

Dear Valued Patient,

Our physicians have received many questions recently about hydroxychloroquine as early outpatient treatment for SARS-CoV-2 infection. The physicians at North Texas Preferred Health Partners follow evidence based, science backed therapy for disease management. The use of hydroxychloroquine as a therapy for COVID 19 treatment or prevention is not supported by the current science.

COVID-19 is a new disease with often rapidly changing recommendations. The worldwide scientific community has diligently been working to find effective therapies for both early outpatient disease and for inpatient disease. Remember back to your basic science courses and the scientific method where we form a hypothesis, test the hypothesis, collect data, analyze data and draw a conclusion? This is what the worldwide scientific community has been working diligently to do and it is important that we remember how important each step is to help us draw the right conclusions.

As of November 2020, we do have therapies that are promising for outpatient severe disease. In Dallas, we have access to several ongoing well-designed clinical trials for early outpatient therapy including IV remdesivir, inhaled remdesivir, monoclonal antibody therapy, oral favipiravir, and oral colchicine. If our patients are interested in early outpatient therapy, we recommend participation in one of the many ongoing randomized, double-blind, placebocontrolled trials in Dallas. Your NTPHP physician can help you decide if a clinical trial is right for you.

At this time, there is no agreed upon "Gold Standard" outpatient therapy. There have been two published randomized clinical trials to date that have evaluated hydroxychloroquine for early outpatient treatment, and benefit has not been shown. Similarly, 4 randomized controlled trials have failed to demonstrate the benefit of hydroxychloroquine in hospitalized patients with COVID-19. Randomized, double blind, placebo-controlled trials are the most accurate for determining if any therapy is beneficial to a population of patients. The few studies that suggested a benefit of hydroxychloroquine are primarily observational studies, which are less accurate and are subject to much bias. This can make a therapy appear to be helpful when it is not. All medications have side effects and those of hydroxychloroquine are rare but can be very serious. If you are interested in reading more about the hydroxychloroquine randomized controlled trials, here is a helpful link that consolidates the available evidence: http://www.medscape.com/viewarticle/935058.

Similarly, three randomized clinical trials regarding the use of hydroxychloroquine for prevention of COVID-19 have been published to date that concluded that hydroxychloroquine



was ineffective in preventing COVID-19. Baylor University Medical Center conducted a study to "assess the efficacy of hydroxychloroquine treatment weekly for a total of 7 weeks in the prevention of COVID-19 infection." This study was completed in July and results have not yet been published. In addition, UTSW is one study site for a double blind, placebo-controlled study in approximately 2,000 healthcare workers at risk for being exposed to COVID-19. Participants will be randomly assigned to either hydroxychloroquine treatment or placebo and the course of treatment is 30 days. Enrollment ends in November 2020 and we expect results in early 2021. If the data from these additional studies support the use of hydroxychloroquine for prevention, our physicians will update their recommendations.

We understand the desire of all physicians is to find effective therapies to help reduce the risk of disease progression. We also recognize that during a pandemic rapid evaluation of available scientific data is needed and that reliable data is often available in advance of an official guideline. It is important to study the data, follow the science, and adapt as more information becomes available. Our physicians spend many hours per week participating in educational activities advancing our knowledge regarding COVID-19. We also regularly consult with our local infectious disease and public health experts. The physicians at NTPHP are committed to providing the best, science based, up-to-date care for all our patients.

Sincerely,

North Texas Preferred Health Partners



Please complete listing of the sources used for content in the letter below:

http://www.medscape.com/viewarticle/935058

https://pubmed.ncbi.nlm.nih.gov/32673060/

https://pubmed.ncbi.nlm.nih.gov/32674126/

https://www.nejm.org/doi/full/10.1056/NEJMoa2022926

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7397548/

https://acpinternist.org/weekly/archives/2020/08/04/1.htm

https://www.acponline.org/acp-newsroom/acp-evidence-does-not-support-chloroquine-or-hcg-use-alone-or-in-combination-with-azithromycin-as

https://www.ijidonline.com/article/S1201-9712(20)30534-8/fulltext

https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-reiterates-importance-close-patient-supervision-label-use

https://www.fda.gov/drugs/drug-safety-and-availability/fda-cautions-against-use-hydroxychloroquine-or-chloroquine-covid-19-outside-hospital-setting-or

https://clinicaltrials.gov/ct2/show/NCT04333225

https://www.clinicaltrials.gov/ct2/show/study/NCT04334148

https://www.bmj.com/content/369/bmj.m1849

https://www.nejm.org/doi/full/10.1056/nejmoa2019014

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https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2771265