Effective Date: 05/01/2021
Reviewed: 02/2021, 2/2022, 3/2023, 3/2024, 3/2025, 4/2026 Scope: Medicaid

Pyrimethamine

POLICY

I. CRITERIA FOR APPROVAL

An authorization may be granted when all the following criteria are met:

A. Medication is prescribed by or in consultation with an infectious disease specialist; **AND**
B. Dose and frequency does not exceed FDA approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines; **AND**
C. The drug is being prescribed for a pediatric member with congenital toxoplasmosis, **OR**
D. The drug is being prescribed for treatment of toxoplasmosis, **OR**
E. The drug is being prescribed for treatment of Toxoplasma gondii encephalitis; **OR**
F. The drug is being prescribed for toxoplasmosis prophylaxis or Pneumocystis jiroveci pneumonia prophylaxis AND the member has experienced a failure, contraindication or intolerance, to sulfamethoxazole/trimethoprim; **AND**
    a. The member has not had a CD4 cell count of greater than 200/mm^3 for at least 3 months; **OR**
G. The drug is prescribed for Cystoisosporiasis and the patient has an intolerance or contraindication to sulfamethoxazole/trimethoprim; **AND**
    a. The patient has not had a CD4 cell count of greater than 200/mm^3 for at least 6 months

II. CONTINUATION OF THERAPY

Prophylaxis treatment of one of the following: Toxoplasmosis, Pneumocystis Jiroveci pneumonia, Cystoisosporiasis

A. All initial criteria is met and the member is tolerating therapy
B. Documentation of recent CD4 cell counts

III. QUANTITY LIMIT AND DOSING

Pyrimethamine 25mg: 3 tablets a day

Indication	Dosing
Toxoplasmosis or Toxoplasma gondii encephalitis (initial)	200 mg for 1 dose, then 50 mg (less than 60 kg) to 75 mg (60 kg or greater) daily for at least 6 weeks.
Toxoplasmosis-AIDS-related (primary prophylaxis)	25mg-50mg once daily until CD4 count >200 cells/μL for at least 6 months.
Toxoplasmosis-AIDS-related chronic maintenance therapy (secondary prophylaxis)	25mg-50mg once daily until CD4 count >200 cells/μL for at least 6 months.

Pneumocystis Jiroveci pneumonia in patients with HIV (primary prophylaxis)	50mg or 75mg weekly OR 25mg once daily until CD4 count >200 cells/μL for at least 3 months
Cystoisosporiasis in patients with HIV	50 to 75mg once daily for 3-4 weeks
Cystoisosporiasis in patients with HIV (secondary prophylaxis)	25mg once daily until CD4 count >200 cells/μL for at least 6 months.

IV. COVERAGE DURATION

- Congenital toxoplasmosis: 12 months
- Toxoplasmosis or Toxoplasma gondii encephalitis: 6 weeks
- Toxoplasmosis prophylaxis or Pneumocystis Jiroveci pneumonia prophylaxis: 3 months
- Cystoisosporiasis initial: 1 month
- Cystoisosporiasis prophylaxis: 6 months

V. REFERENCES

Pyrimethamine [package insert]. Morristown, NJ: Alvogen, Inc., July 2021.