

## Information Sheet &amp; Frequently Asked Questions

## FDA's Change to Authorization of Evusheld

On January 26, [FDA announced](#) that Evusheld is not currently authorized for emergency use in the U.S. until further notice by the agency because the therapeutic is unlikely to be active against more than 90% of the SARS-CoV-2 variants currently circulating in the U.S. based on the latest CDC data.

There are many things that people can do to protect themselves against COVID-19. First, if vaccination is recommended for you, get vaccinated and stay up to date. This means getting the updated (bivalent) vaccine if you haven't received it yet.

Second, develop a [COVID-19 Action Plan](#) so that you have all of the information you need on hand if you get sick with COVID-19.

If you develop signs or symptoms of COVID-19, reach out to your doctor, another healthcare provider, or a [Test to Treat site](#) (in person or via telehealth) immediately, even if your symptoms are mild. As an additional option for patients who are unable to access their healthcare provider, Test to Treat sites have health clinics at the sites where people can get tested for COVID-19 and evaluated by a healthcare provider (in person or via telehealth). People who test positive and are eligible can get a prescription to treat the infection and have the prescription filled at an affiliated pharmacy.

Finally, taking multiple prevention steps can provide additional layers of protection against COVID-19:

- Wear a well-fitting, high-quality mask or respirator in public places to reduce your chances of becoming infected with COVID-19, or any other respiratory illnesses. Properly fitting respirators provide the highest level of protection.
- When indoors with others, try to improve ventilation as much as possible.
- Avoid poorly ventilated or crowded indoor settings.
- Wash your hands often with soap and water or use a hand sanitizer that contains at least 60% alcohol.
- Encourage people you live with or spend time with to stay up to date on COVID vaccines and take all necessary prevention actions to protect themselves against COVID-19, or hospitalization and death if exposed.
- Avoid people who are sick, including people who have COVID-19, even if they do not feel or seem sick.
- Talk with your doctor in advance about what treatments may be appropriate for you and how to access the medication if you experience symptoms.

### Frequently Asked Questions

#### What is Evusheld?

Evusheld is a long-acting antibody therapeutic. Since December 2021, Evusheld has been an option for pre-exposure prophylaxis, in other words as preventive protection from COVID-19.

Specifically, Evusheld was authorized for:

- People who have moderate to severe immune compromise due to a medical condition or receipt of immunosuppressive medications or treatments and may not mount an adequate immune response to COVID-19 vaccination, or

- People for whom vaccination with any available COVID-19 vaccine is not recommended due to a history of severe adverse reaction to a COVID-19 vaccine and/or components of a COVID-19 vaccine.

### Why did FDA take action to pause the authorization of Evusheld?

Evusheld is not currently authorized for emergency use in the U.S. because it is unlikely to be active against more than 90% of the SARS-CoV-2 variants currently circulating in the U.S. The latest CDC NOWCAST estimate shows that these variants are causing more than 90% of the cases today.

This FDA action follows several previous announcements and guidance updates for Evusheld by federal agencies over the past few months, including:

- At the beginning of October, [FDA informed health care providers and individuals](#) taking Evusheld of its loss of activity against some Omicron variants and the increased risk of breakthrough infections, especially as resistant variants became more prevalent as they are today.
- On December 20, the Centers for Disease Control and Prevention (CDC) issued a [Health Alert Network \(HAN\) Health Update](#) to supplement the CDC HAN Health Advisories issued on April 25, 2022 and May 24, 2022 to emphasize to healthcare providers, public health departments, and reduced susceptibility to Evusheld.
- On January 6, 2023 [FDA released additional communication](#) stating that they were closely monitoring the emergence of the XBB.1.5 subvariant, a SARS-CoV-2 Omicron variant that is currently increasing in prevalence in the U.S. Because of its similarity to variants that are not neutralized by Evusheld (e.g., XBB), FDA does not anticipate that Evusheld will neutralize XBB.1.5.
- On January 10, 2023, NIH's COVID-19 Treatment Guidelines Panel released a [statement](#) indicating that the prevalence of SARS-CoV-2 subvariants likely to be resistant to Evusheld was increasing.

### I am immunocompromised and used Evusheld for protection. What does this decision mean for me?

If you've already received Evusheld, it's important to know that it does not provide protection against the

variants of COVID-19 that are most common today. Because of this, you may now have less protection from developing COVID-19 if you are exposed to currently circulating variants.

If vaccination is recommended for you, get vaccinated and stay up to date to protect yourself against COVID-19. This means getting the updated (bivalent) vaccine if you haven't received it yet.

If you haven't already, consider developing a [COVID-19 Action Plan](#) so you have all of the information you need on hand if you get sick with COVID-19. Talk with your doctor in advance about what treatments may be appropriate for you and how to access the medication if you do get sick.

