TABLE 1 TREATMENTS FOR COVID-19*

Treatment Name	Mode of Action	Approval Status	Indication for Use	Scientific Evidence for EUA/Approval
Bamlanivimab and etesevimab	Antibodies that bind to the SARS-CoV-2 spike protein and block its interaction with the human ACE2 receptor thereby preventing viral attachment to host cells.	EUA**	Mild-to-moderate COVID-19 in adult and pediatric patients (including newborns) with SARS-CoV-2 positive viral test, and at high risk for progression to severe COVID-19.	While this combination therapy is approved for postexposure treatment, the data supporting authorization came from a clinical trial that evaluated bamlanivimab alone for prevention of COVID-19. Those treated with bamlanivimab had a reduced risk (compared to placebo) of being infected with COVID-19. The FDA expects that bamlanivimab and etesevimab together may be safe and effective for postexposure treatment, as bamlanivimab and etesevimab administered together will provide an advantage over bamlanivimab alone against certain SARS-CoV-2 viral variants.
Baricitinib (Olumiant)	By inhibiting the protein Janus kinase (JAK) it blocks signaling mediated by the inflammatory cytokine, IL-6.	EUA	Hospitalized adult and pediatric patients (two years or older) with COVID-19 requiring supplemental oxygen, noninvasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation.	The authorization was supported by data from a clinical trial of hospitalized patients with COVID-19, where baricitinib showed a reduction (compared to standard of care) in the proportion of patients who died during 28 days of follow-up.
Casirivimab and imdevimab (REGEN-COV)	Antibodies that bind to the SARS-CoV-2 spike protein and block its interaction with the human ACE2 receptor thereby preventing viral attachment to host cells.	EUA	Mild-to-moderate COVID-19 in adult and pediatric patients (12 years and older weighing at least 40 kg) with SARS-CoV-2 positive viral test, and at high risk for progression to severe COVID-19.	Most important evidence for authorization came from a clinical trial that showed that the treatment lowered disease progression, hospitalizations, and emergency room visits (compared to placebo) among patients who are at high risk for severe COVID-19.
COVID-19 convalescent plasma (with high antibody levels)	Contains antibodies that can block SARS-CoV-2 attachment to host cells and reduce the amount of virus in the host.	EUA	Hospitalized patients with COVID-19 early in the disease course and those hospitalized patients who have impaired immunity and cannot produce an adequate antibody response. Plasma with low levels of antibodies has not been shown to be helpful in COVID-19.	Based on available scientific evidence the FDA determined that it is reasonable to believe that COVID-19 convalescent plasma may be effective in lessening the severity or shortening the length of COVID-19 illness in some hospitalized patients.
Molnupiravir (Lagevrio)	Blocks viral multiplication by promoting widespread mutations during the replication of viral RNA.	EUA	Mild-to-moderate COVID-19 in adults with SARS-CoV-2 positive viral test who are at high risk for progression to severe COVID-19, for whom alternative treatment options are not accessible or clinically appropriate.	The data supporting this EUA are from the MOVe-OUT clinical trial that showed that only 6.8 percent of COVID-19 patients who received molnupiravir were hospitalized or died compared to 9.7 percent of those who received placebo.
Nirmatrelvir and ritonavir (Paxlovid)	Blocks SARS-CoV-2 multiplication by inhibiting the viral protein, nsp5 protease.	EUA	Mild-to-moderate COVID-19 in adult and pediatric patients (12 years and older weighing at least 40 kg) with SARS-CoV-2 positive viral test, and at high risk for progression to severe COVID-19.	The data supporting this EUA are from the EPIC-HR clinical trial that showed that only 0.8 percent of COVID-19 patients who received Paxlovid were hospitalized or died compared to six percent of those who received placebo.
Remdesivir (Veklury)	An inhibitor of the SARS-CoV-2 protein RNA-dependent RNA polymerase, which is essential for viral replication.	Approved	Adult and pediatric patients (12 years and older and weighing at least 40 kg) for the treatment of COVID-19 requiring hospitalization, only to be administered in a hospital or in a health care setting capable of providing acute care comparable to inpatient hospital care.	The approval was supported by the FDA's analysis of data from three clinical trials which showed that treatment with remdesivir either reduced (compared to placebo) time to recovery or increased the odds of symptoms improving among patients hospitalized with mild, moderate, or severe COVID-19.
Sotrovimab (Xevudy)	Antibody that binds to the SARS-CoV-2 spike protein and inhibits viral infection of human cells.	EUA	Mild-to-moderate COVID-19 in adult and pediatric patients (12 years and older weighing at least 40 kg) with SARS-CoV-2 positive viral test, and at high risk for progression to severe COVID-19.	The data supporting the EUA are based on an interim analysis of a clinical trial that showed that progression to severe COVID-19 (hospitalization or death) was reduced in patients treated with sotrovimab compared to those who received placebo.
Tixagevimab and cilgavimab (Evusheld)	Antibodies that bind to the SARS-CoV-2 spike protein and block its interaction with the human ACE2 receptor thereby preventing viral attachment to host cells.	EUA	To prevent COVID-19 in adults and children (12 years and older weighing at least 40 kg) who are not currently infected with SARS-CoV-2 but are immunocompromised and may not mount an adequate immune response to COVID-19 vaccines or for whom vaccination is not recommended due to a history of severe adverse reaction.	Data supporting this EUA came from the PROVENT clinical trial which showed that Evusheld recipients had a 77 percent reduced risk of developing COVID-19 compared to those who received a placebo and the reduction in risk of developing COVID-19 was maintained for six months.
Tocilizumab (Actemra)	Antibody that binds to the receptor of the inflammatory cytokine IL-6 and inhibits IL-6-mediated signaling.	EUA	Hospitalized adult and pediatric patients with COVID-19 (two years and older) who are receiving systemic corticosteroids and require supplemental oxygen, noninvasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation.	The critical evidence on the potential benefit of tocilizumab came from two clinical trials. In the RECOVERY trial, treatment with tocilizumab reduced (compared to usual care) the probability of death and median time to discharge among hospitalized patients with severe COVID-19. In the EMPACTA trial, treatment with tocilizumab reduced (compared to placebo) progression to mechanical ventilation or death.

*This table includes therapeutics that have received EUA and/or approval from FDA as of January 1, 2022, for the treatment of COVID-19. Not included are agents that are authorized for managing COVID-19-induced complications (such blood clotting) or for sedating ventilated patients.

**Emergency Use Authorization (EUA) provides faster access to critical medical products that may help during an emergency when there are no adequate, approved, and available options. To issue an EUA, FDA quickly evaluates the evidence that is currently available, carefully balancing the risks and benefits of a product as known at the time, among other criteria.

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