

## Commercial/Healthcare Exchange PA Criteria

Effective: March 1, 2009

**Prior Authorization:** Antimalarials

**Products Affected:** Coartem (artemether and lumefantrine) oral tablet, mefloquine hydrochloride oral tablet, chloroquine phosphate oral tablet, Malarone (atovaquone and proguanil)

**Medication Description:**

Mefloquine is an antimalarial agent. Its exact mechanism of action is not known.

Atovaquone and proguanil HCl, antimalarial agents, act against the erythrocytic and exoerythrocytic stages of plasmodium species. Atovaquone selectively inhibits mitochondrial electron transport. Proguanil HCl is metabolized into the active metabolite cycloguanil which inhibits dihydrofolate reductase required for deoxythymidylate (pyrimidine) synthesis, with subsequent disruption of DNA synthesis in the malarial parasite.

**Covered Uses:**

1. Coartem: Treatment of acute, uncomplicated malaria infections due to Plasmodium falciparum (*P. falciparum*) in patients 2 months of age and older with a bodyweight of 5 kg and above.
2. Mefloquine hydrochloride: Treatment of mild to moderate acute malaria caused by mefloquine-susceptible strains of *P. falciparum* (both chloroquine-susceptible and resistant strains) or by Plasmodium vivax.
3. Chloroquine phosphate: Suppressive treatment and for acute attacks of malaria due to *P. vivax*, *P. malariae*, *P. ovale*, and susceptible strains of *P. falciparum*. The drug is also indicated for the treatment of extraintestinal amebiasis.
4. Malarone is indicated for the treatment of acute, uncomplicated *P. falciparum* malaria.

**Exclusion Criteria:**

1. Coartem:
  - a. Coadministration of strong inducers of CYP3A4 such as rifampin, carbamazepine, phenytoin, and St. John's wort
  - b. Patients with severe or complicated *P. falciparum* malaria.
2. Mefloquine hydrochloride: Patients with a known hypersensitivity to mefloquine or related compounds (e.g., quinine and quinidine)
3. Chloroquine phosphate:
  - a. Patients with retinal or visual field changes either attributable to 4-aminoquinoline compounds or to any other etiology
  - b. Patients with known hypersensitivity to 4-aminoquinoline compounds.
4. Atovaquone/Proguanil –
  - a. Known hypersensitivity reactions (e.g., anaphylaxis, erythema multiforme or Stevens-Johnson syndrome, angioedema, vasculitis) to atovaquone or proguanil hydrochloride or any component of the formulation.

**Required Medical Information:**

1. Diagnosis

**Age Restrictions:**

Coartem: 2 months of age and older

Mefloquine hydrochloride: 6 months of age and older

Chloroquine phosphate: N/A

Atovaquone/Proguanil HCl: weight based  $\geq 5$ kg

**Prescriber Restrictions:** N/A

**Coverage Duration:** 2 weeks

**Other Criteria:**

***Coartem***

- A. Patient has a diagnosis of acute, uncomplicated malaria infections due to Plasmodium falciparum (P. falciparum)

***Mefloquine hydrochloride***

- A. Patient has a diagnosis of mild to moderate acute malaria caused by mefloquine-susceptible strains of P. falciparum (both chloroquine-susceptible and resistant strains) or by Plasmodium vivax.

***Chloroquine phosphate***

- A. Patient has a diagnosis of acute malaria due to P. vivax, P. malariae, P. ovale, and susceptible strains of P. falciparum OR extraintestinal amebiasis.

***Atovaquone and Proguanil***

- A. Patient has a diagnosis of acute, uncomplicated malaria infections due to P. Falciparum

***\*Note: Malaria prevention is a benefit exclusion per the ConnectiCare Membership Agreement***

**References:**

1. MEFLOQUINE HYDROCHLORIDE oral tablets, mefloquine HCl oral tablets. Barr Laboratories Inc. (per DailyMed), Sellersville, PA, 2013
2. COARTEM(R) oral tablets, artemether lumefantrine oral tablets. Novartis Pharmaceuticals Corporation (per FDA), East Hanover, NJ, 2019
3. Chloroquine phosphate oral tablets, chloroquine phosphate oral tablets. West-ward Pharmaceutical Corp, Eatontown, NJ, 2009
4. Product Information: MALARONE(R) oral tablets, pediatric tablets, atovaquone proguanil HCl oral tablets, pediatric tablets. GlaxoSmithKline (per manufacturer), Research Triangle Park, NC, 2019.

**Policy Revision history**

<b>Rev #</b>	<b>Type of Change</b>	<b>Summary of Change</b>	<b>Sections Affected</b>	<b>Date</b>
1	New Policy	New Policy	All	3/2009
2	Update	Moved to updated template Added age restrictions	All	2/7/2020
3	Update	Added Atovaquone/Proguanil HCL to products affected, medication description, covered uses, exclusion criteria, age restrictions and other criteria.	Products affects, medication description, covered uses, exclusion criteria, age restriction, other criteria	11/2022

Last Rev. November 2022