

January 26, 2023

COVID-19 Therapeutics Information Brief

Changes to the document from the previous version are highlighted in yellow.

IMPORTANT/NEW COVID-19 Therapeutics Information

- **Evusheld Update**
- **Treatments Approved For Use**
- **Therapeutics Ordering Schedule**
- **Expiration Dating Extension Reminder**
- **COVID-19 Therapeutics Information Resources**

Evusheld Update

The U.S. Food and Drug Administration (FDA) announced on January 26, 2023, that the Emergency Use Authorization (EUA) for Evusheld (tixagevimab co-packaged with cilgavimab) has been revised and based on this revision, Evusheld is not currently authorized for use in the U.S. This is because it 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. However, people who have used Evusheld still have options to increase their protection against the most serious consequences of COVID-19, including hospitalization and death.

According to the most recent CDC Nowcast data, certain SARS-CoV-2 variants are projected to make up more than 90% of the variants currently circulating in the U.S. This means that Evusheld is not expected to provide protection against developing COVID-19 if exposed to those variants. Given that a COVID-19 infection is likely to be caused by one of these non-susceptible variants, and consistent with the terms and conditions of the Letter of Authorization, Evusheld is not currently authorized for emergency use in any U.S. region at this time. HHS and AstraZeneca have paused distribution of Evusheld until further notice by the Agency.

Treatments Approved For Use

Details about treatment options that are expected to retain activity against COVID-19 can be found [here](#) and below:

Paxlovid is authorized for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death.

Lagevrio is authorized for the treatment of mild-to-moderate COVID-19 in adults with positive results of direct SARS-CoV-2 viral testing who are at high risk for progression to severe COVID-19, including hospitalization or death, and for whom alternative COVID-19 treatment options approved or authorized by FDA are not accessible or clinically appropriate.

Veklury is approved for the treatment of adults and pediatric patients (28 days of age and older and weighing at least 3 kg) with positive results of direct SARS-CoV-2 viral testing, who are not hospitalized and have mild-to-moderate COVID-19 and are at high risk for progression to severe COVID-19, including hospitalization or death.

COVID-19 convalescent plasma with high titers of anti-SARS-CoV-2 antibodies is authorized for the treatment of COVID-19 in patients with immunosuppressive disease or receiving immunosuppressive treatment, in inpatient or outpatient settings.

Therapeutics Ordering Schedule

Effective January 2023 Therapeutic Ordering transitioned to a monthly cadence. The planned schedule for upcoming orders are below:

<u>Survey Sent</u>	<u>Survey Closed</u>	<u>Order Placed</u>
2/13/2023	2/14/2023	2/15/2023

- **Iowa HHS encourages entities who do receive allocations of therapeutic products to notify and work with prescribers and LPHAs on the availability of therapeutic products in the community.**
- The Department of Health and Human Services has released a [COVID-19 Therapeutics locator](#).

Expiration Dating Extension Reminder

Recent shelf-life extensions have been issued for several products. Before wasting any product, be sure to check for expiration date extensions by using one or more of the following resources:

- [FDA COVID-19 Therapeutics Extensions](#)
- Call: 515-281-7317
- Email: C19Therapeutics@idph.iowa.gov

COVID-19 Therapeutics Information Resources

- **COVID-19 Therapeutics Call Center: 515-281-7317.**
- **COVID-19 Therapeutics Email:** Therapeutic questions from healthcare providers can be emailed to: C19Therapeutics@idph.iowa.gov
- **COVID-19 Therapeutics Table:** IDPH has developed a table of therapeutic products available for the treatment or prevention of COVID-19.
- [Outpatient Therapeutics Decision Aid](#)
- [Side-by-Side Overview Outpatient Therapeutics](#)
- [NIH COVID-19 Treatment Guidelines](#)