primary prophylaxis of toxoplasmosis, B) pneumocystis jiroveci pneumonia prophylaxis

AND

AND

• The patient has had a CD4 cell count of less than 200/mm3 within the past 3 months

OR

• The requested drug is being prescribed for the treatment of cystoisosporiasis

OR

The requested drug is being prescribed for secondary prophylaxis of cystoisosporiasis

AND

o The patient has had a CD4 cell count less than 200/mm3 within the past 6 months

REFERENCES

- 1. Daraprim [package insert]. New York, NY: Vyera Pharmaceuticals, LLC; August 2017.
- 2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Hudson, OH: Wolters Kluwer Clinical Drug Information, Inc. http://online.lexi.com/. Accessed December 2020.
- 3. Micromedex (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. http://www.micromedexsolutions.com/. Accessed December 2020.

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- 4. Panel on Opportunistic Infections in HIV-Infected Adults and Adolescents. Guidelines for the prevention and treatment of opportunistic infections in HIV-infected adults and adolescents: 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/sites/default/files/inline-files/adult_oi.pdf. Accessed December 2020.
- 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. Recommendations from the National Institutes of Health, Centers for Disease Control and Prevention, the HIV Medicine Association of the Infectious Diseases Society of America, the Pediatric Infectious Diseases Society, and the American Academy of Pediatrics. Available at
- http://aidsinfo.nih.gov/contentfiles/lvguidelines/oi_guidelines_pediatrics.pdf. Accessed December 2020.
- 6. Guidelines for the Treatment of Malaria in the United States. Centers for Disease Control and Prevention. Available at https://www.cdc.gov/malaria/resources/pdf/Malaria_Treatment_Table_120419.pdf. Accessed December 2020.
- 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/sites/default/files/guidelines/documents/AdultandAdolescentGL.pdf. Accessed December 2020.

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