Pharmacy Medical Necessity Guidelines:
Quinine

Effective: January 13, 2026

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM
These pharmacy medical necessity guidelines apply to the following: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RXUM: 617.673.0939	

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

Quinine is indicated for the treatment of uncomplicated chloroquine-resistant *P. falciparum* malaria in conjunction with other antimalarial agents.

Quinine has a Black Box Warning, recommending that it not be used for the treatment or prevention of nocturnal leg cramps, as it 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 treatment or prevention of nocturnal leg cramps outweighs any potential benefit.

COVERAGE GUIDELINES

The plan may authorize coverage of quinine for Members when **ALL** of the following criteria are met:

1. Documented diagnosis of malaria

LIMITATIONS

1. Approval will be limited to 42 capsules for a one-time 7-day treatment course.
2. Quinine will not be approved for the treatment of leg cramps.
3. Requests for brand-name products, which have AB-rated generics, will be reviewed according to Non-covered Medications criteria.

CODES

None

REFERENCES

1. Arch Intern Med. 2012 Jan 23;172(2):120-6. doi: 10.1001/archinternmed.2011.1029. Epub 2011 Dec 12.
2. Qualaquin (quinine sulfate) [prescribing information]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc; March 2021.

APPROVAL HISTORY

October 11, 2022: Reviewed by Pharmacy & Therapeutics Committee.
Subsequent endorsement date(s) and changes made:

1. May 9, 2023: No changes.
2. January 9, 2024: Effective February 1, 2024, updated fax number for RxUM.
3. January 14, 2025: No changes
4. January 13, 2026: No changes.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.

Provider Services