COVID-19 Therapeutics Bi-Weekly Update
June 13th, 2022

Clinical Corner

Paxlovid: notes for providers from the FDA

Dr. John Farley, Director of the Office of Infectious Diseases, answers some questions to support providers in prescribing Paxlovid.

Do patients need a positive PCR test before being treated with Paxlovid?

Confirmation of a positive antigen test with a PCR test, even if a home rapid antigen variety, is not required.

How do providers assess a patient to be "high risk for progression to severe COVID-19"?

The CDC maintains a list of medical conditions/factors that are associated with severe COVID-19 based on reviews of data and literature. More than one risk factor is NOT required, and these factors should be considered regardless of vaccination status - though vaccination status can be appropriate to consider in assessing a patient's risk.

Tools to help evaluate drug-drug interactions

- FDA's Fact Sheet for Health Care Providers has been updated to include specific recommendations for some drugs
- FDA developed a Prescriber Patient Eligibility Screening Checklist
- NIH Treatment Guidelines
- University of Liverpool Drug Interactions

Is dose adjustment needed for patients with renal impairment?

Yes - there are two dose packs, one of which is intended for patients with moderate renal impairment (eGFR between 30-60 mL/min). This dose pack has an adjusted dosage of the nirmatrelvir component of Paxlovid.

How do I locate a community pharmacy with Paxlovid?

Use the locator tool - you can search by zip code and available pharmacies will be listed in order of proximity.

What do we know about the case reports of COVID rebound after Paxlovid?

Additional analyses have taken place in light of reports of patients who re-test positive for COVID-19 after having tested negative and after completing a course of Paxlovid. Some patients (1-2%) tested positive after having tested negative or experienced an increase in the amount of SARS-CoV-2 detected by PCR, after completing Paxlovid. This finding was also demonstrated in the placebo group. Analyses have also shown that patients did not have symptoms upon the re-test, and notably there was NO increase in hospitalization or death from rebound.

The reports do not change the conclusions related to Paxlovid as the first line therapeutic option due to its marked reduction in hospitalization or death.

Clinical reminder: What therapeutics are currently authorized?

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

Pre-exposure prophylaxis:	EVUSHELD
Treatment:	Paxlovid (first line oral antiviral)
	Molnupiravir (second line oral antiviral)
	Bebtelovimab (monoclonal antibody)
	Remdesivir (IV antiviral)

These therapeutics are currently deauthorized by the FDA, and should not be ordered, dispensed, or administered:

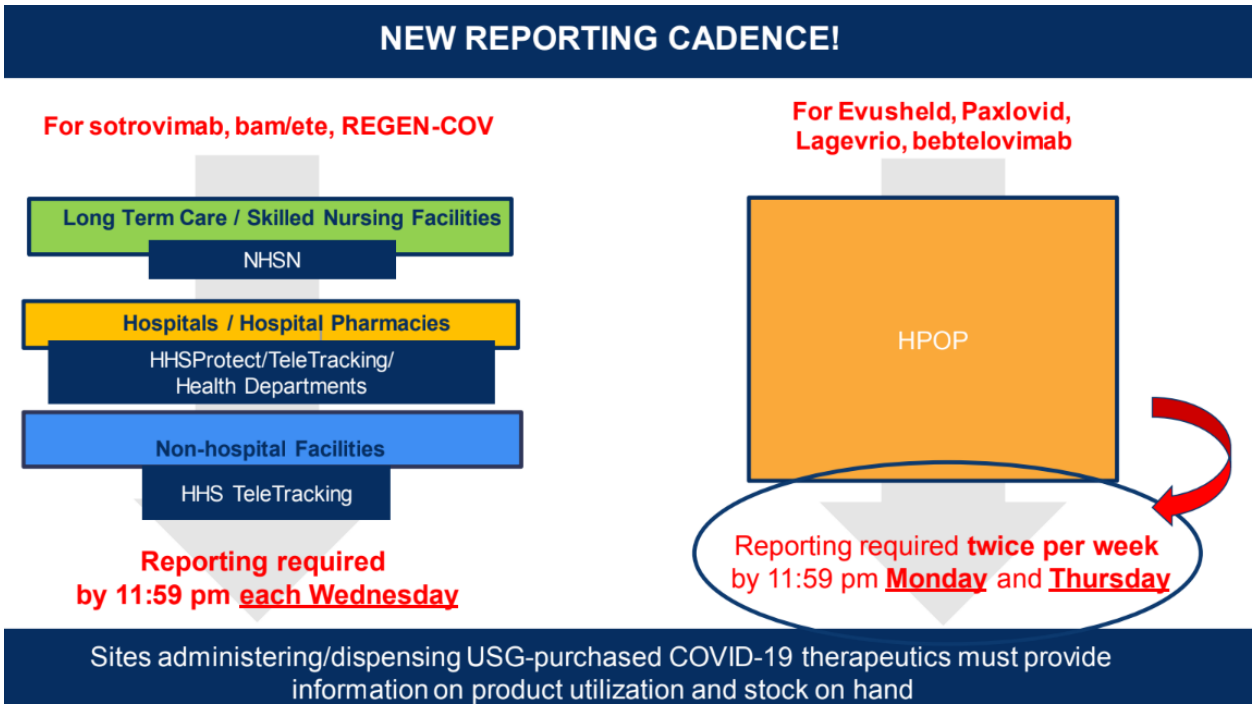
REGEN-COV (Casirivimab and Imdevimab)
Sotrovimab
Bamlanivimab and Etesevimab ("Bam-ete")

