Pharmacy Medical Necessity Guidelines: Quinine

Effective: January 12, 2021

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:

Commercial Products

☐ Tufts Health Plan Commercial products – large group plans
☐ Tufts Health Plan Commercial products – small group and individual plans
☐ Tufts Health Freedom Plan products – large group plans
☐ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Public Plans Products

☐ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☒ Tufts Health RITogether – A Rhode Island Medicaid Plan

Fax Numbers:
RXUM: 617.673.0988

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. Qualaquin (quinine sulfate) [prescribing information]. Detroit, MI: Caraco Pharmaceutical Laboratories, Ltd; July 2014.
2. Arch Intern Med. 2012 Jan 23;172(2):120-6. doi: 10.1001/archinternmed.2011.1029. Epub 2011 Dec 12.

APPROVAL HISTORY

January 13, 2015: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. January 1, 2016: Administrative change to rebranded template.
2. June 14, 2016: Removed limitation #2 "Requests for quantities that exceed the quantity limit will be reviewed according to the Quantity Limit criteria." Added limitation #2 "Requests for brand-name products, which have AB-rated generics, will be reviewed according to Non-covered Medications criteria."

3. May 9, 2017: Administrative update. Effective 6/1/2017, Medical Necessity Guideline applies to Tufts Health RITogether.
4. June 13, 2017: No changes.
5. June 12, 2018: Effective 10/1/2018, removed criteria for leg cramps. Updated approval quantity limits to remove the treatment dose and duration for leg cramps. Added to the limitations section that quinine will not be approved for the treatment of leg cramps.
6. February 12, 2019: Administrative changes made to template.
7. January 14, 2020: No changes.
8. January 12, 2021: 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.