

Pharmacy Policy Bulletin

Title: Quinine Sulfate (Qualaquin®)

Policy #: Rx.01.77

Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, quantity, or formulary restrictions (ie limits on non-preferred drugs). Individual member benefits must be verified.

This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

Intent:

The intent of this policy is to communicate the medical necessity criteria for **quinine sulfate (Qualaquin®)** as provided under the member's prescription drug benefit.

Description:

Quinine sulfate (Qualaquin®) is an oral antimalarial agent that is indicated for the treatment of uncomplicated Plasmodium falciparum malaria.

Quinine sulfate (Qualaquin®) inhibits nucleic acid synthesis, protein synthesis, and glycolysis in Plasmodium falciparum organisms. It also binds to hemazoin in parasitized erythrocytes. However, the precise mechanism of antimalarial activity of quinine sulfate (Qualaquin®) is not completely understood.

Quinine is associated with side effects including, but not limited to, abnormal heart rhythms and severe hypersensitivity reactions. Due to the serious health risks associated with the drug, quinine sulfate (Qualaquin®) should be used only for the treatment of uncomplicated Plasmodium falciparum malaria.

Policy:

Quinine sulfate (Qualaquin®) is approved when there is documentation of BOTH of the following:

1. Diagnosis of uncomplicated Plasmodium falciparum malaria; AND
2. One of the following:
 - a) Both of the following:
 - I. Treatment in areas of chloroquine-sensitive malaria; and
 - II. Inadequate response or inability to tolerate chloroquine or hydroxychloroquine; OR
 - b) Treatment in areas of chloroquine-resistant malaria.

Authorization duration: 2 years

Black Box Warning as shown in the drug Prescribing Information:

Quinine use for the treatment or prevention of nocturnal leg cramps may result in serious and life-threatening hematologic reactions, including thrombocytopenia and hemolytic uremic syndrome/thrombotic thrombocytopenic purpura (HUS/TTP). Chronic renal impairment associated with the development of TTP has been reported. The risk associated with quinine use in the absence of evidence of its effectiveness in the treatment or prevention of nocturnal leg cramps outweighs any potential benefit.

Guidelines:

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the prescription drug benefits of the Company's products when the medical necessity criteria listed

in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

References:

Qualaquin® (Quinine Sulfate) [package insert]. Mumbai, India. Sun Pharmaceuticals. December 2018.
<https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=0b5bbefd-5b56-46f9-84f5-1456371577fd>. Accessed: July 24, 2021

Applicable Drugs:

Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

Brand Name	Generic Name
Qualaquin®	quinine sulfate

Cross References:

Off-Label Use policy Rx.01.33

Policy Version Number:	12.00
P&T Approval Date:	June 10, 2021
Policy Effective Date:	October 01, 2021
Next Required Review Date:	June 10, 2022

The Policy Bulletins on this web site were developed to assist the Company in administering the provisions of the respective benefit programs, and do not constitute a contract. If you have coverage through the Company, please refer to your specific benefit program for the terms, conditions, limitations and exclusions of your coverage. Company does not provide health care services, medical advice or treatment, or guarantee the outcome or results of any medical services/treatments. The facility and professional providers are responsible for providing medical advice and treatment. Facility and professional providers are independent contractors and are not employees or agents of the Company. If you have a specific medical condition, please consult with your doctor. The Company reserves the right at any time to change or update its Policy Bulletins.
