pennsylvania
DEPARTMENT OF HEALTH

October 21, 2020[1]

COVID-19 and Treatment Drugs
Frequently Asked Questions

Q: What drugs has the U.S. Food and Drug Administration (FDA) approved to treat COVID-19?
A: Currently, there are no drugs or vaccines approved by the FDA to treat patients with COVID-19. However, On August 23, 2020, the FDA issued an Emergency Use Authorization (EUA) to allow the use of convalescent plasma for the treatment of hospitalized patients with COVID-19. Also, on October 1, 2020, the FDA reissued the EUA for Remdesivir. The reissuance allows for emergency use of Remdesivir by healthcare providers to treat suspected or laboratory-confirmed COVID-19 in all hospitalized adult and pediatric patients. The authorization does not mean that this drug and biological product are FDA-approved as safe and effective for treating COVID-19; clinical trials are still needed to determine effectiveness.

On June 15, 2020, the FDA revoked its previous EUA for the emergency use of oral formulations of hydroxychloroquine and chloroquine after determining that those drugs are unlikely to be effective in treating patients with COVID-19. The revocation of the EUA letter can be found here.

Q: What is COVID-19 convalescent plasma?
A: COVID-19 convalescent plasma is human plasma collected from individuals whose plasma contains anti-SARS-CoV-2 antibodies, and who meet all donor eligibility requirements. It is an investigational product and is not currently approved or licensed for any indication, but is authorized through an EUA for the treatment of COVID-19.

Q: Is convalescent plasma effective for treating COVID-19?
Patients with COVID-19 may improve faster if they receive plasma from those who have recovered from COVID-19, because it may have the ability to fight the virus that causes COVID-19. The blood from people who recover from COVID-19 contains substances called antibodies, which are capable of fighting the virus that causes the illness.

Q: Where can I get more information about COVID-19 convalescent plasma?
A: For more information, please read the FDA's Fact Sheet for Patients and Parents/Caregivers: Emergency Use Authorization (EUA) of COVID-19 Convalescent Plasma for Treatment of COVID-19 in Hospitalized Patients.

Q.: What is Remdesivir?
A.: Remdesivir is an investigational antiviral medicine to treat patients in the hospital with COVID-19. Remdesivir is investigational because it is still being studied. Remdesivir was shown in a clinical trial to shorten the recovery time in some people. There are no medicines approved by the FDA as safe and effective to treat people in the hospital who have COVID-19. Therefore, the FDA has authorized the emergency use of Remdesivir for the treatment of COVID-19 under an EUA.

[1] This updates the *Frequently Asked Questions for COVID-19 and Treatment Drugs* last issued on July 24, 2020. Substantive changes are shown in red font.

Q: Is the antiviral drug Remdesivir effective for treating COVID-19?
A: Remdesivir has not undergone the same type of review as an FDA-approved or cleared product. Remdesivir was shown in a clinical trial to shorten the recovery time in some people, but it is still being studied. The EUA for remdesivir is in effect for the duration of the COVID-19 declaration justifying emergency use of this product, unless terminated or revoked (after which the product may no longer be used).

Q: How is the revised EUA for Remdesivir different than the EUA initially granted by the FDA on May 1, 2020?
A: The original EUA authorized the use of Remdesivir for emergency use by licensed health care providers to treat suspected or laboratory-confirmed COVID-19 cases in hospitalized adult and pediatric patients with severe disease (defined as patients with low blood oxygen levels or needing oxygen therapy or more intensive breathing support such as a mechanical ventilator). The revised EUA authorizes the use of Remdesivir by healthcare providers for the treatment of suspected or laboratory-confirmed COVID-19 in all hospitalized adult and pediatric patients, irrespective of their severity of disease.

Q.: Where can I get more information about Remdesivir?
A.: For more information, please read the FDA's Fact Sheet for Patients and Parent/Caregivers: Emergency Use Authorization (EUA) of Remdesivir for COVID-19.

Q: What is Dexamethasone, and is it effective in treating COVID-19?
A: Dexamethosone is a steroid drug that was found in one study to be effective in improving COVID-19 survival in some severely ill hospitalized patients. The study showed that lower mortality associated with the use of dexamethasone was among those who also required respiratory support (and not among those receiving no respiratory support). As a steroid drug, it works to reduce inflammation that can develop in severely ill COVID-19 patients. At this time, Dexamethasone is not FDA approved to treat COVID-19 patients.

Q: What is Regeneron?
A: Regeneron is a pharmaceutical company that has produced an experimental antibody treatment. The name of that treatment is REGN-COV2. It is a combination of two monoclonal antibodies that is designed to block infectivity of SARS-CoV-2 (the virus that causes COVID-19).

Q: Is REGN-COV2 an effective treatment for COVID-19?
A: The use of REGN-COV2 has proven successful in clinical trials. While it is not approved by the FDA as a treatment for COVID-19, it has been available for compassionate use (which the FDA has to approve on an individual basis). On October 7, 2020, Regeneron announced they had submitted a request to the FDA for an EUA for REGN-COV2.

Q: Is a high dose of Vitamin C an effective treatment for COVID-19?
A: No. There is currently no scientific evidence that high doses of Vitamin C will effectively treat or prevent COVID-19.

Q: Is a high dose of Vitamin D effective in preventing or treating COVID-19?
A: While several studies have found an association between low levels of Vitamin D and COVID-19, associations are not always causative. Therefore, there is currently no scientific evidence that high doses of Vitamin D will effectively prevent or treat COVID-19.

Q: How do I get medicine to treat COVID-19?
A: Only your health care provider can determine your treatment. If you have questions about your treatment plan, contact your health care provider. Never take a prescription medicine or drug if it is not prescribed for you by your health care provider for your health condition.

Q: Can antibiotics treat COVID-19?
A: No. COVID-19 is a virus, and antibiotics do not work against viruses as they only work on bacterial infections. Some patients may develop a bacterial infection such as pneumonia. In that case, a health care professional may treat the bacterial infection with an antibiotic.

Q: Is there a vaccine for COVID-19?
A: No, there is currently no vaccine to prevent COVID-19. There are trials underway for a COVID-19 vaccine to ensure safety and effectiveness, but a vaccine is not yet available to the public.

Q: Products online claim to prevent or treat COVID-19. Where can I report websites selling fraudulent medical products?
A: There are currently no FDA-approved drugs or vaccines for COVID-19. You can report fraudulent websites here: https://www.fda.gov/safety/report-problem-fda/reporting-unlawful-sales-medical-products-internet.

Q: Who should I contact with drug-related questions?
A: You can call the FDA's Division of Drug Information at (855) 543-3784 or email druginfo@fda.hhs.gov.

For additional information sources:

- The Food and Drug Administration (FDA): https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/coronavirus-disease-2019-covid-19-frequently-asked-questions
- The Centers for Disease Control and Prevention (CDC): https://www.cdc.gov/coronavirus/2019-ncov/index.html