Additional information related to route, efficacy, and considerations are included below under "additional resources"

Process and logistics updates

Reporting update!

Great news! Based on feedback from providers on the difficulty of reporting daily, as of this week the **new required reporting cadence will be only bi-weekly on Monday and Thursday.** It is hoped that this will reduce the laborious nature of reporting and improve compliance. As a reminder, this reporting is necessary because it fuels all metrics related to utilization of these therapeutics!



Results from our recent Provider Survey

The Therapeutics Unit recently surveyed Virginia's COVID-19 Providers to better understand the provider experience as well as any barriers as it relates to ordering and administering COVID-19 therapeutics. Thank you to those of you who participated!

Highlights and trends from the survey results include:

- *Reporting Compliance*

  Weekly reporting compliance requirements were reported as a barrier. The Virginia Department of Health continues to work with the Department of Health and Human Services to relay provider feedback and collaborate to improve the reporting compliance process.

- *Low Demand and prescriber and patient hesitancy*

  In general, one of the leading barriers to utilizing COVID-19 therapeutics reported was low demand. Providers also indicated that prescriber and patient hesitancy both play a role in low utilization of COVID-19 therapeutics.

- *Billing and Reimbursement for Oral Antivirals*

  Issues around billing for therapeutics and reimbursement were frequently reported as a barrier.

- *Provider and Patient Awareness*

  Providers reported that they would like to receive more educational materials, including patient handouts, about COVID-19 therapeutics. The Virginia Department of Health's Therapeutics Unit has several flyers and handouts available and these can be accessed on the VDH COVID-19 Therapeutics webpage, additionally, providers may request printed materials by completing this survey.

Important Note: NPI number in HPoP

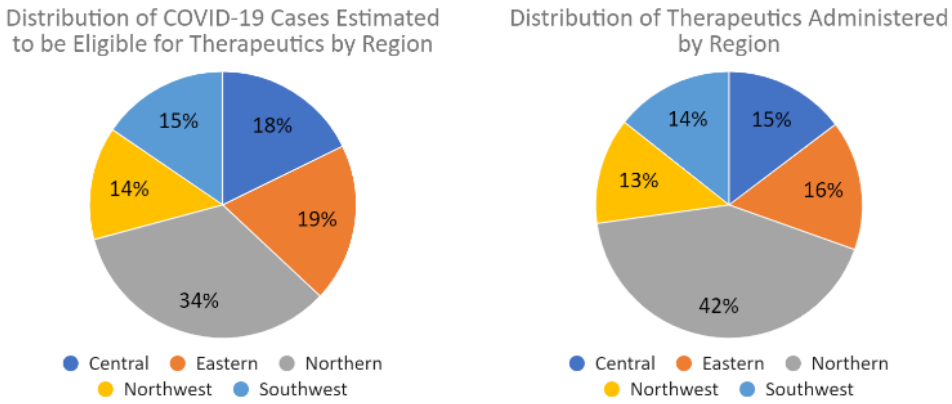
Providers are encouraged to enter their NPI number into HPoP if you haven't done so already. In the near future this will be mandated in order to receive shipments (date TBD by HHS).

