

**COVID-19 Therapeutics Bi-Weekly Update**  
**May 16th, 2022**

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Therapeutics in the news

Olumiant (baricitinib) for the treatment of COVID-19 in *hospitalized adults*

On Tuesday, May 10, the FDA approved a [new indication](#) for Olumiant (baricitinib) for the treatment of COVID-19 in **hospitalized adults** requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO). Olumiant is the first immunomodulatory treatment for COVID-19 to receive FDA approval. The FDA first issued an emergency use authorization (EUA) for [Olumiant in combination with remdesivir](#) to treat COVID-19 in hospitalized adults and pediatric patients on November 19, 2020. On July 28, 2021, the FDA revised the EUA to authorize Olumiant as a standalone treatment. Olumiant remains under EUA status for hospitalized pediatric patients 2 to less than 18 years of age requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or ECMO.

Notes about Paxlovid from the FDA’s OID

Dr. John Farley, director of the Office of Infectious Diseases (OID) in the Center for Drug Evaluation and Research’s Office of New Drugs (OND), responded to some FAQs regarding Paxlovid. See the entire transcript at this [link](#) where he addressed the below questions:

- *What does “direct SARS-CoV-2 viral testing” mean? Do patients need a positive polymerase chain reaction (PCR) test to be treated with Paxlovid?*
- *How should healthcare providers assess a patient for “high risk for progression to severe COVID-19”?*
- *Are there tools to help health care providers manage potential drug-drug interactions?*
- *Is dose adjustment of Paxlovid needed for patients with moderate renal impairment?*
- *How can I locate a community pharmacy that has Paxlovid in stock?*
- *What do we know about the case reports of patients developing symptoms again after completing a course of Paxlovid?*

Dr. Farley’s closing remarks were:

*I would like to reiterate that Paxlovid is now widely available at community pharmacies. There is strong scientific evidence that it reduces the risk of hospitalization and death in patients with mild-to-moderate COVID-19 at high risk for progression to severe disease. It is also expected to be effective against the Omicron variant. For more information about the EUA for Paxlovid, including possible risks of use, the Fact Sheet for Health Care Providers, and Prescriber Patient Eligibility Checklist, please visit FDA’s Emergency Use Authorizations webpage.*

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Process and logistics updates

## Do you need printed materials about therapeutics for your space?

To increase education and awareness of therapeutics across the state, the Virginia Department of Health is offering to send **printed COVID-19 Therapeutic Communication Materials at no cost** to healthcare providers. We encourage providers to have these materials on-hand to post in their practice and provide to patients, with the goal of increasing utilization of therapeutics. To request printed materials, complete the form [here](#). Please allow for 4 to 6 weeks for delivery.

*The digital formats can be accessed on our website via the links below:*

- [EVUSHELD Fact Sheet for Patients\\*](#)
- [Paxlovid Patient Fact Sheet for Patients\\*](#)
- [Lagevrio \(Molnupiravir\) Patient Fact Sheet for Patients\\*](#)
- ["Are you at high risk for COVID-19 illness?" Handout/Poster\\*](#)
- ["Test Positive for COVID-19?" Handout/Poster\\*](#)
- ["Benefits of COVID-19 Vaccination and Medication" Handout](#)

## Bamlanivimab (BAM) Expiration Extension

Wednesday May 4th, the FDA [authorized an extension](#) to the shelf-life from 18 months to 24 months for specific lots of the refrigerated Eli Lilly monoclonal antibody, bamlanivimab. Due to the high frequency of the Omicron variant, bamlanivimab and etesevimab are not currently authorized in any U.S. region. Therefore, these drugs may not be administered for treatment or post-exposure prevention of COVID-19 under the Emergency Use Authorization until further notice by the Agency. However, it is the recommendation of the U.S. Government that the product be retained in the event that future SARS-CoV-2 variants, which may be susceptible to bamlanivimab and etesevimab, emerge and become prevalent in the U.S.

