

## Coronavirus Disease 2019 (COVID-19) - The Search for a Treatment Issues Document

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### Summary

SARS-CoV-2, the virus that can cause coronavirus disease 2019 (COVID-19), has officially been labeled a pandemic by the World Health Organization (WHO). While treatment of the disease currently centers on managing symptoms and supportive care for patients, there is a need for effective vaccines and medications to prevent and treat COVID-19. While pharmaceutical companies, universities and government agencies around the world are working to develop these therapies, there are currently no vaccines or medications approved by the U.S. Food and Drug Administration (FDA) for COVID-19. This document is intended to provide information regarding therapies in development for COVID-19; it will be updated as new data become available.

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### Highlights

- Coronavirus disease 2019 (COVID-19) is an infection from a new strain of coronavirus that has been associated with respiratory symptoms, including progression to severe respiratory illness and death in some patients.
- Currently, there are no FDA approved therapies for the treatment or prevention of COVID-19.
- Pharmaceutical companies, universities and government agencies around the world are working to develop vaccines and treatments for COVID-19.
- Vaccines are in early clinical development with options reaching clinical trials within months.
- There are a vast array of compounds in early trials being evaluated for the treatment of COVID-19. While most are in preclinical development, the promising options will move rapidly through the FDA approval process.
- Another approach is to evaluate currently available therapeutic options to assess their effectiveness in treating and preventing the disease. Some data surrounding SARS and MERS coronaviruses have led investigators to a handful of products, hoping the similarity between these viruses and SARS-CoV-2 will lead to treatment options.
- As development of therapies is rapidly evolving, we intend to update this document frequently to provide the latest information on potential therapies for treating and preventing COVID-19.

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### Current Treatment Recommendations

To date, there are no vaccines or drugs approved by the U.S. Food and Drug Administration (FDA) to treat or prevent SARS-CoV-2, the virus that can cause the disease known as COVID-19. Although there are investigational COVID-19 vaccines and treatments under development, these investigational products are in the early stages of product development and have not yet been fully tested for safety or effectiveness. [According to the CDC](#), clinical management includes prompt implementation of recommended infection prevention and control measures and supportive management of complications, including advanced organ support if indicated.

### FDA and Government Actions

To help expedite the availability of therapies for COVID-19, the FDA can loosen the process for medications and vaccines to enter the market. An [Emergency Use Application](#) (EUA) can be issued to permit the use, based on scientific data, of medical products that may be effective for the diagnosis, treatment, or prevention of a disease or condition when the U.S. Department of Health and Human Services makes the determination that there is a public health emergency that has a significant potential to affect national security or the health and security of U.S. citizens. Recently, [the agency issued an EUA](#) to expedite the availability of additional diagnostic tests for SARS-CoV-2 infections.

## The Search for Coronavirus Treatments

While there are currently no therapies approved by the FDA for the treatment or prevention of COVID-19, pharmaceutical manufacturers, universities and government agencies are casting a wide net looking for effective therapies to treat and/or prevent the disease. SARS-CoV-2 is a coronavirus similar to viruses that cause Middle Eastern Respiratory Syndrome Coronavirus ([MERS-CoV](#)) and Severe Acute Respiratory Syndrome Coronavirus ([SARS-CoV](#)), previously have been associated with the development of severe illness. Therefore, many investigated compounds for treating MERS and SARS are now being evaluated for COVID-19.

## Vaccines in Development

Several vaccines are in early-phase development to protect against COVID-19. Once they reach clinical trials, data will be collected over at least six months, if not more, to determine if the vaccines are both safe and effective for preventing infection with SARS-CoV-2. FDA will expedite the more promising vaccines through the FDA approval process; however, the first vaccine is not expected to be approved for 12-18 months, at the earliest. Table 1 includes examples of vaccines in development for COVID-19.

Table 1

Vaccine	Manufacturer	Route	Status
mRNA-1273	Moderna	Intramuscular (two doses)	Phase 1
BNT-162	Pfizer/BioNTech	Unspecified	Preclinical
Coronavirus Vaccine	Altimmune	Intranasal (one dose)	Preclinical
Coronavirus Vaccine	CureVac	Intramuscular (1-3 doses)	Preclinical
Coronavirus Vaccine	Janssen	Unspecified	Preclinical
COVID-19 S-Trimer	GlaxoSmithKline/Clover	Unspecified	Preclinical
INO-4800	Inovio	Intradermal	Preclinical

## Novel Drugs in Development

There are multiple therapies in early-phase development for the treatment of COVID-19. One product, remdesivir, has rapidly advanced into phase 3 clinical trials for patients with moderate or severe COVID-19 as well as hospitalized patients with mild or moderate COVID-19. Table 2 highlights some of the novel drugs in development for COVID-19. Due to the large number of products being screened for possible use, the table is not intended to be an exhaustive list of potential therapies. Rather, we have highlight some of the more promising agents progressing through the development process.

Table 2

Drug	Manufacturer	Mechanism	Route	Status
remdesivir	Gilead	Broad-spectrum antiviral	IV infusion (5 or 10 days)	Phase 3
favipiravir	FujiFilm Tyoama Chemical	RNA polymerase antiviral	Oral (twice daily x 7 days)	Unspecified
leronlimab	CytoDyne	CCR5 viral entry inhibitor	Subcutaneous	Preclinical

## Existing Drugs in Development

Several existing medications that are currently approved for other uses are being evaluated for efficacy in the treatment of COVID-19. These drugs may be used alone or in combination with other drugs to treat COVID-19. Table 3 shows some of the existing drugs that are in development for COVID-19. However, the use of these products for COVID-19 is still considered investigational as ongoing clinical trials have yet to demonstrate whether or not the products are proven to be both safe and effective for treating COVID-19.

Table 3

Drug	Manufacturer	Mechanism	Route	Status
tocilizumab (Actemra®)	Genentech	Interleukin-6 inhibitor	IV infusion	Unspecified
sarilumab (Kevzara®)	Sanofi/Regeneron	Interleukin-6 inhibitor	Subcutaneous	Unspecified
chloroquine	Generics	RNA polymerase inhibitor	Oral	Unspecified
hydroxychloroquine (Plaquenil®)	Concordia/Generics	RNA polymerase inhibitor	Oral	Phase 2
lopinavir/ritonavir (Kaletra®)	AbbVie	Protease inhibitor/Booster	Oral	Phase 2

***Express Scripts' Recommendations***

There are currently no FDA approved therapies for the treatment or prevention of SARS-CoV-2 infections. While a lot of information is surfacing regarding the screening of potential drugs therapies, available data for the treatment and/or prevention of the virus are limited. The Office of Clinical Evaluation and Policy will continue to monitor the evolving literature, track utilization trends, and revise utilization management solutions, as needed. As always, the Office of Clinical Evaluation and Policy will continue to monitoring this development and provide updates as more information becomes available.

Stay up to date with the latest information regarding COVID-19 infections in the United States at:

<https://www.cdc.gov/coronavirus/2019-ncov/index.html>

<https://www.nih.gov/health-information/coronavirus>