

April 1, 2022

VDH COVID-19 Therapeutics Bi-Weekly Update

Total Allocations to Therapeutic Administration Sites (03/20/2022 to 04/01/2022):

Therapeutic (mAB & OAV*)	Central	Eastern	Northern	Northwest	Southwest	Total
Bebtelovimab	400	60	110	65	20	655
Sotrovimab	0	0	84	0	6	90
Evusheld	408	48	288	696	72	1512
Molnupiravir	0	24	0	0	0	24
Paxlovid	180	20	40	0	40	280
Total	353	119	630	588	576	2266

Oral Antiviral*	Albertsons	CVS	Topco	Walmart	Total
Molnupiravir	0	72	0	0	72
Paxlovid	60	2520	20	2600	5200
Total	60	2592	20	2600	5272

*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.

Update on HRSA Policy

On 03/22/2022, the Health Resources & Services Administration (HRSA) announced that the [HRSA COVID-19 Uninsured Program \(UIP\)](#) and [HRSA COVID-19 Coverage Assistance Fund \(CAF\)](#) will stop accepting claims for COVID-19 testing and treatment services due to a lack of sufficient

funds. HRSA has notified all enrolled providers of this program update. HRSA also announced vaccine claims would be accepted through midnight on 04/05/22. **On 3/25/22, HRSA announced claims will be adjudicated based on available funds.**

While we know that you may have additional questions that have not been addressed, this is an ongoing situation, and we will continue to keep you up to date.

While further specifics are being determined by HRSA, please refer to the following resources for providers:

- CAF - Hours of operation are 8 a.m. to 8 p.m. Eastern Standard Time, Monday through Friday.
 - Provider Support Line: 833-967-0770, TTY dial 888-970-2920
 - cafsupport@ssigroup.com
- UIP - Hours of operation are 8 a.m. to 10 p.m. Central Time, Monday through Friday

Update on Sotrovimab Deauthorization

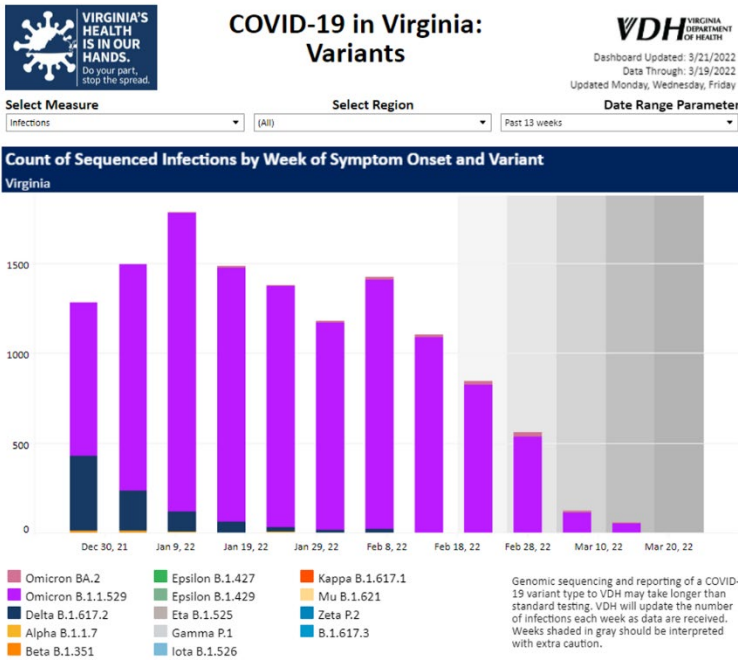
On March 25, the Food & Drug Administration (FDA) determined that the COVID-19 therapeutic, Sotrovimab, has limited effectiveness against the Omicron BA.2 subvariant; new data may be found in the [healthcare provider fact sheet](#).