## Renal Paxlovid ordering in HPoP

Renal Paxlovid Notice: The Renal Paxlovid NDC code in HPoP has been changed to the carton code 0069-1101-20. Background: this was originally in HPoP as 0069-1101-04, however this is incorrect. Please utilize the updated code!

## HPoP License Expiration

Please ensure your license expiration date is up-to-date in HPoP as those whose documented expiration date has passed **will not have their therapeutic orders fulfilled until the expiration date is in the future**. Starting May 3<sup>rd</sup>, providers will receive a warning message from HPoP regarding impending provider license expiration. For additional questions, please contact [COVID19Therapeutics@vdh.virginia.gov](mailto:COVID19Therapeutics@vdh.virginia.gov).

## Federal Government to distribute directly to pharmacies with hopes to increase geographic distribution of product

On April 25, the federal government further optimized therapeutics availability by directly distributing oral antiviral therapeutic products (Lagevrio, Paxlovid, Paxlovid-renal) to Federal Retail Pharmacy

Therapeutics Program (FRPTP) partners. Oral antiviral therapeutic products directly distributed to FRPTP partners will be separate from threshold amounts determined for state and territorial health departments. Through direct distribution to FRPTP partners, we will be able to increase geographic distribution of product and improve patient access, ensure baseline in-field inventory is sufficient to meet demand, and ensure robust distribution channels are poised to mobilize product across jurisdictions during potential COVID-19 surges.

The new threshold allocation scenario will have no impact or change on the state's allocation to providers. Providers will continue to request Therapeutics in VaxMaX by 12pm ET on Tuesdays and VDH will place orders in HPoP by 5pm on Tuesdays.

### Therapeutics locator tool

In case you missed it - recently, the locator tool to identify places to obtain COVID-19 therapeutics was transitioned to the Federal level. You can identify locations to obtain therapeutics [here](#). This link will now appear throughout the [VDH website](#) to ensure you can easily locate services providers.

## Allocation data

### Total Allocations to Therapeutic Administration Sites (5/2/2022 – 5/10/2022):

Therapeutic (mAB & OAV*)	Central	Eastern	Northern	Northwest	Southwest	Total
<b>Bebtelovimab</b>	85	170	380	130	165	<b>930</b>
<b>Evusheld</b>	384	24	24	24	72	<b>528</b>
<b>Lagevrio (Molnupiravir)</b>		0	0	0	24	<b>24</b>
<b>Paxlovid</b>		<b>40</b>	<b>440</b>	<b>100</b>	<b>60</b>	<b>640</b>

\*Oral Antiviral numbers presented do not include those allocated to Community Pharmacy Enhanced Services Network. These Oral Antiviral courses were bulk ordered and distribution to individual site locations is managed by respective Federal Retail Pharmacy Therapeutic Program (FRPTP) partners, VDH does not have visibility of course distribution to each region.

\*Please reference the Outpatient Therapeutic Portfolio- Jurisdiction Allocations for more detail.

## VDH resources

We'd love your feedback

Please take a moment to complete this [quick survey](#) so we can continually improve!

## VDH Therapeutics Website for Healthcare Providers

Check out the VDH Therapeutics webpage [here](#). Reach out to [COVID19Therapeutics@vdh.virginia.gov](mailto:COVID19Therapeutics@vdh.virginia.gov) for questions, comments, or feedback on information you'd like to see.

## COVID-19 Therapeutics Webinars and Open Forum Calls

- VDH is continuing to facilitate webinars and open forums monthly. See below for links to [register](#)!

*May 25 Open Forum:*

[https://vdh.zoom.us/webinar/register/WN\\_aqexxTf3QoeiONWOcJ4jKg](https://vdh.zoom.us/webinar/register/WN_aqexxTf3QoeiONWOcJ4jKg)

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## Additional resources and education

### CDC Resources

The CDC recently sent [this email](#) promoting the use of therapeutics to an open listserv. Take this as an additional opportunity to have discussions with your patients and consider therapeutics in eligible patients!