AETNA BETTER HEALTH® Coverage Policy/Guideline				
Name:	Pyrimethamine		Page:	1 of 2
Effective Date:	3/13/2025		Last Review Date:	1/2025
Applies to:	☐Illinois ☒New Jersey ☐Pennsylvania Kids	☐Florida ☐Maryland ☐Virginia	☐Florida Kids ☐Michigan ☐Kentucky PRMD	

Aetna Better Health® of New Jersey

Protocol for pyrimethamine (Daraprim®)

Approved January 2021

Criteria for approval:

A. Treatment of toxoplasmosis

1. Documentation or confirmed diagnosis of severe acquired toxoplasmosis,
2. including toxoplasmic encephalitis
3. Prescribed by or in consultation with an infectious disease specialist
4. Documentation that pyrimethamine will be used in combination with sulfadiazine or clindamycin and leucovorin per guideline recommendation
5. For HIV/AIDS patients, documentation that patient has tried and failed or has contraindication to trimethoprim-sulfamethoxazole (TMP-SMX)

B. Primary prophylaxis for toxoplasmosis in HIV/AIDS

1. Documentation or confirmed diagnosis of HIV/AIDS
2. Prescribed by or in consultation with an infectious disease or HIV specialist
3. Documentation that pyrimethamine will be used in combination with sulfadiazine or clindamycin and leucovorin per guideline recommendation
4. Patient has tested positive for Toxoplasmosis gondii IgG antibodies
5. Documentation that patient has CD4 count <100 cells/μL
6. Documentation that patient has tried and failed or has contraindication to trimethoprim-sulfamethoxazole (TMP-SMX)
7. Medication is prescribed in accordance with Food and Drug Administration (FDA) established indication and dosing regimens or in accordance with medically appropriate off-label indication and dosing according to American Hospital Formulary Service, Micromedex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs (Lexicomp), national guidelines, or other peer reviewed evidence
8. Adherence to antiretroviral therapy as evidenced by pharmacy claims history or office notes

Initial Approval:

Toxoplasmosis, Primary Prophylaxis – 3 months
Toxoplasmosis, Treatment – 6 weeks

Continuation of Therapy:

1. Compliance to prescribed medication as evidenced by pharmacy claims history or office notes
2. Discontinue treatment once CD4 count >200 cells/μL for at least 3 months

Renewal Approval:

Toxoplasmosis, Primary Prophylaxis – 3 months
Toxoplasmosis, Treatment – 6 weeks

References:

1. Daraprim [Packet Insert]. Vyera Pharmaceuticals, New York, NY. August 2017
2. Konstantinovic N, et al. Treatment of toxoplasmosis: Current options and future perspectives. Food and Waterborne
3. Parasitology. 2019 Jun; 15. Accessed online on September 20, 2020 at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7033996/
4. Toxoplasmosis. Harvard Health Publications. Drugs.Com. Updated May 11, 2020. Accessed online on September 16, 2020 at: https://www.drugs.com/health-guide/toxoplasmosis.html
5. Clinical Pharmacology (online database). Tampa FL: Gold Standard Inc.: 2019. Updated periodically
6. Dunay IR, et al. Treatment of Toxoplasmosis: Historical Perspective, Animal Models, and Current Clinical Practice.
7. Clinical Microbiology Reviews; 31(4). October 2018. https://cmr.asm.org/content/cmr/31/4/e00057-17.full.pdf