Clinical Policy Title:	pyrimethamine
Policy Number:	RxA.88
Drug(s) Applied:	Daraprim®, pyrimethamine
Original Policy Date:	02/07/2020
Last Review Date:	08/28/2024
Line of Business Policy Applies to:	All Line of Business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Initial Therapy for Toxoplasmosis Infection – Active Disease (must meet all)**:**

1. Diagnosis of toxoplasmosis;
2. Member meets one of the following (a or b):
   a. Age < 18 years;
   b. Trial and failure of ≥ 10 days, or radiological deterioration within 7 days, of trimethoprim/sulfamethoxazole (TMP/SMX) at maximum indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
3. Daraprim® is prescribed with one of the following (a or b):
   a. Sulfadiazine or clindamycin or atovaquone or azithromycin, and leucovorin (HIV members).
   b. Sulfonamide (non-HIV members);

Approval Duration

All Lines of Business (except Medicare): 56 days

B. Primary Prophylaxis for Toxoplasmosis – Preventing 1st Episode (off-label) (must meet all):

1. Diagnosis of HIV infection;
2. Request is for prevention for toxoplasmosis;
3. Member meets one of the following (a or b):
   a. Age ≥ 6 years: CD4 count < 100 cells/mm^3;
   b. Age < 6 years: CD4 cell percentage < 15%;
4. Seropositive for Toxoplasma gondii IgG;
5. Member is contraindicated or has experienced clinically significant adverse effects to trimethoprim/sulfamethoxazole (TMP/SMX);
6. Daraprim® is prescribed with leucovorin and dapsone or atovaquone.

Approval Duration

All Lines of Business (except Medicare): 6 months

II. Continued Therapy Approval

A. All Indications in Section I (must meet all):

1. Auto-approval based on lookback functionality within the past 120 days as a proxy for member responding positively to therapy.

Approval Duration

All Lines of Business (except Medicare): 12 months

References

1. Panel on Opportunistic Infections in HIV-infected Adults and Adolescents. Guidelines for prevention and treatment of opportunistic infections in HIV-infected adults and adolescents – Toxoplasma gondii encephalitis: 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. Department of Health and Human Services. Available at: https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-opportunistic-infection/introduction. Updated June 13, 2022. Accessed August 28, 2024.
2. Global Health - Division of Parasitic Diseases and Malaria. Treatment of malaria: guidelines for clinicians (United States). Centers for Disease Control and Prevention. Available at: http://www.cdc.gov/malaria/diagnosis_treatment/treatment.html. Updated September 2022. Accessed August 28, 2024.
3. Global Health - Division of Parasitic Diseases and Malaria. Resources for health professionals: toxoplasmosis. Centers for Disease Control and Prevention. Available at: http://www.cdc.gov/parasites/toxoplasmosis/health_professionals/index.html. Updated July 13, 2022. Accessed August 28, 2024.
4. 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- Toxoplasma gondii encephalitis: 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. Department of Health and Human Services. Available at: https://clinicalinfo.hiv.gov/en/guidelines/hiv-clinical-guidelines-pediatric-opportunistic-infections/toxoplasmosis?view=full. Updated October 29, 2015. Accessed August 28, 2024.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy was established	01/2020	02/07/2020
Updated formatting	04/2020	
Policy was reviewed: 1. Clinical policy title table was updated. 2. Drug(s) applied was updated. 3. Line of Business Policy Applies to was update to all lines of business. 4. Continued Therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance..." 5. Initial approval criteria updated for toxoplasmosis infection for 56 days instead of “whichever is less….” 6. References were reviewed and updated.	02/05/2021	03/09/2021
Policy was reviewed: 1. References were reviewed and updated.	12/08/2021	01/17/2022
Policy was reviewed: 1. Initial Approval Criteria, I.B.4: “CD4 count < 100 cells/mm^3” was replaced with Member meets one of the following (a or b): CD4 count	10/04/2022	01/17/2023

< 100 cells/mm^3; a. Age ≥ 6 years: CD4 count < 100 cells/mm^3; b. Age < 6 years: CD4 cell percentage < 15%. 2. Continued Therapy Approval, II.A.2: "Member is HIV-infected with CD4 count ≤ 200 cells/mm^3 at any time in the previous 6 months" was replaced with Member is HIV-infected with one of the following (a or b): a. Age ≥ 6 years: CD4 count ≤ 200 cells/mm^3 at any time in the previous 6 months; b. Age < 6 years: CD4 percentage has risen < 15% from baseline at any time in the previous 6 months. 3. Continued Therapy Approval, II.B.2: "Member is HIV-infected with CD4 count ≤ 200 cells/mm^3 at any time in the previous 3 months" was replaced with Member is HIV-infected with one of the following (a or b): a. Age ≥ 6 years: CD4 count ≤ 200 cells/mm^3 at any time in the previous 3 months; b. Age < 6 years: CD4 percentage has risen < 15% from baseline at any time in the previous 3 months. 4. References were reviewed and updated.		
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed: 1. Added generic pyrimethamine to Drug(s) Applied. 2. Removed age restrictions. 3. Removed prescriber restrictions. 4. Removed dose restrictions. 5. Updated Continued therapy approval with auto-approval based on lookback functionality within the past 120 days. 6. Removed all other reauthorization requirements. 7. Reauthorization criteria for all the diagnosis merged under "All Indications in Section I". 8. Updated approval duration verbiage. 9. References were reviewed and updated.	08/28/2024	09/13/2024