

# Quinine Sulfate

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

  

Medications	Quantity Limit
Quinine sulfate-various	May be subject to quantity limit

## APPROVAL CRITERIA

Requests for 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**
  - D. Chloroquine-resistant *Plasmodium ovale* (CDC); **OR**
  - E. Chloroquine-sensitive *Plasmodium malariae* (CDC); **OR**
  - F. Chloroquine-sensitive *Plasmodium knowlesi* (CDC); **OR**
  - G. Chloroquine-sensitive *Plasmodium falciparum*, *Plasmodium vivax* or *Plasmodium ovale* AND one of the following (CDC):
    1. Individual is pregnant; **OR**
    2. Chloroquine and hydroxychloroquine are not available;
- OR**
- II. Individual has been diagnosed with severe malaria AND one of the following (CDC):
  - A. Individual is using as interim treatment until intravenous artesunate is available; **OR**
  - B. Individual is using as follow-on treatment after intravenous artesunate;
- 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)

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. Prevention of malaria; **OR**
- III. Individuals with severe hepatic impairment (Child-Pugh C); **OR**
- IV. Individuals with known prolongation of the QT interval; **OR**
- V. Individuals with myasthenia gravis; **OR**
- VI. Individuals with optic neuritis.

**Note:** 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.

**Key References:**

1. Centers for Disease Control and Prevention (CDC). Malaria. Diagnosis & Treatment in the United States. Malaria Treatment (United States). Available at: [https://www.cdc.gov/malaria/diagnosis\\_treatment/treatment.html](https://www.cdc.gov/malaria/diagnosis_treatment/treatment.html). Last Updated: November 2, 2020. Accessed: December 12, 2020.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: December 12, 2020.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2020; Updated periodically.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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