

PROVIDER INFORMATION

Hydroxychloroquine for COVID-19

QUICK FACTS

HYDROXYCHLOROQUINE FDA APPROVED INDICATIONS

Malaria (treatment and prevention),
rheumatoid arthritis, and lupus

INCREASED DRUG PRODUCTION

Several manufacturers have reported
plans to increase production of
hydroxychloroquine

CLINICAL TRIALS – U.S.¹

One phase 2/phase 3 clinical trial is
underway through the University of
Minnesota (seeking 1500 participant
enrollment)

Several more clinical trials planned or
enrolling soon, per CDC²

CLINICAL TRIALS – OUTSIDE U.S.³

There are at least 10 clinical trials with
hydroxychloroquine/chloroquine
underway outside the U.S.

OPEN LABEL STUDY – FRANCE⁴

Results suggest hydroxychloroquine
improved viral clearance compared to
control (n=36 patient results)

IN VITRO STUDIES⁵

Several *in vitro* studies have
demonstrated effect of
hydroxychloroquine on inhibiting
COVID-19 virus

HYDROXYCHLOROQUINE FOR COVID-19

PROCESS FOR PROVIDERS

- Hydroxychloroquine is FDA approved for conditions other than COVID-19 so no additional forms (IRB approval, treatment plan, etc.) need to be completed prior to writing a prescription.
- Hydroxychloroquine is still considered investigational for COVID-19 as it has not been approved or cleared by the FDA as safe or effective for this indication.
- Clinical trials: FDA suggests visiting www.clinicaltrials.gov to determine trial availability for a patient, although enrollment is not always possible or feasible.
- Potential dosing options (*anecdotally per CDC*²):
 - 400 mg BID on day one, then 400 mg daily for 5 days
 - 400 mg BID on day one, then 200 mg BID for 4 days
 - 600 mg BID on day one, then 400 mg daily on days 2-5
- Although not required, consider increased monitoring and data collection in patients taking medication for COVID-19.

SUMMARY OF AVAILABLE DATA

- Preliminary research has shown that hydroxychloroquine may be an effective medication to help **treat and prevent** COVID-19 (prophylaxis demonstrated *in vitro* only).
- Completed Human Trials:
 - The primary outcome of virological cure at day 6 after study inclusion was achieved in 70% (14/20) of hydroxychloroquine-treated patients as compared to 12.5% (2/16) of controls (p = 0.001).⁴
 - In preliminary reports from Chinese authorities, ~100 patients with COVID-19 treated with chloroquine demonstrated faster symptom improvement, shorter recovery time, and inhibited exacerbation of pneumonia compared to controls.⁶

ADDITIONAL INFORMATION

Patients may still be able to spread the COVID-19 virus, even while taking this medication. Continue to recommend strategies to prevent the spread of infection.

References:

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2. Information for Clinicians on Therapeutic Options for COVID-19 Patients. <https://www.cdc.gov/coronavirus/2019-ncov/hcp/therapeutic-options.html>. Updated March 21, 2020. Accessed March 21, 2020.
3. Cortegiani A, et al. A systematic review on the efficacy and safety of chloroquine for the treatment of COVID-19 [published online ahead of print, 2020 Mar 10]. *J Crit Care*. 2020;50883-9441(20)30390-7.
4. Gautret P, Lagier JC, Parola P, et al. Hydroxychloroquine and azithromycin as a treatment of COVID-19: results of an open-label non-randomized clinical trial. *International Journal of Antimicrobial Agents*. In Press March 17, 2020.
5. Yao X, et al. In Vitro Antiviral Activity and Projection of Optimized Dosing Design of Hydroxychloroquine for the Treatment of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2). *Clin Infect Dis*. 2020 Mar 9. [Epub ahead of print]
6. Gao J, Tian Z, Yang X. Breakthrough: Chloroquine phosphate has shown apparent efficacy in treatment of COVID-19 associated pneumonia in clinical studies. *Biosci Trends*. 2020;14(1):72-73.

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