

Market Applicability/Effective Date															
Market	FL & FHK	FL MMA	FL LTC	GA	IND	KS	KY	LA	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	NA	NA	X	X	NA	X	X	X	X	X	X	NA	NA	X

*FHK- Florida Healthy Kids

Qualaquin (quinine)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Qualaquin (quinine)	60 per year
Quinine sulfate-various	60 per year

APPROVAL CRITERIA

Requests for Qualaquin (quinine sulfate) may be approved when the following criteria have been met:

- I. Individual has been diagnosed with uncomplicated malaria caused by one of the following:
 - a. *Plasmodium falciparum* known or suspected to be resistant to chloroquine (CDC 2013); **OR**
 - b. Chloroquine-resistant *Plasmodium vivax* (CDC); **OR**
 - c. An unidentified plasmodial species known or suspected to be resistant to chloroquine (CDC 2013);
- OR**
- II. Individual is using as follow-up treatment after appropriate initial parenteral regimen for treatment of severe or complicated malaria (AHFS);
- OR**
- III. Individual has been diagnosed with babesiosis caused by *Babesia microti* and treatment is in conjunction with IV or oral clindamycin (Drugdex)

Qualaquin (quinine sulfate) **may not** be approved for the following:

- I. Treatment or prevention of nocturnal recumbency leg muscle cramps or other related conditions, such as but not limited to:

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

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- a. Myoclonus; **OR**
- b. Periodic Limb Movements of Sleep (PLMS); **OR**
- c. Restless Leg Syndrome (RLS); **OR**
- II. Initial treatment of severe or complicated *P. falciparum* malaria; **OR**
- III. Prevention of malaria; **OR**
- IV. Individuals with severe hepatic impairment (Child-Pugh C); **OR**
- V. Individuals with known prolongation of the QT interval; **OR**
- VI. Individuals with glucose-6-phosphate dehydrogenase (G6PD) deficiency; **OR**
- VII. Individuals with myasthenia gravis; **OR**
- VIII. Individuals with optic neuritis.

Note: Qualaquin (quinine sulfate) has a black box warning for use to prevent or treat nocturnal leg cramps. Serious and life-threatening hematologic reactions, such as thrombocytopenia and hemolytic uremic syndrome/thrombotic thrombocytopenic purpura (HUS/TTP) may result. The risk associated with use in the absence of evidence of its effectiveness in the treatment or prevention of nocturnal leg cramps outweighs any potential benefit.

State Specific Mandates		
N/A	N/A	N/A

Key References:

Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2015. URL: <http://www.clinicalpharmacology.com>. Updated periodically.

DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: 11/2015.

DrugPoints® System [Internet Database]. Greenwood Village, CO: Thomson Reuters (Healthcare) Inc. Updated periodically.

Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2015; Updated periodically.

NCCN Drugs & Biologics Compendium (NCCN Compendium) 2015 National Comprehensive Cancer Network, Inc. Available at: NCCN.org. Updated periodically.

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