

Commercial/Healthcare Exchange PA Criteria

Effective: June 2007

Prior Authorization: Qualaquin

Products Affected: Qualaquin (quinine sulfate)

Medication Description: Qualaquin is an oral antimalarial agent that is indicated for the treatment of uncomplicated *Plasmodium falciparum* malaria. Qualaquin inhibits nucleic acid synthesis, protein synthesis, and glycolysis in *Plasmodium falciparum* organisms. It also binds to hemazoin in parasitized erythrocytes.

Covered Uses:

1. Uncomplicated *P. falciparum* malaria.
2. For the treatment of active Babesiosis (*Babesia*) infection. (not FDA-approved, but sufficient evidence to support its use)

Exclusion Criteria:

Qualaquin is contraindicated in patients with the following:

1. Prolonged QT interval
2. Glucose-6-phosphate dehydrogenase (G6PD) deficiency
3. Known hypersensitivity reactions to quinine
4. Known hypersensitivity to mefloquine or quinidine
5. Myasthenia gravis
6. Optic neuritis

Required Medical Information:

1. Diagnosis
2. Laboratory values

Age Restrictions: 16 years of age and older

Prescriber Restrictions: N/A

Coverage Duration:

For treatment of uncomplicated *P. falciparum* malaria: 7 days
Babesiosis: 10 days

Other Criteria:

Malaria

- A. Patient has a diagnosis of uncomplicated *Plasmodium falciparum* malaria.

Babesiosis (*Babesia*) infection

- A. Patient has a diagnosis of Babesiosis (*Babesia*) infection [documentation required].

References:

1. Qualaquin full prescribing information. AR Scientific Inc. Philadelphia, PA
2. U.S. Food and Drug Administration (FDA). FDA Orders Unapproved Quinine Drugs From the Market and Cautions Consumers About “Off-Label” Use of Quinine To Treat Leg Cramps. PO6-195 Rockville, MD; December 11,2006. Available at: <http://www.fda.gov/bbs/topics/NEWS/2006/NEW01521.html> Accessed June 4,2006.
3. Reddy JC, Shuman MA, Aster RH. Quinine/quinidine-induced thrombocytopenia:a great imitator. Arch Intern Med 2004;164:218-20.
4. The Sanford Guide To Antimicrobial Therapy 2006. 36th Edition

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	June 2007
2	Policy Update	<p>Updated Template from CCI to EH</p> <p>Updated Exclusion Criteria to include additional FDA labeled contraindications</p> <p>CCI Revision Record: 11/16</p>	All	2/3/2020

3	Policy Update	Updated Covered Uses, Exclusion Criteria and Age Restriction to match FDA label	Covered Uses, Exclusion Criteria, Age Restriction	6/4/2020
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