

Clinical Policy: Quinine Sulfate (Qualaquin)

Reference Number: HIM.PA.144

Effective Date: 10.31.17

Last Review Date: 02.18

Line of Business: Health Insurance Marketplace

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

Quinine sulfate (Qualaquin[®]) is an antimalarial drug.

FDA Approved Indication(s)

Qualaquin is indicated only for treatment of uncomplicated *Plasmodium falciparum* (*P. falciparum*) malaria.

Quinine sulfate has been shown to be effective in geographical regions where resistance to chloroquine has been documented.

Policy/Criteria

Provider must submit documentation (including such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation[®] that Qualaquin is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Malaria (must meet all):

1. Diagnosis of malaria;
2. Failure of a formulary antimalarial agent (e.g., atovaquone-proguanil, Coartem, chloroquine, hydroxychloroquine, mefloquine) unless all are contraindicated or clinically significant adverse effects are experienced, or causative species is resistant to all formulary antimalarial agents;
3. Dose does not exceed 1944 mg/day (6 capsules/day).

Approval duration: 7 days

B. Babesiosis (off-label) (must meet all):

1. Diagnosis of babesiosis;
2. Dose does not exceed 1944 mg/day (6 capsules/day).

Approval duration: Duration of request or 10 days (whichever is less)

C. Other diagnoses/indications

1. Refer to HIM.PHAR.21 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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II. Continued Therapy

A. Malaria or Babesiosis (off-label): Request must be evaluated against the initial approval criteria.

B. Other diagnoses/indications (must meet 1 or 2):

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.

Approval duration: Duration of request or 7 days (whichever is less); or

2. Refer to HIM.PHAR.21 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – HIM.PHAR.21 or evidence of coverage documents;

B. Prevention of malaria;

C. Treatment or prevention of nocturnal leg cramps.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

CDC: Centers for Disease Control and Prevention

FDA: Food and Drug Administration

Appendix B: General Information

For more information on the treatment of malaria, refer to the CDC website:

<https://www.cdc.gov/malaria/resources/pdf/clinicalguidance.pdf>.

For more information on the treatment of babesiosis, refer to the CDC website:

https://www.cdc.gov/parasites/babesiosis/health_professionals/index.html.

V. References

1. Quaalquin Prescribing Information. Philadelphia, PA: Mutual Pharmaceutical Company, Inc.; April 2013. Available at: <https://dailymed.nlm.nih.gov/dailymed/>. Accessed October 12, 2017.
2. Centers for Disease Control guidelines for treatment of malaria. Available at: <http://www.cdc.gov/malaria/resources/pdf/treatmenttable.pdf>. Accessed October 12, 2017.
3. Centers for Disease Control and Prevention. Parasites - Babesiosis: Treatment. https://www.cdc.gov/parasites/babesiosis/health_professionals/index.html. Accessed October 12, 2017.
4. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2016. Available at: <http://www.clinicalpharmacology-ip.com/>. Accessed October 12, 2017.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	10.31.17	02.18

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Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members

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