

April 13, 2023

COVID-19 Therapeutics Information Brief

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

IMPORTANT/NEW COVID-19 Therapeutics Information

- Public Health Emergency Update
- **Treatments Approved For Use**
- **HPOP Enhancement**
- **Therapeutics Ordering Schedule**
- Expiration Dating Extension Reminder
- COVID-19 Therapeutics Information Resources

Public Health Emergency Update

On January 30, 2023, the Biden Administration announced its intent to end the national emergency and public health emergency declarations on May 11, 2023, related to the COVID-19 pandemic. Importantly, the ending of the public health emergency declared by HHS under the Public Health Service Act will not impact FDA's ability to authorize devices (including tests), treatments or vaccines for emergency use. Existing emergency use authorizations (EUAs) for products will remain in effect and the agency may continue to issue new EUAs going forward when criteria for issuance are met. This means the process for obtaining, administering, and reporting COVID-19 therapeutics will remain unchanged. CMS reimbursement is also planned to continue.

Additional details and FAQs may be found [here](#) and [here](#).

Detailed information and resources regarding Medicare and Medicaid Services may be found [here](#).

Treatments Approved For Use

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

Treatments Available to Order from USG Supply

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.

Other Current Approved Treatments

Gohibic (Vilobelimab) 4/4/2023 FDA issued an emergency use authorization (EUA) for the use of Gohibic (vilobelimab) injection for the treatment of COVID-19 in hospitalized adults when initiated within 48 hours of receiving invasive mechanical ventilation or extracorporeal membrane oxygenation (artificial life support).

<https://www.fda.gov/drugs/drug-safety-and-availability/fda-authorizes-gohibic-vilobelimab-injection-treatment-covid-19>

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.

HPOP Enhancement

The enhanced HPOP system will be launched on April 17, 2023. The HPOP enhancement will provide an improved interface and a workflow able to manage products from multiple responses simultaneously.

Current users will need to re-authenticate to log into the enhanced system. The re-authentication notification with the necessary links and the new URL will be sent on the day of the launch (4/17/23) to all current users.

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>
05/01/2023	05/02/2023	05/03/2023
06/05/2023	06/06/2023	06/07/2023

- **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](#).
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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:

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

C19 Therapeutics Call Center: (515) 281-7317 | C19Therapeutics@idph.iowa.gov