December 24, 2020[1]

COVID-19 and Treatment Drugs and Biologics

Frequently Asked Questions

For a product to be widely used to treat COVID-19, it must either be *licensed* by the U.S. Food and Drug Administration (FDA) **or** have received an Emergency Use Authorization (EUA). A product that has received an EUA is considered investigational, meaning that studies using the treatment are ongoing. While the product has been reviewed and can be used to treat persons with COVID-19, it is not licensed by the FDA. The term investigational is different from experimental. Experimental refers to treatments provided as part of a defined clinical trial.

The following frequently asked questions provide information about drugs and biologics that have either been authorized under an EUA or licensed by the FDA. The document is separated by some introductory questions and then by the name of the drug or biologic to provide more detailed information.

INTRODUCTORY QUESTIONS:

Q: What drug has the FDA approved to treat COVID-19?

A: Currently, there is one drug licensed by the FDA to treat patients with COVID-19. The use of remdesivir is approved for adults and pediatric patients (12 years of age and older and weighing at least 40 kg) for the treatment of COVID-19 requiring hospitalization. It should only be administered in a hospital or in a healthcare setting capable of providing acute care comparable to inpatient hospital care.

Q: What drugs or biologics have received EUAs from the FDA to treat COVID-19:

A: The following drugs and biologics have each received an EUA:

- On October 22, 2020, the FDA issued a revised EUA to allow the use of remdesivir for the treatment of suspected or laboratory-confirmed COVID-19 in hospitalized pediatric patients weighing 3.5 kg to less than 40 kg or hospitalized pediatric patients less than 12 years of age weighing at least 3.5 kg.
- On August 23, 2020, the FDA issued an EUA to allow the use of convalescent plasma for the treatment of hospitalized patients with COVID-19. This was reissued on November 30, 2020.
- On November 9, 2020, the FDA issued an EUA to allow the use of bamlanivimab for the treatment of mild to moderate COVID-19 in adults and certain pediatric patients who are at high risk for progressing to severe COVID-19 and/or hospitalization. Bamlanivimab is a monoclonal antibody.
- On November 21, 2020, the FDA issued an EUA to allow the use of casirivimab and imdevimab to be administered together for the treatment of mild to moderate COVID-19 in adults and certain pediatric patients who are at high risk for progressing to severe COVID-19 and/or hospitalization. Casirivimab and imdevimab are monoclonal antibodies.

[1] This updates the *Frequently Asked Questions for COVID-19 and Treatment Drugs* last issued on October 21, 2020. Substantive changes are shown in red font.

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.

REMDESIVIR

Q.: What is Remdesivir?
A.: Remdesivir (brand name Veklury) is an antiviral medicine to treat patients in an inpatient hospital setting (which includes alternate care sites meeting certain criteria) with COVID-19. It was approved by the FDA to treat adults and pediatric patients (12 years of age and older and weighing at least 40 kg) for the treatment of COVID-19 requiring hospitalization. A revised EUA was issued to allow the use of remdesivir to treat suspected or laboratory-confirmed COVID-19 in hospitalized pediatric patients weighing 3.5 kg to less than 40 kg or hospitalized pediatric patients less than 12 years of age weighing at least 3.5 kg. It should only be administered in a hospital or in a healthcare setting capable of providing acute care comparable to inpatient hospital care.

Q.: Where can I get more information about Remdesivir?
A.: For more information, please read the FDA's Frequently Asked Questions for Veklury (remdesivir).

Q. How do I access remdesivir?
A. Treatment by remdesivir is only available through a physician' prescription in an inpatient hospital setting. Healthcare systems can order remdesivir through AmerisourceBergen, the sole distributer of this product.

CONVALESCENT PLASMA

Q: What is COVID-19 convalescent plasma?
A: COVID-19 convalescent plasma is human plasma collected from individuals whose plasma contains 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.

MONOCLONAL ANTIBODIES

Q: What are monoclonal antibodies?

A: Monoclonal antibodies are neutralizing antibodies developed to treat individuals with mild to moderate COVID-19. Treatment with monoclonal antibodies may help delay progression to severe COVID-19 disease and the need for hospitalization.

At the present time, two monoclonal antibody products have received authorization under the FDA's EUA process. While not *licensed* by the FDA, these products are FDA *authorized* as an emergency treatment. This means the products have been reviewed and it is okay to now use them to treat persons with COVID-19.

Monoclonal antibody treatment with an FDA-authorized product (via the EUA process) is considered investigational, meaning that studies using the treatment are ongoing. The term investigational is different from experimental. Experimental refers to treatments provided as part of a defined clinical trial.

