PENNSYLVANIA DEPARTMENT OF HEALTH
2022 – PAHAN – 677-12-15-UPD

UPDATE: Therapeutics to Prevent and Treat COVID-19

DATE:	12/15/2022
TO:	Health Alert Network
FROM:	Denise Johnson, M.D., FACOG, FACHE, Acting Secretary of Health
SUBJECT:	**Update: Therapeutics to Prevent and Treat COVID-19**
DISTRIBUTION:	Statewide
LOCATION:	n/a
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COUNTY:	n/a
MUNICIPALITY:	n/a
ZIP CODE:	n/a

This transmission is a "Health Update," and provides updated information regarding an incident or situation; unlikely to require immediate action.

HOSPITALS: PLEASE SHARE WITH ALL MEDICAL, PEDIATRIC, NURSING AND LABORATORY STAFF IN YOUR HOSPITAL**; EMS COUNCILS:** PLEASE DISTRIBUTE AS APPROPRIATE; **FQHCs:** PLEASE DISTRIBUTE AS APPROPRIATE; **LOCAL HEALTH JURISDICTIONS**: PLEASE DISTRIBUTE AS APPROPRIATE; **PROFESSIONAL ORGANIZATIONS:** PLEASE DISTRIBUTE TO YOUR MEMBERSHIP; **LONG-TERM CARE FACILITIES:** PLEASE SHARE WITH ALL MEDICAL, INFECTION CONTROL, AND NURSING STAFF IN YOUR FACILITY

Summary:

- The SARS-CoV-2 Omicron BQ.1 and BQ.1.1 subvariants are estimated to be the cause of more than 57% of COVID-19 cases combined in the United States, including in Pennsylvania. This trend is expected to increase across all regions of the U.S.
- Vaccination (especially after receipt of a bivalent booster dose) is expected to protect against severe illness, hospitalizations, and deaths from infection with the Omicron variant and its subvariants.
- Therapeutics are also available for preventing and treating COVID-19 in specific at-risk populations.
- Providers are encouraged to consider COVID-19 treatment options, which are updated frequently. Current options include antiviral treatments Paxlovid, Veklury, and Lagevrio, and COVID-19 convalescent plasma.
- Due to data regarding the prevalence of the Omicron subvariants BQ.1 and BQ.1.1 and likely ineffectiveness against it, **Bebtelovimab is no longer authorized for treatment of COVID-19 in the United States. Subsequently, there are currently NO monoclonal antibody treatments authorized for treatment of COVID-19 in the United States.**
- Details on how to obtain currently authorized treatment agents can be found at the PA DOH website.
- If you have questions about this guidance, please call your local health department or 1-877-PA-HEALTH (1-877-724-3258).

A. Background

Pennsylvania Department of Health (DOH) provides this guidance based on available information about COVID-19 and is subject to change.

In Pennsylvania, COVID-19 cases and COVID-19-related hospitalizations continue to occur. DOH aims to provide healthcare providers (in both inpatient and outpatient settings) an outline of the current options available for treatment of COVID-19. This advisory is an update to HAN 620 and HAN 634. Healthcare providers are encouraged to utilize the treatment options, when clinically appropriate, with the goal of reducing hospital admissions and/or duration of hospitalizations, and the overall COVID-19 burden in the community.

The SARS-CoV-2 Omicron BQ.1 and BQ.1.1 subvariants are estimated to be the cause of more than 57% of COVID-19 cases combined in the United States, including in Pennsylvania. This trend is expected to increase across all regions of the U.S. Eligible individuals should get all vaccines and bivalent booster shots as the best preventive measure available against severe disease, hospitalizations, and death due to COVID-19. Vaccination is expected to protect against severe illness, hospitalizations, and deaths from infection with the Omicron variant. Some studies have found lower effectiveness of the primary series of vaccines against infection and demonstrated the importance of booster doses[1-3], including the bivalent mRNA booster[4].

Therapeutics are also available for preventing and treating COVID-19 in specific at-risk populations. These therapeutics differ in efficacy, route of administration, risk profile, and whether they are authorized by the U.S Food and Drug Administration (FDA) for adults only or adults and certain pediatric populations.

There are NO monoclonal antibody treatments that are currently authorized for the treatment of COVID-19 in the U.S.

B. Bebtelovimab

In February 2022, the FDA issued an Emergency Use Authorization (EUA) for the anti-SARS-CoV-2 monoclonal antibody treatment, Bebtelovimab.