If you develop signs or symptoms of COVID-19, reach out to your doctor immediately, even if your symptoms are mild. If your doctor recommends treatment, start it right away. There are [several approved and authorized treatments](#) for COVID-19. Timely treatment can reduce your risk of getting very sick, being hospitalized, or dying.

### What treatments are available for people who might be at higher risk of getting sick now that Evusheld is no longer available?

There are several treatments available for COVID-19 infections.

Currently available data supports their use in reducing the risk of progression to severe disease, including hospitalization and death. Paxlovid (nirmatrelvir/ritonavir) and Veklury

(remdesivir) are the medicines recommended for most people. If those medicines are not available or someone cannot take them, Lagevrio (molnupiravir) is the next choice. COVID-19 convalescent plasma may be another option for certain immunocompromised patients.

If you have signs or symptoms of COVID-19, contact your doctor right away to find out if you should start one of these treatments. You should also talk with your doctor in advance about what treatments may be appropriate for you and how to access the medication if you experience symptoms.

More specifically:

[Paxlovid](#) is authorized to treat mild-to-moderate COVID-19 in adults and children 12 years of age and older

weighing at least 40 kg, (approximately 88 lbs.) and who are at high risk of developing severe COVID-19 leading to hospitalization or death.

[Veklury](#) is approved to treat adults and children 28 days of age and older and weighing at least 3 kg (approximately 6.6 lbs.) who have mild-to-moderate COVID-19 and are at high risk of developing severe COVID-19 leading to hospitalization or death.

[Lagevrio](#) is authorized to treat mild-to-moderate COVID-19 in adults who are at high risk of developing severe COVID-19 leading to hospitalization or death, and who do not have access to alternative COVID-19 treatments that are approved or authorized by FDA or for whom these treatments are not clinically appropriate.

COVID-19 [convalescent plasma](#) with high titers of anti-SARS-CoV-2 antibodies is authorized to treat COVID-19 in patients with immunosuppressive disease or who are receiving immunosuppressive treatment in in-patient or out-patient settings.

### **What is HHS doing to ensure access to treatments for individuals who are immunocompromised or who cannot get vaccinated now that Evusheld is no longer available?**

Over the past year, HHS has dramatically increased access to Paxlovid and Lagevrio, both of which are pills. Supplies of these medicines are now widely available at pharmacies, Test to Treat pharmacies, long-term care facilities, and other locations.

We are encouraging states to support local health departments and health systems in setting up infusion clinics for Veklury (remdesivir) to make it easier for people to get this treatment as soon as possible after being diagnosed with COVID-19.

HHS, state and local health departments, and other healthcare partners also continue to work to ensure access to COVID-19 vaccines, including the updated (bivalent) vaccine.

### **I am immunocompromised. Is there anything I can do to boost my immunity or protect myself?**

Yes: people for whom COVID-19 vaccination is recommended, including people who are immunocompromised, should get and stay up to date with vaccinations. This means getting the updated

(bivalent) vaccine, no matter how many boosters you received before the bivalent vaccine became available in September 2022.

### **Will Evusheld be an option in the future if the variants change?**

FDA will continue to work with ASPR, the CDC, and the National Institutes of Health on surveillance of variants that may impact the use of the therapies authorized for emergency use. We will provide further updates and consider additional action as new information becomes available.

### **Why haven't more prevention and treatment options that work against the current variants been approved or authorized, and when will they be available?**

Several approved or authorized treatments are expected to remain active to fight against the currently circulating variants and are widely available.

The FDA has worked around the clock throughout the pandemic and used the best available data to ensure options are available to prevent and treat COVID-19. This work is particularly important for people who are unable to get vaccinated and for immunocompromised people who may not mount an adequate immune response to vaccination.

Disease experts at HHS continually watch for new variants of any viruses and continue to monitor the potential impact that new variants might have on existing therapies. By taking this approach, we can identify the need for new medical products and ways to expedite development of new medical products to address emerging variants. For example, nearly two years ago, the FDA provided guidance to industry on how to efficiently generate non-clinical and chemistry, manufacturing and controls data that could potentially support an Emergency Use Authorization for monoclonal antibody products that had potential to be effective against emerging variants.

In December 2022, FDA and European Medicines Agency (EMA) convened a workshop to bring together the expertise of academics, clinicians, industry, and regulatory bodies to address the acceptability and challenges of alternative strategies to support the development of novel monoclonal antibody therapies including those based on prototype products that have

demonstrated safety and efficacy in clinical trials. FDA is committed to working with industry sponsors to expedite the development of new drug products to meet unmet needs, such as the need for new preventive therapies for immune suppressed patients who are unlikely to respond to vaccination.

### For More Information

[People Who Are Immunocompromised | CDC](#)

[How to Protect Yourself and Others | CDC](#)