

April 24, 2020

COM-2020-034

Dear provider of healthcare-related services,

As part of our effort to support you and keep you informed regarding rapidly changing measures taken in response to COVID-19, we want to notify you that the Food and Drug Administration (FDA) has published a safety communication for hydroxychloroquine or chloroquine for COVID-19.

The FDA is concerned that hydroxychloroquine and chloroquine are being inappropriately used to treat COVID-19 in non-hospitalized patients or to prevent COVID-19, and is warning that the use of these medications for COVID-19 should be limited to clinical trial settings or for treating certain hospitalized patients under the emergency use authorization (EUA) issued by the agency on March 28, 2020. The EUA issued by the FDA only authorize the temporary use of hydroxychloroquine and chloroquine during the COVID-19 pandemic for treatment of the virus in hospitalized patients when clinical trials are not available, or participation is not feasible. We encourage the revision of the following documents for additional information regarding the EUA issued by the FDA:

- [Emergency Use Authorization For Use of Chloroquine Phosphate or Hydroxychloroquine Sulfate Supplied From the Strategic National Stockpile for Treatment of 2019 Coronavirus Disease](#)
- [Frequently Asked Questions on the Emergency Use Authorization \(EUA\) for Chloroquine Phosphate and Hydroxychloroquine Sulfate for Certain Hospitalized COVID-19 Patients](#)
- [Hydroxychloroquine healthcare provider fact sheet](#)
- [Chloroquine healthcare provider fact sheet](#)

The safety concerns announced by the FDA include:

- Reports of serious heart rhythm problems (e.g. QT interval prolongation and ventricular tachycardia) in patients with COVID-19 treated with hydroxychloroquine or chloroquine, often in combination with azithromycin and other QT prolonging drugs.
- Increased use of hydroxychloroquine and chloroquine through outpatient prescriptions.

The FDA wants to remind healthcare providers and patients of the known risks associated with both hydroxychloroquine and chloroquine and that even though they are under investigation for COVID-19, at the moment, they have not been shown to be safe and effective for treating or preventing COVID-19.

Although healthcare providers may prescribe or administer FDA-approved drugs for unapproved (off-label) uses based on their assessment of the potential benefits versus the risks for their patients, it is of great importance to be aware of the risks of serious and potentially life-threatening heart rhythm problems that can occur with hydroxychloroquine and chloroquine. Healthcare providers making individual patient decisions are encouraged to closely screen and monitor those patients to mitigate the known risks. If a healthcare provider is considering the use of hydroxychloroquine or chloroquine to treat or prevent



COVID-19, the FDA recommends checking [ClinicalTrials.gov](https://clinicaltrials.gov) for a suitable clinical trial and considering enrolling the patient.

Additional information regarding this safety communication from the FDA can be found at [MedWatch: The FDA Safety Information and Adverse Event Reporting Program](#).

The situation with the COVID-19 pandemic is dynamic and constantly changing. We strongly encourage the frequent revision of updated information provided by the FDA, the Centers for Disease and Control Prevention (CDC), and the World Health Organization (WHO), to assure that your practices are consistent with the most updated information.

PharmPix is committed to the health and wellness of our members, and to support you as the COVID-19 pandemic continues to evolve. It is our priority to offer high-quality services and support practices for health promotion and diseases prevention. If you have any questions or wish to have more information regarding this document, you can call us at 787-522-5252, extension 137.

Regards,

Clinical Department

References:

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2. FDA cautions use of hydroxychloroquine/chloroquine for COVID-19. U.S. Food and Drug Administration. (2020). Retrieved April 2020, from https://www.fda.gov/drugs/drug-safety-and-availability/fda-cautions-against-use-hydroxychloroquine-or-chloroquine-covid-19-outside-hospital-setting-or?utm_campaign=New%20FDA%20Drug%20Safety%20Communication%20on%20hydroxychloroquine%20and%20chloroquine&utm_medium=email&utm_source=Eloqua.
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4. Emergency Use Authorization. U.S. Food and Drug Administration. (2020). Retrieved April 2020, from <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>.

