

**COVID-19 Therapeutics Bi-Weekly Update
July 11th, 2022**

Clinical updates

Repeat EVUSHELD dosing now recommended for continued protection

On June 29, 2022, the FDA revised the EVUSHELD [Fact Sheet for Healthcare Providers](#) to recommend **repeat dosing every 6 months(300mg of tixagevimab/300mg cilgavimab) for ongoing protection**. This is new information as the previous fact sheet did not provide a specific recommendation on the dosing interval.

A note about EVUSHELD and circulating variants:

The FDA continues to monitor the neutralizing activity of EVUSHELD against emerging SARS-CoV-2 variants, and data suggests that activity against the currently circulating subvariants is retained for 6 months at drug concentrations achieved following an EVUSHELD dosing. The FDA will provide additional updates as required.

EUA Updates: Paxlovid

On June 29th, the FDA also updated Paxlovid’s EUA, with information related to viral RNA rebound.

- post-treatment increases were observed on day 10 and/or day 14 in a subset of paxlovid AND placebo recipients, regardless of symptoms
- this was not associated with hospitalization or death
- also not associated with drug resistance
- a similar or smaller percentage of placebo recipients experienced viral RNA rebound
- the clinical relevance of increases in viral RNA are unknown

For more in depth information, see [Fact Sheet for Healthcare Providers: EUA for Paxlovid](#)

On July 6th, the FDA made additional revisions to the EUA, to authorize state-licensed pharmacists to prescribe Paxlovid, with certain limitations to ensure appropriate patient assessment and prescribing.

The Board of Pharmacy has confirmed that pharmacists are authorized to prescribe Paxlovid per the Paxlovid EUA. You do not need to wait for a state protocol to prescribe Paxlovid as this is authorized per the 9th amendment of the PREP Act. Please note that pharmacists are only able to prescribe Paxlovid if the following conditions are met:

- 1) Health records less than 12 month old are available to assess renal and hepatic function, AND
- 2) A comprehensive medication list (OTC and Rx) is available to assess drug-drug interactions

Pharmacists should not prescribe Paxlovid and instead refer patients to their primary care provider if the above criteria cannot be met, if a drug-drug interaction must be resolved with modification of another medication or if the patient is not eligible for Paxlovid.

Attn Pharmacists: FAQ related to NPI numbers

1. Why do I need an NPI number?

An NPI number is required for a healthcare provider covered under the Health Insurance Portability and Accountability Act (HIPAA) to transmit any health information in an electronic form between two parties to carry out financial or administrative activities related to healthcare. The individual pharmacist must have an individual NPI as the pharmacist is acting on behalf of themselves, rather than the behalf of the pharmacy. Individual health care providers receive a Type 1 NPI number and health care organizations, such as pharmacies, receive a Type 2 NPI number.

2. How do I obtain an NPI number?

Pharmacists may visit the [National Plan and Provider Enumeration System](#) to register for an NPI number. There is no cost to the provider to obtain an NPI number.

EVUSHELD Shelf-life Extension

On June 28, 2022, the Office of the Assistant Secretary for Preparedness and Response (ASPR) and the Food and Drug Administration (FDA) announced the authorization of an extension to the shelf-life from 18 months to 24 months for the specific lots of the refrigerated AstraZeneca monoclonal antibody therapy, EVUSHELD (tixagevimab co-packaged with cilgavimab), which is currently authorized for emergency use for pre-exposure prophylaxis of COVID-19 in certain adults and pediatric individuals.

As a result of this extension, some batches may be stored for an additional 6 months from the labeled date of expiry (see Table 1 below) and, as required by the emergency use authorization for EVUSHELD, unopened vials of EVUSHELD (150 mg/1.5 mL of tixagevimab and 150 mg/1.5mL of cilgavimab), must be stored under refrigerated temperature at 2°C to 8°C (36°F to 46°F) in the original carton to protect from light. FDA granted this extension following a thorough review of data submitted by AstraZeneca. This extension applies to all unopened vials of EVUSHELD that have been held in accordance with storage conditions detailed in the authorized [Fact Sheet for Health Care Providers](#) and the [Letter of Authorization for Emergency Use Authorization \(EUA\) 104 for EVUSHELD](#).

EVUSHELD has fixed expiration dates on the label of each vial and carton. The date identified on the vial and carton reflects the original shelf-life of 18 months and does not reflect the extended 24-month shelf-life. The table below provides a list of the updated expiry, by batch, for distributed EVUSHELD. If the batch number on the vial/carton is not included in this listing, the product is labeled with the correct expiration date. If this changes or more lot numbers are added to this list of extended expirations we will provide that information as it becomes available.

Note: one lot was NOT INCLUDED in the EVUSHELD shelf-life extension: **AZ2200491, “lot 12” will still expire August 31, 2022.**

Table 1: Extended Expiry Dating for EVUSHELD (Tixagevimab Co-Packaged with Cilgavimab) Authorized under EUA 104

Co-Pack Lot Numbers	Labeled Co-Pack Expiration Dates	Extended Co- Pack Expiration Dates	Component Lot Numbers
AZ210059	Jul 2022	Jan 31, 2023	Cilgavimab: 2100505 Tixagevimab: 2100511
AZ210062	Jul 2022	Jan 31, 2023	Cilgavimab: 2100505 Tixagevimab: 2100511
AZ210065	Jun 2022	Dec 31, 2022	Cilgavimab: 2100503 Tixagevimab: 2100509
AZ220033	Aug 2022	Feb 28, 2023	Cilgavimab: 2100550 Tixagevimab: 2100551
AZ220036	Aug 2022	Feb 28, 2023	Cilgavimab: 2100552 Tixagevimab: 2100549
AZ220061	Aug 2022	Feb 28, 2023	Cilgavimab: 2100552 Tixagevimab: 2100549
AZ220042	Jul 2022	Jan 31, 2023	Cilgavimab: 2100552 Tixagevimab: 2100511
AZ220053	Jul 2022	Jan 31, 2023	Cilgavimab: 2100507 Tixagevimab: 2100509
AZ220059	Jul 2022	Jan 31, 2023	Cilgavimab: 2100507 Tixagevimab: 2100511
AZ220056	Jul 2022	Jan 31, 2023	Cilgavimab: 2100507 Tixagevimab: 2100513

Process and logistics updates

NEW ALERT: 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 transitioned from the previous COVID-19 Therapeutics ordering process that took place in VaxMaX to a new process that takes place in the Health Partner Order Portal ([HPoP](#)). This change occurred on Friday, 6/24/2022 at 4:00 PM Eastern. All providers who need to request therapeutics will be required to order through the portal using the updated process. For your convenience, an ordering link to HPOP was added to the [VDH Therapeutics Webpage](#).

Please note this new DOR for COVID-19 **Therapeutics** will not affect the process for ordering COVID-19 vaccines. Vaccines will still be ordered in VaxMax and Therapeutics will be ordered in HPoP.

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.

Allocation data

Total Allocations to Therapeutic Administration Sites (6/23/2022 – 07/06/2022):

Therapeutic (mAB & OAV*)	Central	Eastern	Northern	Northwest	Southwest	Total
Bebtelovimab	30	410	270	320	310	1345
Evusheld	221	96	144	120	24	605
Lagevrio (Molnupiravir)	0	48	0	0	72	120

Paxlovid	260	140	760	180	220	1560
Renal Paxlovid	5	45	20	15	25	110

*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.

Resources

Therapeutics locator tool:

Find where to access therapeutics [here](#).

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 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!](#)

July 13 Webinar:

https://vdh.zoom.us/webinar/register/WN_G_yp2canSdqHzZ3pnbSKKA