Regional Distribution of COVID-19 Cases compared to Therapeutics Administered

The Therapeutics Unit has been tracking the regional distribution of COVID-19 cases estimated to be eligible for Therapeutics compared to the distribution of COVID-19 Therapeutics administered in a given week, as shown below. If you are located in a region with high COVID-19 case counts and have questions about increasing your Therapeutics orders or administrations, contact COVID19Therapeutics@vdh.virginia.gov for support.

The Distribution of COVID-19 Cases vs. Therapeutics Administered by Region

Week of 5/30/2022 - 6/5/2022



Note: The population of COVID-19 cases eligible for COVID-19 Therapeutics is estimated as (30% of the COVID-19 cases of aged 18-64 population) + (All COVID-19 cases of aged 65+ population).

Reminder: A note about Bebtelovimab supply

Oral antiviral supply continues to be ample; however, bebtelovimab has a finite and therefore somewhat limited supply due to limited funding from the federal government. 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.**

Reminder: Therapeutics (Bebtelovimab, Paxlovid, and Sotrovimab) have extended shelf lives

See below for labeled and corresponding expiry dates for these therapeutics. It is important that providers maintain supply of all therapeutics, including those that are currently deauthorized, in anticipation of any potential activity these medications may retain against future strains of COVID-19.

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

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

Efforts are underway at the Virginia Department of Health to establish a redistribution capability for COVID-19 therapeutics. The aim is to reduce potential waste of therapeutics due to expiration and to provide a provider-to-provider cross level capability to stretch the supply of therapeutics within our Commonwealth, should supply become constrained. 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 (5/26/2022 – 6/08/2022):

Therapeutic (mAB & OAV*)	Central	Eastern	Northern	Northwest	Southwest	Total
Bebtelovimab	260	225	395	265	385	**1530**
Evusheld	312	312	336	48	48	**1056**
Lagevrio (Molnupiravir)	0	120	0	0	24	**144**
Paxlovid	120	120	100	140	200	**680**
Renal Paxlovid	10	35	0	0	35	**80**

*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

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***!

  June 15 Webinar:
  https://vdh.zoom.us/webinar/register/WN_NXBqf6eBSXqMUJAKcE6UGA

Additional resources and education

Consider joining the CDC's webinar on therapeutics this Thursday June 16, 2-3 PM:

What Clinicians Need to Know About Available Therapeutic Options for COVID-19

- Subject matter experts will present an overview of COVID-19 therapeutic options, including indications, efficacy, and distribution.
- Join the webinar here
  - Passcode: 308026
  - Webinar ID: 160 396 0029
  - Dial in: 669-254-5252 or 646-828-7666 or 551-285-1373 or 669-216-1590

Available Therapeutics

	Type	Classification	Use	How is it given?	When is it given?
Prevention	Tixagevimab / cilgavimab (EVUSHELD)	Monoclonal antibody for pre-exposure prophylaxis	• For those NOT infected with COVID-19 • No known exposure to COVID-19 AND • Moderate to severe immune system compromise or who may not mount an adequate immune response to vaccination	By injection into muscle	When NOT currently infected with COVID-19 AND no known recent exposure
Treatment	Bebtelovimab	Monoclonal antibody	For treatment of mild-moderate COVID-19	By infusion into a vein	Within 7 days of symptoms starting
	Remdesivir (Veklury)	IV Antiviral	For treatment of COVID-19 (inpatient or outpatient)	By infusion into a vein	Within 7 days of symptoms starting
	Nirmatrelvir/ritonavir (Paxlovid)	Oral Antiviral	For treatment of mild-moderate COVID-19	By oral tablet	Within 5 days of symptoms starting
	Molnupiravir (Lagevrio)				

Therapeutics Efficacy

Therapeutics	Risk reduction of hospitalization or death
EVUSHELD	83% (risk reduction of developing COVID)
Paxlovid	88-90%
Remdesivir	87%
Bebtelovimab	40% (relative reduction in viral load)
Lagevrio (Molnupiravir)	30%

For more information about each of these therapeutics and their clinical considerations, please join us Wednesday June 15th at noon EST for a webinar. Register here!