Alabama Department of Public Health (ADPH)
Alabama Emergency Response Technology (ALERT)
Health Alert Network (HAN)
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FDA Advises Caution on Use of Hydroxychloroquine Outside of Hospital and Clinical Trials

Prescribers should exercise care when prescribing hydroxychloroquine for patients diagnosed with 2019 coronavirus disease (COVID-19). Currently, there are limited data showing the effectiveness of hydroxychloroquine in treating COVID-19, and it is not approved for the treatment of COVID-19 by the Food and Drug Administration (FDA). While an emergency use authorization (EUA) has been issued by the FDA for hydroxychloroquine, it is only for hospitalized patients who do not have access to a clinical trial and who can be closely monitored, and only covers hydroxychloroquine distributed from the Strategic National Stockpile. If prescribed under the EUA, healthcare providers must report all serious adverse effects and other data, such as outcomes, as specified in the EUA. To review the U.S. FDA Letter of Approval for Emergency Use Authorization go to https://www.fda.gov/media/136534/download

Hydroxychloroquine has significant and serious side effects, such as QT prolongation and hypoglycemia. Cases of life-threatening cardiomyopathy have been reported with its use, as have ventricular arrhythmias, torsades de pointes, irreversible retinal damage and critical issues with blood glucose. Please consider these complications before prescribing the drug to patients with heart rhythm conditions, kidney disease, liver disease, diabetes, certain blood problems, retinal concerns, or those who drink large amounts of alcohol. Hydroxychloroquine interacts with digoxin and potentiates the QT prolongation of azithromycin. Dosing recommendations for COVID-19 patients are higher than those for malaria. The drug is rapidly and completely absorbed after ingestion, and signs of complications can exhibit within 30 minutes. While it is common to prescribe some medications for unapproved conditions, it is important that there is scientific data showing the medication is safe and effective before prescribing off-label. For more on the FDA Safety Communication on use of hydroxychloroquine and chloroquine for COVID-19 visit https://www.fda.gov/media/137250/download

There are clinical trials of a number of other drugs that show some promise that can be found on the FDA website at https://www.fda.gov/drugs/coronavirus-covid-19-drugs/coronavirus-treatment-acceleration-program-ctap

There are numerous drugs being studied, but the one with most immediate promise appears to be remdesivir. On May 1, 2020, FDA issued an EUA to allow remdesivir to be distributed and used by licensed health care providers to treat adults and children hospitalized with severe COVID-19. Severe COVID-19 is defined as patients with an oxygen saturation (SpO2) ≤ 94% on room air or requiring supplemental oxygen or requiring mechanical ventilation or requiring extracorporeal membrane oxygenation (ECMO), a heart-lung bypass machine. The EUA requires that fact sheets that provide important information about using remdesivir in treating COVID-19 be made available to health care providers and patients.