

Market Applicability														
Market	DC	FL & FHK	FL MMA	FL LTC	GA	KS	KY	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

*FHK- Florida Healthy Kids

Qualaquin (quinine)

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

Medications	Quantity Limit
Qualaquin (quinine) Quinine sulfate-various	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Qualaquin (quinine sulfate) may be approved if the following criteria are 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); **OR**
 - B. Chloroquine-resistant *Plasmodium vivax* (AHFS, CDC); **OR**
 - C. An unidentified plasmodial species known or suspected to be resistant to chloroquine (AHFS, CDC);
- 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 (AHFS, DrugPoints B IIa).

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:
 - A. Myoclonus; **OR**
 - B. Periodic Limb Movements of Sleep (PLMS); **OR**
 - C. Restless Leg Syndrome (RLS); **OR**
- II. Initial treatment of severe or complicated malaria; **OR**

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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- 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		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

Key References:

1. Centers for Disease Control and Prevention (CDC). Guidelines for treatment of malaria in the United States (Based on drugs currently available for use in the United States - July 1, 2013). Available at <http://www.cdc.gov/malaria/resources/pdf/treatmenttable.pdf>. Accessed: October 2, 2018.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2018. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
3. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: October 1, 2018.
4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2018; Updated periodically.

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