COVID-19 Therapeutics Bi-Weekly Update
May 31st, 2022

We'd love your feedback

Please take a moment to complete the Provider Pulse Check survey by clicking here!

Therapeutics in the news

A new Health Alert Network (HAN) Alert from the CDC!

On May 24th, the CDC issued a HAN alert related to COVID-19 rebound after Paxlovid treatment. The notice can be reviewed here. COVID-19 rebound, defined as a recurrence of symptoms 2-8 days after initial recovery and/or a positive re-test after testing negative, has been reported. It is also noted that a brief return of symptoms may be a part of the natural course of the virus, independent of Paxlovid treatment and independent of vaccination status. Paxlovid continues to be recommended for early-stage treatment of mild-moderate disease among eligible individuals.

Recommendations for healthcare providers include:

- There is currently no evidence that additional treatment is needed after rebound
- Isolation precautions in efforts to prevent transmission are recommended after rebound
- Consider clinical evaluation of patients who rebound, particularly if symptoms persist or worsen
- Report rebound to both Pfizer and the FDA

US sees a spike in Paxlovid usage

New data from HHS shows that 162,000 courses of Paxlovid were administered across the U.S. last week. This continues a streak of increases week over week, which in part signals improving awareness around COVID-19 therapeutics and how to access them. Some of the spike in usage is attributed to the federal test-to-treat program, which allows a prescriber to order and pharmacy to dispense treatments all in the same location where a patient tests positive. Pfizer does not have any concerns about the ability to maintain supply even as usage increases.

Pfizer to expand manufacturing site to support Paxlovid

Pfizer is planning to expand its largest manufacturing facility in support of the rollout and increasing demand of Paxlovid. This expansion will boost jobs and is a site responsible for producing 150 products and shipping to 113 countries around the world.

Updated: from the FDA: *Know Your Treatment Options for COVID-19*

The FDA published the refreshed consumer update webpage with the latest information on COVID-19 therapies. The FDA has approved two drug treatments for COVID-19 (remdesivir for adults and peds, hospitalized and outpatient; baricitnib for hospitalized adults) and has authorized others for emergency use during this public health emergency. This is a great resource to review and share with your patients!

Updated: from HHS

HHS also recently updated two resources to reflect recent changes (specifically the renal dose packaging for Paxlovid and the status of remdesivir to "approved" from "authorized").

Review them here:
Side by Side Overview of Therapeutics
Clinical Implementation Guide

Process and logistics updates

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!

A note about Bebtelovimab supply

Oral antiviral supply continues to be ample; however, bebtelovimab has a finite and therefore somewhat limited supply due to a lack of funding to renew federal government funding of the medication. It is important for providers to be stewards of this medication and reserve it for cases where paxlovid is not appropriate or contraindicated, for example in situations where the patient is outside the 5 day eligibility window for Paxlovid but still within the 7 day window for bebtelovimab. **As a reminder, Paxlovid remains the first line treatment for COVID-19 per the NIH Treatment Panel Recommendations and should be considered first for patients who qualify.**

New! Bebtelovimab and Paxlovid have extended shelf-life

On May 20th, the FDA authorized an extension to the shelf-life from 12 to 18 months for bebtelovimab. As a reminder, unopened vials must be stored at 2 to 8 degrees C in its original carton to protect the medication from light.

Extended Expiry Dating for Bebtelovimab Authorized under EUA 111

Batch Number	Labelled Expiry Date	Extended Expiry Date
D476887	2022-07-11	2023-01-11
D476886	2022-07-13	2023-01-13
D487999	2022-07-13	2023-01-13
D480382	2022-10-27	2023-04-27
D488000	2022-10-27	2023-04-27
D492098	2023-02-16	2023-08-16
D494710	2023-02-16	2023-08-16
D493128	2023-02-17	2023-08-17

Reminder: Sotrovimab and Paxlovid Expiration

Sotrovimab and Paxlovid have an extended expiration date. And remember, even though Sotrovimab is not currently authorized for treatment of COVID-19, it may have efficacy in the future with yet unknown strains of COVID-19, so all providers should continue to store and maintain it in the event that it will be required at a later date. Review more on Sotrovimab from HHS here.

Extended Expiry Dating for Sotrovimab Authorized under EUA 100

Batch Number	Labeled Expiry Date	Extended Expiry Date
658W	2022-02	2022-08
XV6W	2022-04	2022-10
Y74D	2022-04	2022-10
JP9Y	2022-04	2022-10
287F	2022-04	2022-10
287X	2022-05	2022-11
432U	2022-05	2022-11
433C	2022-05	2022-11

Reminder: Extended Expiry Dates on Paxlovid

Drug Name	Lot#	Extended Expiry Date
Paxlovid	FL4516, FL4517, FR7229	The initial 3 lots were extended from 7/31 to 10/31/22.
	FR9088	4th lot was extended from 8/31 to 11/30/22

Redistribution Efforts Underway

There are efforts underway at the Virginia Department of Health to establish a redistribution plan for therapeutics. Stay tuned in the coming weeks to hear more about what this will look like and what it means for you.

Allocation data

Total Allocations to Therapeutic Administration Sites (5/11/2022 – 5/25/2022):

Therapeutic (mAB & OAV*)	Central	Eastern	Northern	Northwest	Southwest	N/A	FRPTP	Total
Bebtelovimab	130	255	665	365	265	0	0	**1680**
Evusheld	264	72	144	0	48	0	0	**528**
Lagevrio (Molnupiravir)	72	24	0	0	0	24	72	**192**
Paxlovid	120	60	1260	380	140	20	60	**2040**
Renal Paxlovid	0	25	30	55	20	0	0	**130**

*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 for questions, comments, or feedback on information you'd like to see.