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, gender or quantity restrictions. 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 pharmacy benfit.

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 uncomplicated Plasmodium falciparum malaria.

Black Box Warning:

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 pharmacy 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]. Cranbury, NJ. Sun Pharmaceutical Industries, Inc. July 2014. Available at: https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=1c44c8b7-8b38-4487-a8ba-a94f708d1f50&type=display. Accessed January 31, 2017.

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:

Policy Version Number:	8.00
P&T Approval Date:	January 12, 2017
Policy Effective Date:	March 01, 2017
Next Required Review Date:	January 12, 2018