

**Generic Name:** Atovaquone

**Therapeutic Class or Brand Name:** Mepron®

**Applicable Drugs (if Therapeutic Class):** N/A

**GPI Code:** 1640002000

**Preferred:** Atovaquone suspension

**Non-preferred:** Mepron® suspension

**Date of Origin:** 2/1/2013

**Date Last Reviewed / Revised:** 1/17/2020

## PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through III are met)

- I. Documented diagnosis of one of the following conditions A through C AND must meet criteria listed under applicable diagnosis:
  - A. Prevention of Pneumocystis jiroveci pneumonia or Pneumocystis carinii pneumonia (PCP) and criterion 1 is met:
    1. Documented intolerance to, treatment failure, or contraindication to Trimethoprim-Sulfamethoxazole (TMP-SMX).
  - B. Acute oral treatment of mild-to-moderate Pneumocystis jiroveci pneumonia or Pneumocystis carinii pneumonia (PCP) and criterion 1 is met:
    1. Documented intolerance to, treatment failure, or contraindication to Trimethoprim-Sulfamethoxazole (TMP-SMX).
  - C. Treatment for active Babesiosis (Babesia) infection and criterion 1 is met:
    1. Laboratory confirmation of Babesiosis is required.
- II. Mepron® is prescribed by, or after consultation with, an infectious disease physician.
- III. Non-preferred products (i.e. Mepron® suspension) require a documented clinical reason containing details as to why generic atovaquone is not appropriate or is contraindicated.

## EXCLUSION CRITERIA

- N/A

## OTHER CRITERIA

- Usual Doses:
  - Prevention of Pneumocystis jiroveci pneumonia or Pneumocystis carinii pneumonia (PCP): 1500 mg (10ml) per day.
  - Acute oral treatment of mild-to-moderate Pneumocystis jiroveci pneumonia or Pneumocystis carinii pneumonia (PCP): 750 mg (5ml) twice daily for 21 days.

- Treatment for active Babesiosis (Babesia) infection: 750 mg (5ml) twice daily for 7 to 10 days [use with Azithromycin 500–1000 mg on day 1 and 250 mg (up to 1000 mg for immunocompromised patients) once per day thereafter].

### QUANTITY / DAYS SUPPLY RESTRICTIONS

- Treatment: the amount needed to complete one course of therapy (see Usual Doses under Other Criteria).
- Prevention: 300mls per 30 days.

### APPROVAL LENGTH

- **Authorization:**
  - Treatment: One course of therapy
  - Prevention: 6 months.
- **Re-Authorization:**
  - Treatment: N/A
  - Prevention: An updated letter of medical necessity or progress notes showing the medication is effective and that prevention is still recommended.

### APPENDIX

N/A

### REFERENCES

1. Medi-Span.
2. [https://www.gsksource.com/pharma/content/dam/GlaxoSmithKline/US/en/Prescribing\\_Information/Mepron/pdf/MEPRON.PDF](https://www.gsksource.com/pharma/content/dam/GlaxoSmithKline/US/en/Prescribing_Information/Mepron/pdf/MEPRON.PDF)
3. The Clinical Assessment, Treatment, and Prevention of Lyme Disease, Human Granulocytic Anaplasmosis, and Babesiosis: Clinical Practice Guidelines by the Infectious Diseases Society of America <http://cid.oxfordjournals.org/content/43/9/1089.long>.
4. Centers for Disease Control and Prevention: Parasites-Babesiosis [http://www.cdc.gov/parasites/babesiosis/health\\_professionals/index.html#tx](http://www.cdc.gov/parasites/babesiosis/health_professionals/index.html#tx).

