COVID-19 treatments: What's FDA authorized, and what works

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What's the news: New cases of COVID-19 infections are surging in the U.S. and are at the highest levels of the pandemic. The fast-spreading variant, B.1.1.529, more widely known as Omicron, is fueling this acceleration, according to the Centers for Disease Control and Prevention (CDC).

The agency recommends vaccines and booster shots as the best preventive measures against severe illness, hospitalizations and death. But, in a health advisory issued by the CDC Health Alert Network, it notes that there are therapeutics available for preventing and treating COVID-19 in specific at-risk populations—such as patients with cancer, chronic kidney disease, obesity, chronic obstructive pulmonary disease or diabetes.

The advisory also notes, however, that these medications differ in efficacy, route of administration, risk profile, Food and Drug Administration (FDA) authorization status and availability.

The advisory is intended to help familiarize physicians and other clinicians with what therapeutics are available, understand how and when to prescribe them, recognize contraindications, and how to prioritize their use when faced with supply constraints.

These therapeutics include monoclonal antibodies, antivirals and pre-exposure prophylaxis products. The advisory details their effectiveness and also provides strategies for high-risk groups.

Why it's important: In its "Omicron Variant: What you need to know" document, the CDC said it "expects that anyone with Omicron infection can spread the virus to others, even if they are vaccinated or don't have symptoms."

More than 832,000 people in the U.S. have died from COVID-19, with the first death caused by the Omicron variant recorded in the Houston area Dec. 20.

The CDC health advisory notes that the Omicron variant “is not neutralized” by the commonly prescribed monoclonal antibody-based COVID-19 treatments bamlanivimab, etesevimab, casirivimab or imdevimab.

Sotrovimab has been shown to be effective against all COVID-19 variants including Omicron, but there are limited supplies of this monoclonal antibody medication and there has been “some reduction in neutralization concentration,” the advisory says.

The FDA issued an emergency use authorization for sotrovimab (PDF) for mild-to-moderate COVID-19 in patients older than 12 and weighing at least 40 kilograms who are at high risk for progression to severe illness. It is not authorized for patients already hospitalized for COVID-19 or who require oxygen because of COVID-19.

Early studies found that remdesivir, an antiviral drug first used to treat Ebola, could reduce hospital stays for patients with COVID-19 if given within seven days of symptom onset. The advisory cites a more recent study, “Early Remdesivir to Prevent Progression to Severe COVID-19 in Outpatients,” published last month in *The New England Journal of Medicine*, which found that a three-day course of remdesivir resulted in an 87% lower risk of hospitalization or death compared with a placebo.

The advisory notes, however, that outpatient use of remdesivir requires the use of an intravenous infusion center with skilled staffing.

Two oral antivirals, paxlovid (PDF) and molnupiravir (PDF), were made available for outpatients with mild to moderate COVID-19 under FDA emergency use authorization. Both drugs are taken twice daily for five days. Compared with placebo, paxlovid is more effective against hospitalization and death, 88%, than molnupiravir, 33%, but it is in short supply. Treatment with these oral antivirals must begin within five days of symptom onset to maintain product efficacy.

President Joe Biden announced this week that the U.S. government has committed to buy a total of at least 20 million courses of paxlovid from Pfizer. Given the existing shortage, however, the CDC advisory recommends the treatment be prioritized for high-risk populations.

Both also carry risks. Paxlovid has a potential for a severe interaction with ritonavir, which is used for HIV treatment. Molnupiravir is not recommended for patients who are pregnant or breastfeeding.

Evusheld (PDF) is the only product to receive FDA emergency use authorization for pre-exposure prophylaxis for COVID-19. It includes two long-acting anti-SARS-CoV-2 monoclonal antibodies and is intended for the “highest risk immunocompromised patients” for whom vaccination is not expected to be effective. It is not intended as a treatment.

The advisory highlights the need for virus-specific diagnostic testing by noting that two pairs of monoclonal antibody treatments bamlanivimab and etesevimab (PDF) and casirivimab and imdevimab (PDF) received emergency use authorization for the Delta variant, but are considered ineffective against Omicron.

The advisory also recommends encouraging patients to keep appointments for routine care and adhere to treatment regimens.

Learn more: Visit the AMA COVID-19 resource center for clinical information, guides and resources, and updates on advocacy and medical ethics.