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:** 1/2/18

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:

- 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.
3. http://cid.oxfordjournals.org/content/43/9/1089.long.
4. http://www.cdc.gov/parasites/babesiosis/health_professionals/index.html#tx.

MEDICATION POLICY

Historical Tracking Of Changes Made To Policy	
1/2/2018	1. Policy reviewed: no changes made.
10/8/2016	1. **Changed** "N/A" **to** "Preferred: Atovaquone suspension (generic); Non-Preferred: Mepron® suspension" **following Applicable Drugs**. 2. **Added** "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" **under Prior Authorization Criteria**. 3. **Removed** "http://www.connecticare.com/provider/PDFs/Pharmacy/Mepron.pdf" **from References** (link no longer valid).
5/26/2015	1. **Changed** "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)" **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**. 2. **Changed** "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]" **for "Treatment for active Babesiosis (*Babesia*) infection" under Other Criteria**. 3. **Changed** "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" **under Quantity/Days Supply Restrictions**. 4. **Changed** "Acute oral treatment of mild-to-moderate *Pneumocystis jiroveci* pneumonia or *Pneumocystis carinii* pneumonia (PCP) PCP treatment: 1 time only; Treatment for active Babesiosis (*Babesia*) infection: 1 time only; Prevention of *Pneumocystis jiroveci* pneumonia or *Pneumocystis carinii* pneumonia (PCP): 3 months" **to** "Treatment: One course of therapy; Prevention: 6 months" **for Authorization under Approval Length**. 5. **Changed** "Acute oral treatment of mild-to-moderate *Pneumocystis jiroveci* pneumonia or *Pneumocystis carinii* pneumonia (PCP): N/A; Treatment for active Babesiosis (*Babesia*) infection: N/A; Prevention of *Pneumocystis jiroveci* pneumonia or *Pneumocystis carinii* 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" **for Re-Authorization under Approval Length**. 6. **Added** "http://cid.oxfordjournals.org/content/43/9/1089.long" **and** "http://www.cdc.gov/parasites/babesiosis/health_professionals/index.html#tx" **under References**.
1/9/2014	1. **Adapted policy to new format.** 2. **Added GPI code**. 3. **Changed Prior Authorization Criteria from**: . "Patient requires prophylaxis treatment or treatment for an acute Pneumocystis carinii 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 (Babesia) infection AND laboratory confirmation of Babesiosis is required" **to:** "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 *Pneumocystis jiroveci* pneumonia or *Pneumocystis carinii* pneumonia (PCP) and

Historical Tracking Of Changes Made To Policy	
	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 *Pneumocystis jiroveci* pneumonia or *Pneumocystis carinii* 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 (*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". 4. **Changed Other Criteria from** "N/A" **to** "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 plus Azithromycin 500 mg on day 1 followed by 250 mg Azithromycin daily for 7 days". 5. **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)". 6. **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 *Pneumocystis jiroveci* pneumonia or *Pneumocystis carinii* pneumonia (PCP) PCP treatment: 1 time only; Treatment for active Babesiosis (*Babesia*) infection: 1 time only; Prevention of *Pneumocystis jiroveci* pneumonia or *Pneumocystis carinii* pneumonia (PCP): 3 months". 7. **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 *Pneumocystis jiroveci* pneumonia or *Pneumocystis carinii* pneumonia (PCP): N/A; Treatment for active Babesiosis (*Babesia*) infection: N/A; Prevention of *Pneumocystis jiroveci* pneumonia or *Pneumocystis carinii* pneumonia (PCP): An updated letter of medical necessity or progress notes showing the medication is effective and that prevention is still recommended". 8. **Updated references** to Medi-Span.