### HISTORICAL TRACKING OF CHANGES MADE TO POLICY

Date	Notes/Changes
------	---------------

1/17/2020	<ol style="list-style-type: none"> <li>Updated GSK link "<a href="https://www.gsksource.com/pharma/content/dam/GlaxoSmithKline/US/en/PrescribingInformation/Mepron/pdf/MEPRON.PDF">https://www.gsksource.com/pharma/content dam/GlaxoSmithKline/US/en/Prescribing Information/Mepron/pdf/MEPRON.PDF</a></li> </ol>
12/4/2018	<ol style="list-style-type: none"> <li>Policy reviewed: no changes made</li> </ol>
1/2/2018	<ol style="list-style-type: none"> <li>Policy reviewed: no changes made</li> </ol>
10/8/2016	<ol style="list-style-type: none"> <li><b>Changed</b> "N/A" to "Preferred: Atovaquone suspension (generic); Non-Preferred: Mepron® suspension" <b>following Applicable Drugs.</b></li> <li><b>Added</b> "III. Non-preferred products (i.e. Mepron® suspension) require a documented clinical reason containing details as to why generic atovaquone is not appropriate or is contraindicated" <b>under Prior Authorization Criteria.</b></li> <li><b>Removed</b> "<a href="http://www.connecticare.com/provider/PDFs/Pharmacy/Mepron.pdf">http://www.connecticare.com/provider/PDFs/Pharmacy/Mepron.pdf</a>" <b>from References</b> (link no longer valid).</li> </ol>
5/26/2015	<ol style="list-style-type: none"> <li><b>Changed</b> "Patient has an intolerance to, treatment failure, or contraindication to Trimethoprim-Sulfamethoxazole (TMP-SMX). A physician chart note is required documenting the trial and outcome" to "Documented intolerance to, treatment failure, or contraindication to Trimethoprim-Sulfamethoxazole (TMP-SMX)" <b>for criterion 1 under "A. Prevention of..." and "B. Acute oral treatment of..." "Pneumocystis jiroveci pneumonia or Pneumocystis carinii pneumonia (PCP)" under Prior Authorization Criteria.</b></li> <li><b>Changed</b> "750 mg (5ml) twice daily plus Azithromycin 500 mg on day 1 followed by 250 mg Azithromycin daily for 7 days" to "750 mg (5ml) twice daily for 7 to 10 days [use with Azithromycin 500–1000 mg on day 1 and 250 mg (up to 1000 mg for immunocompromised patients) once per day thereafter]" <b>for "Treatment for active Babesiosis (<i>Babesia</i>) infection" under Other Criteria.</b></li> <li><b>Changed</b> "For Prevention: 300mls per 30 days; For all other diagnoses: the amount needed to complete one course of therapy (see Usual Doses under Other Criteria)" to "Treatment: the amount needed to complete one course of therapy (see Usual Doses under Other Criteria); Prevention: 300mls per 30 days" <b>under Quantity/Days Supply Restrictions.</b></li> <li><b>Changed</b> "Acute oral treatment of mild-to-moderate <i>Pneumocystis jiroveci</i> pneumonia or <i>Pneumocystis carinii</i> pneumonia (PCP) PCP treatment: 1 time only; Treatment for active Babesiosis (<i>Babesia</i>) infection: 1 time only; Prevention of <i>Pneumocystis jiroveci</i> pneumonia or <i>Pneumocystis carinii</i> pneumonia (PCP): 3 months" to "Treatment: One course of therapy; Prevention: 6 months" <b>for Authorization under Approval Length.</b></li> <li><b>Changed</b> "Acute oral treatment of mild-to-moderate <i>Pneumocystis jiroveci</i> pneumonia or <i>Pneumocystis carinii</i> pneumonia (PCP): N/A; Treatment for active Babesiosis (<i>Babesia</i>) infection: N/A; Prevention of <i>Pneumocystis jiroveci</i> pneumonia or <i>Pneumocystis carinii</i> pneumonia (PCP): An updated letter of medical necessity or progress notes showing the medication is effective and that prevention is still recommended" to "Treatment: N/A; Prevention: An updated letter of medical necessity or progress notes showing the medication is effective and that prevention is still recommended" <b>for Re-Authorization under Approval Length.</b></li> </ol>

