

March 18, 2022

VDH COVID-19 Therapeutics Bi-Weekly Update

Total Allocations to Therapeutic Administration Sites (03/07/2022 to 03/20/2022):

Therapeutic (mAB & OAV ¹)	Central	Eastern	Northern	Northwest	Southwest	Total
Bebtelovimab	65	35	50	20	80	250
Sotrovimab	0	0	72	0	72	144
Evusheld	168	0	408	528	240	1344
Molnupiravir	0	24	0	0	24	48
Paxlovid	120	60	100	40	160	480
Total	353	119	630	588	576	2266

Oral Antiviral ¹	CVS	Med Shoppe	Topco	Walgreens	Walmart	Total
Molnupiravir	1416	168	24	120	0	1728
Paxlovid	3160	0	0	300	1240	4700
Total	4,576	168	24	420	1240	6428

¹Oral 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 see Page 4 for the Outpatient Therapeutic Portfolio- Jurisdiction Allocations for more detail.

Therapeutics Allocation Sweep

HHS has initiated a new policy practice to sweep any unordered Therapeutic product back into the Federal Pool beginning the end of this week (Saturday, March 19 – 8:00 am ET). This allows HHS to centralize unused Therapeutic inventory and more efficiently direct doses to those states that need them. This should have minimal impact on VDH's ability to fulfill the Commonwealth's COVID-19 Therapeutic needs and the process used by our providers and pharmacy partners to obtain them. Moving forward, at the end of each week, any remaining Therapeutic Inventory will be swept by HHS. Note, EVUSHELD will be swept at the end of each month due to its monthly allocation. VDH still requires that all Therapeutic requests be submitted by Tuesdays at noon.

Therapeutics Ordering Process for Federal Retail Pharmacy Therapeutic Program (FRPTP) Partners

Continuing our efforts to increase access to therapeutic treatments, Virginia Department of Health (VDH) rolled out our new oral antiviral ordering process for Federal Retail Pharmacy Therapeutic Program (FRPTP) partners. FRPTP partners now have the option to allow their individual locations to

manage their own oral antivirals requests through VaxMaX *OR* our FRPTP partners can opt to request oral antivirals in bulk for their respective chains by completing a REDCap Bulk Order Survey. For additional questions, contact covid19therapeutics@vdh.virginia.gov

Federal Initiatives for Oral Antivirals

- **Test to Treat Program**
 - Select Federal Retail Pharmacy Partnership (FRPP) with existing clinics located inside of their facilities will now be able to order the oral antivirals Paxlovid and Monupiravir directly from the federal government.
 - VDH confirmed two pharmacy chains are participating in the Test to Treat Program in Virginia: **CVS** and **Kroger**
 - Please note only these pharmacies with clinics participate in this program
 - FRPP pharmacy locations will increase opportunities for successful end-to-end Test and Treat model by co-locating testing, provider, and treatment in single location
 - Reduce barriers to rapid linkage to treatment for high-risk COVID-19+ individuals
 - Opens additional pathway of direct ordering of oral antivirals for eligible retail health clinic locations
 - Linkage to a clinical evaluation by licensed healthcare provider after positive result to provide prescription
- **Long-term Care Pharmacy Partner Program**
 - Long Term Care (LTC) Pharmacies who are participating in FRPP will now have access to order Paxlovid and Monupiravir through the Federal government.
 - Participating LTC pharmacies and FRPP partners include MHA, Omnicare and TigRx Pharmacy.

Therapeutics Usage & Inventory Reporting Requirements

- VDH is working to develop a redistribution process for therapeutics that are not anticipated to be used. More information to follow.
- **Sites with continued non-compliance with usage and inventory reporting may not have their orders fulfilled until they regularly report**
- Reporting for Sotrovimab, Regen-cov, Bam/ETE are **due every Wednesday by 11:59PM ET** in the U.S. Healthcare COVID-19 Portal (i.e., TeleTracking/NHSN)
 - VDH has published a job aid for the U.S. Healthcare COVID-19 Portal, which can be accessed [here](#)
- Reporting courses administered and daily on-hand for Paxlovid, Molnupiravir, Evusheld and Bebtelovimab are **due daily by 11:59pm EDT** in the [HHS Health Partner Order Portal \(HPoP\)](#).
 - VDH has published a job aid for the HHS Health Partner Order Portal (HPoP) [here](#)

