



## MEDICATION POLICY

**Generic Name:** Atovaquone

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

**Applicable Drugs** (if Therapeutic Class):

Preferred: Atovaquone suspension (generic)

Non-Preferred: Mepron® suspension

**Date of Origin:** 2/1/13

**Date Last Reviewed/Revised:** 10/8/16

**GPI Code:** 1640002000

### **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:**

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- 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. [http://us.gsk.com/products/assets/us\\_mepron.pdf](http://us.gsk.com/products/assets/us_mepron.pdf).
3. <http://cid.oxfordjournals.org/content/43/9/1089.long>.
4. [http://www.cdc.gov/parasites/babesiosis/health\\_professionals/index.html#tx](http://www.cdc.gov/parasites/babesiosis/health_professionals/index.html#tx).

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<b>Historical Tracking Of Changes Made To Policy</b>	
10/8/2016	<ol style="list-style-type: none"> <li>1. <b>Changed</b> “N/A” to “Preferred: Atovaquone suspension (generic); Non-Preferred: Mepron® suspension” <b>following Applicable Drugs.</b></li> <li>2. <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>3. <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>1. <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” <b>to</b> “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>2. <b>Changed</b> “750 mg (5ml) twice daily plus Azithromycin 500 mg on day 1 followed by 250 mg Azithromycin daily for 7 days” <b>to</b> “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>3. <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)” <b>to</b> “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>4. <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” <b>to</b> “Treatment: One course of therapy; Prevention: 6 months” <b>for Authorization under Approval Length.</b></li> <li>5. <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” <b>to</b> “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> <li>6. <b>Added</b> “<a href="http://cid.oxfordjournals.org/content/43/9/1089.long">http://cid.oxfordjournals.org/content/43/9/1089.long</a>” <b>and</b> “<a href="http://www.cdc.gov/parasites/babesiosis/health_professionals/index.html#tx">http://www.cdc.gov/parasites/babesiosis/health_professionals/index.html#tx</a>” <b>under References.</b></li> </ol>
1/9/2014	<ol style="list-style-type: none"> <li>1. <b>Adapted policy to new format.</b></li> <li>2. <b>Added GPI code.</b></li> <li>3. <b>Changed Prior Authorization Criteria from:</b>  “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</li> </ol>

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<b>Historical Tracking Of Changes Made To Policy</b>	
	<p>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”.</p> <p>4. <b>Changed Other Criteria from “N/A” to “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”.</b></p> <p>5. <b>Changed Quantity/Days Supply Restrictions from “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” to “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)”.</b></p> <p>6. <b>Changed Authorization under Approval Length from “1 time only for PCP treatment; 1 time only for Babesiosis treatment; 3 months for PCP prophylaxis” to “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”.</b></p> <p>7. <b>Changed Re-Authorization under Approval Length from “An updated letter of medical necessity or progress notes showing improvement or maintenance on medication” to “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”.</b></p> <p>8. <b>Updated references to Medi-Span.</b></p>

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