The drug is [no longer authorized for use](#) in Regions 1, 2, 5, 9, and 10 of the United States, where BA.2 represents more than 50% of COVID cases

CDC Nowcast data estimates that [BA.2 subvariant accounts for more than 50% of cases in the affected regions](#)

In HHS **Region 3** (Virginia, West Virginia, Delaware, District of Columbia, Maryland, and Pennsylvania) the BA.2 subvariant accounts for approximately 48.3% of cases, thus Sotrovimab is still authorized in this region. **This is likely to change in the near future as the BA.2 subvariant spreads.**

If you are interested to track the numbers on VDH's COVID-19 Variant Dashboard. You can now filter for the new BA.2 Omicron variant. Check out the updated variants dashboard at <https://www.vdh.virginia.gov/coronavirus/see-the-numbers/covid-19-data-insights/variants/>



You may find more information about the FDA updates on Sotrovimab usage [here](#).

Administration Update

On 3/18/2022, the U.S. Department of Health & Human Services (HHS) informed all jurisdictions that the National COVID-19 Response effort **has not been appropriated funding from Congress to continue operations** resulting in HHS approaching the point where all jurisdictions will begin to experience adverse impacts as early as May. This matter is consequential and we wanted to share some context, key points, and the impact on VDH and Virginia, along with some next steps that we can do immediately to utilize the limited resources more effectively. Although there is no funding in place, HHS remains hopeful that funding will occur and disruption in supply can be mitigated.

HHS' goal remains the same, to *ensure that these needed drugs remain available and accessible across all communities*. Given the circumstances, HHS is working towards their goal by centralizing allocations so that they may *direct them to the areas of greatest need* and so they can *extend the available supply*. Utilization will be a major factor in determining HHS' allocations.

There *are steps we can take to be effective custodians of these limited resources*. VDH is developing a COVID19 Therapeutics redistribution plan which will be released shortly. The aim of this plan is to source from within the Commonwealth when it is advantageous to do so, thereby reducing risk of waste and improving utilization. *You, our providers and pharmacy partners, can do your part by only ordering what is needed* (i.e. not stockpiling). You can also ensure you are **reporting accurately**, bearing in mind that our *utilization plays an important role in a supply constrained environment*.

Further guidance and updates are expected as more is known. Please provide your questions and comments to covid19therapeutics@vdh.virginia.gov.

Test to Treat Program

- The Test to Treat locator went live on 03/30/22
 - Please find the locator [here](#)
 - This model leverages pharmacies for end-to-end services, however, it is not limited to just pharmacies

Direct Ordering Requests (DORs)

- Beginning on 04/18/22 at 9AM EST, providers will be able to request all therapeutics for order
- Central partners will enable the DORs for providers

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. HHS recommends that mAb administration sites keep existing supplies of Bam/Ete and REGEN-COV since these drugs may be useful in the future.

- 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. Per HHS, products can be shipped to other states if needed.
 - 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 and/or will not be used at a future date**
- 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**
- Unused products that are still in date should not be discarded/destroyed and reported as wastage

340b Pass Through Designation Approval for Velkury

- On 04/01/2022, 340b pass through designation was approved for Velkury
 - Medicare Part B drugs are typically reimbursed at average sales price (ASP)+6%, 340B drugs administered in the hospital outpatient department are subject to a Medicare Part B payment rate of ASP - 22.5%
 - Medicare reimburses at this lower rate assuming that hospitals administering 340B outpatient drugs are purchasing the drug at a discounted price and therefore should be subject to reduced reimbursement
 - Drugs with pass-through status designation are excluded from this payment reduction and instead are reimbursed at ASP + 6% regardless of whether the drug is acquired under 340B, meaning hospitals can attain higher margins on 340b drugs that have this designation

COVID-19 Therapeutics Webinar and Open Forum Call

- VDH will facilitate an April webinar. Registration is required:
 - [04/13/2022](#)
- VDH will facilitate one April open forum call. Registration is required:
 - [04/13/2022](#)