Therapeutics Return Process for bam/ete and REGEN-COV products

All mAb products are property of the USG and must be used in accordance with EUA guidance. Any returned product will be destroyed, as product integrity cannot be verified

- Considerations for return process for bam/ete and REGEN-COV products:
 - All sites should first check with respective state and local health department(s) to ensure product cannot be used elsewhere in the state or region
 - Long-term utility of authorized mAb product is expected
 - Upon these considerations, if undamaged product needs to be returned, follow the below instructions:
 - For bam and bam/ete, see The Lilly Return Goods Procedure, detailed guidance can be found at: <https://www.lillytrade.com/>
 - For REGEN-COV, call 844-734-6643
 - Reconstituted (diluted) product SHOULD NOT be returned and should be treated as waste per your facility's SOP

Therapeutic Wastage Reporting Requirements

- As part of a new feature in the Health Partner Order Portal (HPoP), providers are now able to report therapeutic wastage in the portal
- Reporting of wastage is required only if therapeutics in your inventory expire
- Unused products that are still in date should not be discarded/destroyed and reported as wastage
 - VDH is working to develop a redistribution process for therapeutics already deployed and not anticipated to be used.
- For information regarding how to report therapeutic wastage in HPoP, please refer to the updated HPoP Job Aid [here](#)
- If you are having challenges with reporting or have questions, please contact COVID19Therapeutics@vdh.virginia.gov for assistance.

HHS Biweekly Webinar: Federal COVID-19 Response: COVID-19 Therapeutics Clinical Webinar

- Please email ASPRStakeHolderNoReply@hhs.gov to request access

New VDH Webpage

- Please note that the VDH Therapeutics webpage has been redesigned
- You can find the new webpage [here](#)

COVID-19 Therapeutics Webinar

- VDH will facilitate March webinars. Registration is required:
 - [03/23/2022](#)

COVID-19 Therapeutics Open Forum Calls

- VDH will facilitate open forum calls every other week in March
 - [03/30/2022](#)

Outpatient Therapeutic Portfolio – Jurisdiction Allocations

For Planning Purposes Only – Subject to Change

	Drug Class	Allocation Cadence	Sweep Schedule*	Allocation Mar 7	Allocation Mar 14*	Planned Allocation Mar 21*	Planned Allocation Mar 28*	Planned Allocation Apr 4*
Paxlovid Pfizer	Oral antiviral for treatment	Weekly	Transition to Weekly; Saturday	125,000	125,000	125,000	125,000	125,000
Molnupiravir Merck	Oral antiviral for treatment	Weekly	Transition to Weekly; Saturday	125,000	125,000	50,000	50,000	50,000
Sotrovimab GSK/Vir	Monoclonal for treatment	Weekly	Transition to Weekly; Saturday	52,250	52,250	35,000	35,000	35,000
Bebtelovimab Lilly	Monoclonal for treatment	Weekly	Transition to Weekly; Saturday	49,000	49,000	30,000	30,000	30,000
Evusheld AstraZeneca	Monoclonal for prevention	Monthly	Transition to Monthly; end of month	200,000 (monthly)	N/A (order against monthly)	N/A (order against monthly)	N/A (order against monthly)	200,000 (monthly)
Bam/Ete Lilly	Monoclonal; omicron resistance	Weekly	Weekly; Saturday	Distribution pause ¹	Distribution pause ¹	Distribution pause ¹	Distribution pause ¹	Distribution pause ¹
REGEN-COV Regeneron	Monoclonal; omicron resistance	Weekly	Weekly; Saturday	Distribution pause ¹	Distribution pause ¹	Distribution pause ¹	Distribution pause ¹	Distribution pause ¹
Remdesivir Gilead	IV antiviral for treatment	Commercial Market	Commercial Market	Commercial Market	Commercial Market	Commercial Market	Commercial Market	Commercial Market

1. In accordance with the FDA EUA update on 1/24/2022, bam/ete and REGEN-COV distribution is paused nationally due to the high prevalence of the omicron variant. Resumption of allocation will be considered based on variant prevalence data and/or availability of patient level variant diagnostic testing.

* Beginning Saturday, March 19, unordered doses of Paxlovid, molnupiravir, sotrovimab, and bebtelovimab will be swept weekly and put back into federal inventory for re-distribution as needed. Evusheld doses will be swept at the end of each month starting Thursday, March 31.

Unclassified / For Public Distribution