Efficacy Update: Monoclonal Antibodies

The HHS Office of the Administration for Strategic Preparedness and Response (ASPR) highlighted in a recent discussion the retained efficacy of monoclonal antibodies, EVUSHELD and Bebtelovimab, against the current circulating variants. However, live virus data for BA.4/5 remains pending. For more in depth reporting see the EUA Factsheet EVUSHELD and EUA Factsheet Bebtelovimab.

### Efficacy of Evusheld

<table>
<thead>
<tr>
<th>Lineage</th>
<th>Country</th>
<th>WHO Nomenclature</th>
<th>Key Substitutions Tested</th>
<th>Fold Reduction (Pseudotyped VLPs)</th>
<th>Fold Reduction (Authentic Virus)</th>
</tr>
</thead>
<tbody>
<tr>
<td>BA.1</td>
<td>Botswana</td>
<td>Omicron (BA.1)</td>
<td>G339D+S371L+S373P+ S375F+K417N+N440K+G446S+S477N+T478K + E484A+Q493R+Q496S+Q489R+H501Y+Y505H</td>
<td>132- to 163-fold#</td>
<td>12- to 30-fold</td>
</tr>
<tr>
<td>BA.2</td>
<td>Multiple country origin</td>
<td>Omicron (BA.2)</td>
<td>G339D+S371F+S373P+ S375F+T376A+D405N+ R408S+K417N+N440K+S444G+S477N+T478K+G446A+Q433R+Q498R+H501Y+Y505H</td>
<td>No Change5</td>
<td>5.4-fold</td>
</tr>
</tbody>
</table>
Prescribing Paxlovid: What Pharmacists Need to Know

The process remains very new and adjustments will take time. Main points for pharmacists to consider:

- Kidney and renal function cannot be verified
- Drug-drug interaction(s) must be resolved with modification of another medication
- Patient is not eligible for Paxlovid

The pharmacist should refer the patient to a medical provider for further consultation. For more in depth information, see Fact Sheet for Healthcare Providers: EUA for Paxlovid [here](https://www.fda.gov/drugs/professionals-drug-information-fda-authorized-use-extension-paxlovid).

**REMINDER: EVUSHELD Dosing**

Please see below for important information on repeat EVUSHELD doses.
COVID-19 Public Health Emergency Declaration Renewed

Effective July 15, U.S Health and Human Services Secretary Xavier Becerra renewed the COVID-19 public health emergency declaration to meet the continued needs during the ongoing COVID-19 pandemic. Health care providers and state and territorial health departments need continued flexibility to respond to the pandemic. Renewing the public health emergency declaration ensures these needs are met.

HHS will provide states and territories with no less than 60 days’ notice prior to the termination of the public health emergency declaration for COVID-19.

Visit ASPR’s website to read the latest information about the COVID-19 public health emergency declaration renewal, and to learn more about public health emergency declarations.

HHS Reorganized to Better Meet Pandemic Needs

It was just announced by US DHHS Secretary O’Connell that Administration for Strategic Preparedness and Response (ASPR), formerly known as the Office of the Assistant Secretary for Preparedness and Response, has undergone some organizational changes. The current statutory authorities and responsibilities of ASPR remain unchanged. Read more of the Washington Post article here.

Changes include:

● New name: Administration for Strategic Preparedness and Response (ASPR)
● Addition of an institutional profile of an “operating division” (OpDiv) who will work alongside other HHS agencies such as the FDA and the CDC.
NEW: Renal Paxlovid-Out of Cycle (OOC) Request

At the current, temporary, supply environment HHS is unable to support any OOC request for Renal Paxlovid. When the supply environment improves we can re-engage with these requests.

As a reminder, when dispensing Paxlovid for the renally impaired and renal packaging is not available, healthcare professionals should complete the following:

- Remove **two** nirmatrelvir tablets from daily blister cards (i.e., **one** of the 150 mg nirmatrelvir tablets from the morning dose and **one** of the 150 mg nirmatrelvir tablets from the evening dose) prior to dispensing
- Notify patients that blister cards have been altered at the pharmacy and counseling patients about renal dosing instructions. Stickers are placed over the area that has been punched out.

