

COVID-19 Therapeutics Bi-Weekly Update
August 22, 2022

Process and logistics updates

Bebtelovimab is Available for Purchase Commercially

- As of **August 15, 2022**, Bebtelovimab has become [commercially available for purchase](#). Orders can be placed directly through AmerisourceBergen.
- USG will allocate the remaining supply of Bebtelovimab to jurisdictions based on populations on **September 6, 2022**. Providers should not bill patients or insurance for any USG-procured product.
- VDH places a high priority on equitable availability of product. If a facility does not serve the under and/or uninsured, VDH encourages these locations to utilize the [redistribution process](#) to reallocate USG product for this vulnerable population.

Guidance on Ordering Bebtelovimab Commercially

A maximum order limit of 270 doses per week per provider site will be imposed. There will be no minimum order quantity. Exceptions for weekly dose quantities beyond 270 will be evaluated on a case-by-case basis. Please note that to limit the potential for overstocking, no returns will be accepted for Bebtelovimab.

Unique batch numbers will differentiate between USG product and commercial product. Review the batch number prior to claim submission to determine if the product was USG procured or commercially-procured and ensure appropriate billing.

Additional Shelf Life Extension - Sotrovimab

Shelf life extension for all lots of Sotrovimab from 18 months to 24 months. See table 1 below.

Table 1: Extended Expiry Dating for Sotrovimab Authorized under EUA 100

Batch Number	Labeled Expiry Date (YYYY-MM)	Extended Expiry Date (YYYY-MM)
658W	2022-02	2023-02
XV6W	2022-04	2023-04
Y74D	2022-04	2023-04
JP9Y	2022-04	2023-04
287F	2022-04	2023-04

287X	2022-05	2023-05
432U	2022-05	2023-05
433C	2022-05	2023-05
BX3T	2022-11	2023-05
9W8S	2023-03	2023-09
A39T	2023-03	2023-09
BD8F	2023-04	2023-10
BC9P	2023-04	2023-10
C86N	2023-04	2023-10
CC3D	2023-04	2023-10
CK9V	2023-04	2023-10
D74S	2023-04	2023-10
J23C	2023-06	2023-12
JJ7J	2023-06	2023-12
J67D	2023-06	2023-12
MJ8W	2023-07	2024-01
ME3Y	2023-07	2024-01
MJ8X	2023-07	2024-01

Current Medicare Payment Structure for Bebtelovimab

- Administration during the [Public Health Emergency](#)
- CMS updated [COVID-19 Toolkit](#) for Healthcare Providers and Medicare COVID-19 Monoclonal [Antibodies Toolkit](#)
- Medicare product payment amount of \$2394.00 when sites purchase the product
- No product payment for Bebtelovimab received for free from the USG
- Guidance from the Federal government for **commercially** acquired product, bill and submit for payment for the drug and the administration cost. If you have **USG procured supply**, only charge for administration and **NOT** the drug. Enter \$0.01 for the drug.

HCPCS Code	HCPCS Short Descriptor	Labeler Name	National Payment Allowance Effective for Claims with DOS on or after 05/6/2021	National Payment Allowance Effective for Claims with DOS through 05/5/2021	Effective Dates
Q0222	Bebtelovimab 175mg	Eli Lilly	\$2394[1][1a]	Code not active during this time period	02/11/2022- TBD
M0222	Bebtelovimab injection	Eli Lilly	\$350.50[3]	Code not active during this time period	02/11/2022- TBD
M0223	Bebtelovimab injection (home)	Eli Lilly	\$550.50[3]	Code not active during this time period	02/11/2022- TBD

^[1] Providers shouldn't bill for the product if they received it for free through the USG-purchased inventory.
^[1a] Payment rate effective for dates of service on or after August 15, 2022. Providers should only bill Medicare for commercially-purchased products.
^[3] These rates will be geographically adjusted for many providers. For providers and suppliers with payments that are geographically adjusted by the methodology used by the Medicare Physician Fee Schedule (MPFS), files with the geographically adjusted payment rates for monoclonal antibody administration are included in the "Additional Resources" section below. Certain settings utilize other payment methodologies, such as payment based on reasonable costs

Read more about reimbursement and the table above [here](#).

