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	Updated Template from CCI to EH Updated Exclusion Criteria to include additional FDA labeled contraindications CCI Revision Record: 11/16	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