AmerisourceBergen has additional stickers for this and sites can place requests directly to them if more stickers are required. In addition, at this time we do not expect the thresholds at the jurisdictional channel to be impacted, and should continue with similar amounts of Renal Paxlovid. If an order fulfillment is delayed, please reach out directly to AmerisourceBergen at c19therapies@amerisourcebergen.com to obtain stickers to implement a renal dose adjustment.

**Reminder: Paxlovid Shelf-Life Extension**

<table>
<thead>
<tr>
<th>Lot#</th>
<th>Extended Expiry Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>FL4516, FL4517, FR7229</td>
<td>The initial 3 lots were extended from 7/31 to 10/31/22.</td>
</tr>
<tr>
<td>FR9088</td>
<td>4th lot was extended from 8/31 to 11/30/22</td>
</tr>
</tbody>
</table>

**EVUSHELD: How to properly report inventory**

Reporting is required in HPOP, at a minimum of **twice per week**

To stay consistent with historical reporting, we ask that you continue to report Evusheld inventory and administrations per 300mg units (1 carton)

- Thus, **one patient dose with 600mg should be reported as 2 administrations**!!
● Administrations reporting should **always** be an **even number**
● 2 patients dosed → report in HPOP as “4” (2 patients, 4 cartons, 8 vials)
● 6 patients dosed → report in HPOP as “12” (6 patients, 12 cartons, 24 vials)

If you have been reporting differently (as 600mg units), please reach out to us at covid19therapeutics@vdh.virginia.gov and we will work with you to correct your reporting.

**REMINDER: HPoP Direct Order Temporary Suspension on TUESDAYS**

HPoP Direct Ordering will be temporarily suspended every Tuesday from **12:00-5:00 PM EST** to allow for order processing. This will provide adequate time to verify orders and coordinate redistribution of products between providers. We apologize for any inconvenience that may cause providers. We appreciate your continued work and support in providing COVID-19 therapeutics across the Commonwealth of Virginia. Any questions regarding Direct Ordering should be sent to covid19therapeutics@vdh.virginia.gov.

**REMINDER: HPoP Direct Order Request (DOR) Process**

VDH hosted a webinar on 6/23 to go over the Direct Order Request (DOR) process. The recording for this webinar can be accessed [here](#). For further instructions on the DOR process, please use the [HPoP Job Aid](#).

**REMINDER: Federal Holiday Therapeutics Thresholds and Compliance Reporting**

Therapeutic threshold determinations and notifications **will not occur** on the following federal holidays that fall on a Monday: Labor Day 9/5/22, Columbus Day 10/11/22, and Christmas 12/26/22. Deliveries will occur as scheduled on all Fridays **prior** to the corresponding Federal Holiday. If you wish to hold orders on Friday, please contact Amerisource Bergen at C19therapies@amerisourcebergen.com

Provider compliance reporting should occur on Mondays and Thursdays by 11:59 PM EST. However, on these federal holidays that fall on a Monday, the **deadlines will be shifted one day** and should be performed on the **next business day** (Tuesdays 9/6/22, 10/12/22 and 12/27/22) by 11:59 PM EST.

Any questions regarding therapeutics thresholds and notifications or provider reporting compliance should be sent to covid19therapeutics@vdh.virginia.gov.

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### Allocation data

**Total Allocations to Therapeutic Administration Sites (07/07/2022 - 07/20/2022):**

<table>
<thead>
<tr>
<th>Therapeutic (mAB &amp; OAV*)</th>
<th>Central</th>
<th>Eastern</th>
<th>Northern</th>
<th>Northwest</th>
<th>Southwest</th>
<th>Total</th>
</tr>
</thead>
</table>