Additional monoclonal antibody treatments are being developed or are in clinical trials and are expected to be approved over time. Prescribing clinicians should review information provided under the EUA for each authorized treatment as this information may vary from product to product. The two EUAs for monoclonal antibodies:

- Bamlanivimab on November 9, 2020; and
- Casirivimab and imdevimab on November 21, 2020.

Q: Can monoclonal antibody treatment be used in nursing homes?
A: Currently, clinicians may prescribe bamlanivimab or casirivimab/imdevimab to residents of Pennsylvania nursing homes under the current EUA.

Pennsylvania state licensure regulations require all experimental research or treatment be approved in advance by the PA Department of Health. Monoclonal antibody products that have been authorized by the FDA are recognized as an accepted medical practice.

Clinicians do not need Department of Health permission to use monoclonal antibodies for the treatment of residents with COVID-19 if the resident receiving the treatment is not part of a clinical research trial.

Q: What is bamlanivimab?
A: Bamlanivimab is a monoclonal antibody that is specifically directed against the spike protein of SARS-CoV-2, designed to block the virus' attachment and entry into human cells. It is an investigational medicine used for the treatment of COVID-19 in non-hospitalized adults and adolescents 12 years of age and older with mild to moderate symptoms who weigh 40 kg or more, and who are at high risk for developing severe COVID-19 symptoms or the need for hospitalization. This includes those who are 65 years of age or older, or who have certain chronic medical conditions. It is administered through an intravenous (IV) infusion.

Q: Is bamlanivimab effective in treating COVID-19?
A: While the safety and effectiveness of this investigational therapy continues to be evaluated, bamlanivimab was shown in clinical trials to reduce COVID-19-related hospitalization or emergency department visits in patients at high risk for disease progression within 28 days after treatment when

compared to placebo. Bamlanivimab is not authorized for patients who are hospitalized due to COVID-19 or require oxygen therapy due to COVID-19.

Q: Where can I get more information about bamlanivimab?
A: The FDA's Fact Sheet for Patients, Parents and Caregivers - Emergency Use Authorization (EUA) of Bamlanivimab for Coronavirus Disease 2019 (COVID-19) is a good source of information.

Q: What are casirivimab and imdevimab?
A: Casirivimab and imdevimab are monoclonal antibodies that are specifically directed against the spike protein of SARS-CoV-2, designed to block the virus' attachment and entry into human cells. They are to be administered together for the treatment of mild to moderate COVID-19 in adults and pediatric patients (12 years of age or older weighing at least 40 kg) with positive test results for COVID-19 and who are at high risk for progressing to severe COVID-19. This includes those who are 65 years of age or older or who have certain chronic medical conditions. Casirivimab and imdevimab must be administered together by intravenous (IV) infusion.

Q: Are casirivimab and imdevimab effective in treating COVID-19?
A: In a clinical trial of patients with COVID-19, casirivimab and imdevimab, administered together, were shown to reduce COVID-19-related hospitalization or emergency department visits in patients at high risk for disease progression within 28 days after treatment when compared to placebo. The safety and effectiveness of this investigational therapy for use in the treatment of COVID-19 continues to be evaluated.

Q: Where can I get more information about casirivimab and imdevimab?
A: The FDA's Fact Sheet for Patients, Parents and Caregivers – Emergency Use Authorization (EUA) of Casirivimab and Imdevimab for Coronavirus Disease 2019 (COVID-19) is a good source of information.

Q. How do I access one of these monoclonal antibody treatments?
A: Monoclonal antibodies currently require a physician's order and must be administered in a clinical setting by a healthcare provider. These products are currently being allocated through the federal Department of Health and Human Services to state health departments, who are then allocating products to healthcare providers for use; currently in Pennsylvania, products are being allocated to healthcare systems, who are providing these products throughout their networks. As more product becomes available, the PA Department of Health may increase the types of facilities who will receive allocations of these products.

OTHER:

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: 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 healthcare provider can determine your treatment. If you have questions about your treatment plan, contact your healthcare provider. Never take a prescription medicine or drug if it is not prescribed for you by your healthcare 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 healthcare professional may treat the bacterial infection with an antibiotic.

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.

INFORMATION SOURCES:

Most content for this document was sourced from FDA's website, specifically the Emergency Use Authorization page at https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.

Frequently asked questions on FDA's website can be found at 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 also has information available at https://www.cdc.gov/coronavirus/2019-ncov/index.html.