

Pharmacy Medical Necessity Guidelines: Chloroquine and Hydroxychloroquine

Effective: 7/14/2020

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	MED	Department to Review	RxUM
<p>This Pharmacy Medical Necessity Guideline applies to the following:</p> <p>Tufts Health Plan Commercial Plans</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Tufts Health Plan Commercial Plans – large group plans <input checked="" type="checkbox"/> Tufts Health Plan Commercial Plans – small group and individual plans <p>Tufts Health Public Plans</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Tufts Health Direct – Health Connector <input checked="" type="checkbox"/> Tufts Health Together – A MassHealth Plan <input checked="" type="checkbox"/> Tufts Health RITogether – A RItE Care + Rhody Health Partners Plan <p>Tufts Health Freedom Plan products</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Tufts Health Freedom Plan - large group plans <input checked="" type="checkbox"/> Tufts Health Freedom Plan - small group plans <ul style="list-style-type: none"> • This policy also applies to SCO-Medi (Medicaid Only) members 		<p>Fax Numbers:</p> <p>All plans except Tufts Health Public Plans: PRECERT: 617.972.9409</p> <p>Tufts Health Public Plans only: MM: 888.415.9055</p> <p>RXUM: 617.673.0988</p>	

Note: For Tufts Health Plan Medicare Preferred Members, please refer to the Tufts Health Plan Medicare Preferred Prior Authorization Criteria. Background, applicable product and disclaimer information can be found on the last page.

OVERVIEW

The medications listed in this Pharmacy Medical Necessity Guidelines are approved for use in the treatment of several diseases. The purpose of this policy is to prevent the stockpiling, misuse and/or overuse of the medications listed herein.

COVERAGE GUIDELINES

The plan may authorize coverage of hydroxychloroquine and chloroquine for Members when all of the following criteria are met:

1. Documentation that the intended use is for an FDA approved indication or is supported by clinical compendia (e.g. Malaria, rheumatoid arthritis, systemic lupus erythematosus, etc.)

AND

2. The prescribing physician attests that they have a patient-physician relationship, has examined the patient (physical exam or via telemedicine), and is prescribing within the scope of their practice.

LIMITATIONS

- This policy applies to members who are new to the treatment with hydroxychloroquine and chloroquine
- Coverage of Hydroxychloroquine and Chloroquine will not be authorized for treatment of COVID infection

CODES

None

REFERENCES

1. All Provider Bulletin 291, MassHealth Coverage and Reimbursement Policy for Services Related to Coronavirus Disease 2019 (COVID-19). March 2020. Available: <https://www.mass.gov/doc/all-provider-bulletin-291-masshealth-coverage-and-reimbursement-policy-for-services-related-0/download>
2. Bulletin 2020-06: Administration of Prescription Drug Benefits during COVID-19 (Coronavirus) Public Health Crisis. Available: <https://www.mass.gov/doc/bulletin-2020-06-administration-of-prescription-drug-benefits-during-covid-19-coronavirus-public/download>

3. Off label prescribing of medications for Covid-19. Title 216, Chapter 20, Subchapter 20, Part 6. State of Rhode Island Department of Health. Available: https://risos-apa-production-public.s3.amazonaws.com/DOH/REG_11012_20200323093426.pdf
4. Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak. March 13, 2020. <https://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/>
5. FDA Press Announcement: "Coronavirus (COVID-19) Update: FDA Revokes Emergency Use Authorization for Chloroquine and Hydroxychloroquine", released on June 15, 2020. Available at: <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-revokes-emergency-use-authorization-chloroquine-and>

APPROVAL HISTORY

April 2, 2020: Reviewed and Approved by Tufts Health Plan's Clinical Pharmacy Team.

Subsequent endorsement date(s) and changes made:

- July 14, 2020: Removed coverage criteria for hydroxychloroquine and chloroquine for treatment of COVID infection. Added reference about FDA's announcement to revoke emergency use authorization of these medications.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. They are used in conjunction with a Member's benefit document and in coordination with the Member's physician(s). 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.

This Pharmacy Medical Necessity Guideline does not apply to Uniformed Services Family Health Plan Members or to certain delegated service arrangements. Unless otherwise noted in the Member's benefit document or applicable Pharmacy Medical Necessity Guideline, Pharmacy Medical Necessity Guidelines do not apply to CareLinkSM Members. For self-insured plans, drug coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a coverage guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern. Applicable state or federal mandates will take precedence.

For Tufts Health Plan Medicare Preferred, please refer to Tufts Health Plan Medicare Preferred Prior Authorization Criteria.

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.