	<p>6. <b>Added</b> "http://cid.oxfordjournals.org/content/43/9/1089.long" and "http://www.cdc.gov/parasites/babesiosis/health_professionals/index.html#tx" <b>under References.</b></p>
<p>1/9/2014</p>	<ol style="list-style-type: none"> <li>1. Adapted policy to new format.</li> <li>2. Added GPI code.</li> <li>3. Changed Prior Authorization Criteria from:                      "Patient requires prophylaxis treatment or treatment for an acute <i>Pneumocystis carinii</i> pneumonia (PCP) infection AND patient has an intolerance to, treatment failure, or contraindication to Trimethoprim-Sulfamethoxazole (TMP-SMX). A physician chart note is required documenting the trial and outcome; OR Patient is being treated for active Babesiosis (<i>Babesia</i>) infection AND laboratory confirmation of Babesiosis is required"  <b>to:</b>                      "May be considered medically necessary when criteria I through II are met: I. Documented diagnosis of one of the following conditions A through C AND must meet criteria listed under applicable diagnosis: A. Prevention of <i>Pneumocystis jiroveci</i> pneumonia or <i>Pneumocystis carinii</i> pneumonia (PCP) and criterion 1 is met: 1. Patient has an intolerance to, treatment failure, or contraindication to Trimethoprim-Sulfamethoxazole (TMP-SMX); A physician chart note is required documenting the trial and outcome; B. Acute oral treatment of mild-to-moderate <i>Pneumocystis jiroveci</i> pneumonia or <i>Pneumocystis carinii</i> pneumonia (PCP) and criterion 1 is met: 1. Patient has an intolerance to, treatment failure, or contraindication to Trimethoprim-Sulfamethoxazole (TMP-SMX); A physician chart note is required documenting the trial and outcome; C. Treatment for active Babesiosis (<i>Babesia</i>) infection and criterion 1 is met: 1. Laboratory confirmation of Babesiosis is required; II. Mepron® is prescribed by, or after consultation with, an infectious disease physician".</li> <li>4. <b>Changed Other Criteria from "N/A" to</b> "Usual Doses: Prevention of <i>Pneumocystis jiroveci</i> pneumonia or <i>Pneumocystis carinii</i> pneumonia (PCP): 1500 mg (10ml) per day; Acute oral treatment of mild-to-moderate <i>Pneumocystis jiroveci</i> pneumonia or <i>Pneumocystis carinii</i> pneumonia (PCP): 750 mg (5ml) twice daily for 21 days; Treatment for active Babesiosis (<i>Babesia</i>) infection: 750 mg (5ml) twice daily plus Azithromycin 500 mg on day 1 followed by 250 mg Azithromycin daily for 7 days".</li> <li>5. <b>Changed Quantity/Days Supply Restrictions from</b> "PCP Prevention: 1500 mg (10ml) per day; Mild to Moderate PCP Treatment: 750 mg (5ml) twice daily for 21 days; Babesiosis treatment: 750 mg (5ml) twice daily plus Azithromycin 500 mg on day 1 followed by 250 mg Azithromycin daily for 7 days" <b>to</b> "For Prevention: 300mls per 30 days; For all other diagnoses: the amount needed to complete one course of therapy (see Usual Doses under Other Criteria)".</li> <li>6. <b>Changed Authorization under Approval Length from</b> "1 time only for PCP treatment; 1 time only for Babesiosis treatment; 3 months for PCP prophylaxis" <b>to</b> "Acute oral treatment of mild-to-moderate <i>Pneumocystis jiroveci</i> pneumonia or <i>Pneumocystis carinii</i> pneumonia (PCP) PCP treatment: 1 time only; Treatment for active Babesiosis (<i>Babesia</i>) infection: 1 time only; Prevention of <i>Pneumocystis jiroveci</i> pneumonia or <i>Pneumocystis carinii</i> pneumonia (PCP): 3 months".</li> <li>7. <b>Changed Re-Authorization under Approval Length from</b> "An updated letter of medical necessity or progress notes showing improvement or maintenance on medication" <b>to</b> "Acute oral treatment of mild-to-moderate <i>Pneumocystis jiroveci</i></li> </ol>

	<p>pneumonia or <i>Pneumocystis carinii</i> pneumonia (PCP): N/A; Treatment for active Babesiosis (<i>Babesia</i>) infection: N/A; Prevention of <i>Pneumocystis jiroveci</i> pneumonia or <i>Pneumocystis carinii</i> pneumonia (PCP): An updated letter of medical necessity or progress notes showing the medication is effective and that prevention is still recommended".</p> <p>8. Updated references to Medi-Span</p>
--	---

**DISCLAIMER:** Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.