Alabama Department of Public Health (ADPH)
Alabama Emergency Response Technology (ALERT)
Health Alert Network (HAN)
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FDA Issues Emergency Use Authorization for Paxlovid to Treat COVID-19 Infection

On Wednesday, December 22, 2021, the U.S. Food and Drug Administration (FDA) issued an emergency use authorization[1] (EUA) for Pfizer's Paxlovid (nirmatrelvir and ritonavir) for the treatment of mild to moderate COVID-19 infection in patients 12 years of age and older and weighing more than 40kgs (88lbs) who are at high risk[2] of progression to severe COVID-19, including hospitalization or death[3]. Paxlovid is not authorized for the pre-exposure or post-exposure prevention of COVID-19 or for initiation of treatment in those requiring hospitalization due to severe or critical COVID-19, and patients must have positive results of direct SARS-CoV-2 testing.

A recent randomized, double-blind, placebo-controlled clinical trial was performed to study Paxlovid for the treatment of more than 2,000 non-hospitalized symptomatic adults 18 years of age and older with a laboratory confirmed diagnosis of SARS-CoV-2 infection and with a prespecified risk factor for progression to severe disease or were 60 years and older regardless of prespecified chronic medical conditions. Paxlovid significantly reduced the proportion of people with COVID-19 related hospitalization or death from any cause by 88% compared to placebo among patients treated within five days of symptom onset and who did not receive COVID-19 therapeutic monoclonal antibody treatment. Additionally, only 0.8% who received Paxlovid were hospitalized or died during 28 days of follow-up compared to 6% of the patients who received placebo. The safety and effectiveness of Paxlovid for the treatment of COVID-19 continue to be evaluated[4].

Possible side effects of Paxlovid include impaired sense of taste, diarrhea, high blood pressure and muscle aches. As Paxlovid contains ritonavir, a potent inhibitor of the Cytochrome P450 3A4 (CYP3A4) enzyme, precaution should be used in patients that might have undiagnosed HIV infection and/or are taking medications that might be affected by this inhibition. Additionally, patients with underlying liver or kidney disease need special consideration[5].

Paxlovid is administered as three tablets (two tablets of nirmatrelvir and one tablet of ritonavir) taken together orally twice daily for five days, for a total of 30 tablets and should be initiated as soon as possible after diagnosis of COVID-19 and within five days of symptom onset. Paxlovid is available by prescription only and the EUA fact sheets for patients can be found linked below[6].

The federal government has purchased a total of 10 million courses of Paxlovid which will be provided to state and territorial health departments for free. Although the product will be limited at first, production will ramp up significantly in the coming months. An initial 65,000 courses of Paxlovid will be made available for shipment to states and territories, and select

HRSA funded health clinics, and will begin arriving in states and territories during the first week of January. Alabama will receive 780 patient courses (with a 20-course minimum per site) for this first allocation, enough for approximately 39 sites.

With a goal to prioritize the equitable distribution and access to oral antivirals across Alabama, the Alabama Department of Public Health (ADPH) will initially partner with a Federal Retail Pharmacy Partner using a pharmacy dispensing model. This partner has the broadest reach of pharmacy locations in the state of Alabama, helping us to reach our goal of equitable distribution and access to products. Once allocation increases, ADPH will begin to expand sites and providers.

Importantly, Paxlovid is not a substitute for vaccination in individuals for whom COVID-19 vaccination and a booster dose are recommended. The FDA, the Centers for Disease Control and Prevention (CDC), and ADPH urges the public to get vaccinated and receive a booster if eligible.

1. https://www.fda.gov/media/155049/download
2. https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html
3. https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-first-oral-antiviral-treatment-covid-19
4. https://www.pfizer.com/news/press-release/press-release-detail/pfizer-receives-us-fda-emergency-use-authorization-novel
5. https://www.fda.gov/media/155050/download
6. https://www.fda.gov/media/155051/download