

Mepron (atovaquone) Policy Number: C8408-A

CRITERIA EFFECTIVE DATES:

ORIGINAL EFFECTIVE DATE	LAST REVIEWED DATE	NEXT REVIEW DATE
11/2015	12/2018	12/2019
J CODE	TYPE OF CRITERIA	LAST P&T APPROVAL
	RxPA	Q1

PRODUCTS AFFECTED: Mepron (atovaquone)

DRUG CLASS: Antiprotozoal Agents

ROUTE OF ADMINISTRATION:

Oral

PLACE OF SERVICE:

Retail Pharmacy

AVAILABLE DOSAGE FORMS: MEPRON SUS 750MG/5ML, ATOVAQUONE SUS 750MG/5ML,

FDA-APPROVED USES: indicated for the prevention of *Pneumocystis carinii* pneumonia in patients who are intolerant to trimethoprim-sulfamethoxazole (TMP-SMX) and indicated for the acute oral treatment of mild-to-moderate PCP in patients who are intolerant to TMP-SMX.

COMPENDIAL APPROVED OFF-LABELED USES: HIV infection - *Toxoplasma encephalitis* (treatment or prophylaxis)

COVERAGE CRITERIA: INITIAL AUTHORIZATION

DIAGNOSIS: prevention of *Pneumocystis carinii* pneumonia, acute oral treatment of mild-to-moderate PCP, HIV infection - *Toxoplasma encephalitis* (treatment or prophylaxis)

REQUIRED MEDICAL INFORMATION:

- A. FOR PROPHYLAXIS OR TREATMENT OF PCP:
 - 1. Documentation that member has an intolerance to, or treatment failure, or contraindication to trimethoprim;sulfamethoxazole (TMP-SMX) and dapsone
AND
 - 2. FOR PROPHYLAXIS: Documentation of member that is immunocompromised which requires prevention of *Pneumocystis carinii* pneumonia (PCP) AND Documentation of members CD4 count

- B. FOR TREATMENT OF TOXOPLASMA ENCEPHALITIS:
 - 1. Documentation of supporting diagnosis for treatment

- C. PROPHYLAXIS OF TOXOPLASMA ENCEPHALITIS:
 - 1. Documentation of supporting diagnosis for prophylaxis
AND

2. Documentation that member has an intolerance to, or treatment failure, or contraindication to trimethoprim;sulfamethoxazole (TMP-SMX)

DURATION OF APPROVAL: Initial authorization: treatment 21 days, prevention 12 months.
Continuation of authorization: prevention 12 months.

QUANTITY: Prophylaxis: 1500mg daily, Treatment: up to 1500mg twice daily (3000mg daily)

PRESCRIBER REQUIREMENTS: Prescribed by or in consultation with an infectious disease specialist, oncologist, or HIV specialist.

AGE RESTRICTIONS: 13 years of age and older

GENDER:

Male and female

CONTINUATION OF THERAPY:

A. FOR ALL INDICATIONS:

1. Documentation of patient compliance to the prescribed medication

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION: All other uses of Mepron (atovaquone) are considered experimental/investigational and therefore, will follow Molina's Off-Label policy

OTHER SPECIAL CONSIDERATIONS: None

BACKGROUND: None

APPENDIX: None

REFERENCES:

1. Mepron full prescribing information. GlaxoSmithKline Research Triangle Park, NC
2. The Sanford Guide to Antimicrobial Therapy 2004. 34th Edition.
3. AIDSinfo: Guidelines for 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. AIDSinfo. Rockville, MD. 2017. Available from URL: https://aidsinfo.nih.gov/contentfiles/lvguidelines/adult_oi.pdf