Clinical updates

EUA Updates

8/5/2022 Paxlovid - Additional post-authorization requirements for Pfizer to conduct

- A clinical trial in patients with "COVID-19 rebound" to evaluate a subsequent 5-day treatment in patients with rebound
- A clinical trial evaluating different durations of treatment in immunocompromised patients with mild-to-moderate COVID-19 to evaluate safety and efficacy for either 5, 10, or 15 days of treatment

8/5/2022 Lagevrio - Microbiology (Section 12.4)

- Addition of viral RNA rebound
- Approximately 1% of both Lagevrio and placebo recipients had evidence of recurrent COVID-19 symptoms coinciding with a rebound in viral RNA levels in nasopharyngeal samples
- Post-treatment viral RNA rebound was not associated with the primary clinical outcome of hospitalization or death

Updated COVID 19 Treatment Guidelines

8/8/2022 Updates posted by the [COVID 19 Treatment Guidelines Panel](#); all recommendations included in the Guidelines are endorsed by a majority of Panel members (see [Guidelines Development](#) for additional details on the development process).

The updates are in accordance with the rapidly growing information available regarding COVID-19 treatment.

What's New in the Guidelines:

- [Special Considerations in People Who Are Immunocompromised](#)
- [Clinical Management of Children](#)
- [Clinical Spectrum of SARS-CoV-2 Infection](#)
- [Prevention of SARS-CoV-2 Infection](#)
- [Therapeutic Management of Nonhospitalized Adults With COVID-19](#)
- [Kinase Inhibitors: Janus Kinase Inhibitors and Bruton's Tyrosine Kinase Inhibitors](#)

Allocation data

Total Allocations to Therapeutic Administration Sites (08/05/2022 - 08/18/2022):

Therapeutic (mAB & OAV*)	Central	Eastern	Northern	Northwest	Southwest	Total
Bebtelovimab	190	365	295	175	320	1345
Evusheld	288	192	264	216	144	1104
Lagevrio (Molnupiravir)	0	48	0	0	144	192
Paxlovid	120	80	100	280	220	800
Renal Paxlovid	50	5	45	20	40	160

*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.

Redistribution

VDH can redistribute therapeutics within our Commonwealth. Any providers wishing to make their therapeutics available for transfer can do so by clicking the link "Redistribute Excess Therapeutics" on the [VDH home page](#). The VDH Therapeutics team will prioritize these available therapeutics before pulling from federal supplies whenever it is advantageous to do so.

Listen to the Redistribution webinar [here](#). The Redistribution discussion starts at 8:55.

Resources and Tools

New HHS Information Sheet for Providers - Paxlovid

HHS has developed a new information sheet to assist providers understanding and prescribing Paxlovid. Read more [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 for Providers

- VDH is continuing to facilitate webinars and open forums monthly. See below for links to **register!**

August 24 *COVID-19 Therapeutics Healthcare Provider Forum featuring INOVA Health System*: Register [here](#).

September 7 *COVID-19 Therapeutics Healthcare Provider Webinar*: Register [here](#).

Other resource links:

[VDH: COVID-19 Therapeutics FAQs for Providers](#)

[VDH: Guidance on Expiring & Expired Therapeutics](#)

[VDH: EVUSHELD Fact Sheet for Providers](#)

[VDH: Lagevrio \(Molnupiravir\) Prescribing Checklist](#)

[VDH: Paxlovid Prescribing Checklist](#)

[VDH: Paxlovid Prescribing Checklist- Pharmacists](#)

[HHS: ASPR Test to Treat Fact Sheet](#)

[Treatment of Monkeypox: Information for Virginia Healthcare Providers](#)

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