---
<table>
<thead>
<tr>
<th></th>
<th>Bebtelovimab</th>
<th>Evusheld</th>
<th>Lagevrio (Molnupiravir)</th>
<th>Paxlovid</th>
<th>Renal Paxlovid</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>85</td>
<td>270</td>
<td>285</td>
<td>190</td>
<td>320</td>
</tr>
<tr>
<td></td>
<td>270</td>
<td>285</td>
<td>190</td>
<td>320</td>
<td>1150</td>
</tr>
<tr>
<td></td>
<td>285</td>
<td>190</td>
<td>320</td>
<td>1150</td>
<td>270</td>
</tr>
<tr>
<td></td>
<td>190</td>
<td>320</td>
<td>1150</td>
<td>270</td>
<td>85</td>
</tr>
<tr>
<td></td>
<td>320</td>
<td>1150</td>
<td>270</td>
<td>85</td>
<td>285</td>
</tr>
<tr>
<td></td>
<td>1150</td>
<td>270</td>
<td>85</td>
<td>285</td>
<td>320</td>
</tr>
</tbody>
</table>

*Oral Anti-viral numbers presented do not include those allocated to Community Pharmacy Enhanced Services Network. These Oral Anti-viral 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.

**REMINDER on Redistribution**

VDH can redistribute therapeutics within our Commonwealth. Any providers wishing to make their therapeutics available for transfer can do so by clicking the link “Redistribute Excess Therapeutics” on the VDH home page. The VDH Therapeutics team will prioritize these available therapeutics before pulling from federal supplies whenever it is advantageous to do so.

Listen to the Redistribution webinar [here](#). The Redistribution discussion starts at 8:55.

**CLINICAL REMINDER: What therapeutics are currently authorized?**

There are currently 5 therapeutics authorized. Other therapeutics should not be prescribed or administered at this time.
Available Therapeutics

<table>
<thead>
<tr>
<th>Type</th>
<th>Classification</th>
<th>Use</th>
<th>How is it given?</th>
<th>When is it given?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prevention</td>
<td>Tixagevimab / cilgavimab (EVUSHELD)</td>
<td>Monoclonal antibody for pre-exposure prophylaxis</td>
<td>By injection into muscle</td>
<td>When NOT currently infected with COVID-19 AND no known recent exposure</td>
</tr>
<tr>
<td>Treatment</td>
<td>Bebtelovimab</td>
<td>Monoclonal antibody</td>
<td>By infusion into a vein</td>
<td>Within 7 days of symptoms starting</td>
</tr>
<tr>
<td></td>
<td>Remdesivir (Veklury)</td>
<td>IV Antiviral</td>
<td>By infusion into a vein</td>
<td>Within 7 days of symptoms starting</td>
</tr>
<tr>
<td></td>
<td>Nirmatrelvir/ritonavir (Paxlovid)</td>
<td>Oral Antiviral</td>
<td>By oral tablet</td>
<td>Within 5 days of symptoms starting</td>
</tr>
<tr>
<td></td>
<td>Molnupiravir (Lagevrio)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**These therapeutics are currently deauthorized by the FDA, and should not be ordered, dispensed, or administered:**
- REGEN-COV (Casirivimab and Imdevimab)
- Sotrovimab
- Bamlanivimab and Etesevimab (“Bam-ete”)

Link to sign up for the newsletter:

Did your colleague share this newsletter with you, and you'd like to sign up to receive it directly? Do you know of a colleague that would benefit from receiving information on therapeutics from VDH? Click [here to sign up](#).

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 for Providers

- VDH is continuing to facilitate webinars and open forums monthly. See below for links to register!

  - **July 27 Open Forum:** Register [here](#).
  - **July 27 Pharmacist Webinar for Prescribing Paxlovid:** Register [here](#).
  - **August 10 Healthcare Provider COVID-19 Therapeutics Webinar:** Register [here](#).

Other resource links:
- [VDH: COVID-19 Therapeutics FAQs for Providers](#)
- [VDH: Guidance on Expiring & Expired Therapeutics](#)
- [VDH: EVUSHELD Fact Sheet for Providers](#)
VDH: Lagevrio (Molnupiravir) Prescribing Checklist
VDH: Paxlovid Prescribing Checklist
VDH: Paxlovid Prescribing Checklist- Pharmacists
HHS: ASPR Test to Treat Fact Sheet

Find where to access therapeutics here.