However, due to the increased prevalence of Omicron BQ.1 and BQ.1.1 subvariants in the United States, and data that show that it is unlikely that the authorized dose of Bebtelovimab will be effective against the SARS-CoV-2 Omicron BQ.1 and BQ.1.1 subvariants, the use of Bebtelovimab is no longer authorized in any U.S. state or territory at this time.

Effective November 30, 2022, the Office of the Assistant Secretary for Preparedness and Response (ASPR) has paused Bebtelovimab distribution in all U.S. states and territories. Additionally, the FDA has updated the EUA Fact Sheet for Bebtelovimab to reflect restrictions in the product's use. Healthcare providers are encouraged to review the Antiviral Resistance information in Section 12.4 of the EUA Fact Sheet for Bebtelovimab.

C. Currently Authorized Therapeutics to Prevent and Treat COVID-19

Prevention

Vaccination remains the mainstay of prevention against severe illness, hospitalizations, and deaths from COVID-19. It is recommended that all eligible people stay up-to-date on COVID-19 vaccination.

EVUSHELD (tixagevimab plus cilgavimab) is a long-acting anti-SARS-CoV-2 monoclonal antibody combination that was issued an EUA by the FDA for use as pre-exposure prophylaxis against severe illness, hospitalizations, and deaths from COVID-19 for high-risk groups.

Treatment

Antiviral Treatments

- Paxlovid (nirmatrelvir with ritonavir) is authorized for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients (12 years of age and older, weighing at least 40kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death.

- Veklury (remdesivir) is approved for the treatment of adults and pediatric patients (28 days of age and older, weighing at least 3kg) with positive results of direct SARS-CoV-2 viral testing, who are not hospitalized and have mild-to-moderate COVID-19 and are at high risk for progression to severe COVID-19, including hospitalization or death.

- Lagevrio (molnupiravir) is authorized for the treatment of mild-to-moderate COVID-19 in adults with positive results of direct SARS-CoV-2 viral testing who are at high risk for progression to severe COVID-19, including hospitalization or death, and for whom alternative COVID-19 treatment options approved or authorized by FDA are not accessible or clinically appropriate.

COVID-19 Convalescent plasma with high titers of anti-SARS-CoV-2 antibodies is authorized for the treatment of COVID-19 in immunocompromised patients, in both inpatient and outpatient settings.

Details on how to obtain the currently authorized therapeutic agents can be found at the PA DOH website.

D. Additional Information

For the most up-to-date information on COVID-19 monoclonal antibody treatment changes: The U.S. Dept of Health & Human Services, Office of ASPR maintains a webpage for Public Health Emergency and Preparedness which maintains the most up-to-date information on COVID-19 monoclonal antibody treatment changes, including issuance/reversals of EUAs, and/or pauses in distribution of monoclonal antibodies. (https://aspr.hhs.gov/COVID-19/Therapeutics/Pages/default.aspx)

Clinicians with questions about approved treatments and those with EUAs issued by the FDA may refer to the reference National Institutes of Health web page: Therapeutic Management | COVID-19 Treatment Guidelines (https://www.covid19treatmentguidelines.nih.gov/management/), and/or CDC's Interim Clinical Considerations for COVID-19 Treatment in Outpatients (Interim Clinical Considerations for COVID-19 Treatment in Outpatients | CDC).

References

1. Andrews N, Stowe J, Kirseborm F, et al. Effectiveness of COVID-19 vaccines against the Omicron (B.1.1529) variant of concern. medRxiv 2021. doi: https://doi.org/10.1101/2021.12.14.21267615.
2. Ferguson N, Ghani A, Cori A, et al. Report 49: Growth, population distribution and immune escape of Omicron in England. Imperial College London (2021-12-20). doi: https://doi.org/10.25561/93038 (direct link: https://spiral.imperial.ac.uk/handle/10044/1/93038).
3. Discovery Health. Real world analysis of Omicron outbreak in South Africa including vaccine effectiveness. Accessed 2021-12-23 at https://www.discovery.co.za/corporate/news-room (direct link: https://resources.mynewsdesk.com/image/upload/fl_attachment/lw9szzdtqfvwitkfbcoq).
4. Link-Gelles R, Ciesla AA, Fleming-Dutra KE, et al. Effectiveness of Bivalent mRNA Vaccines in Preventing Symptomatic SARS-CoV-2 Infection – Increasing Community Access to Testing Program, United States, September-November 2022. MMWR Morb Mortal Wkly Rep 2022;71:1526-1530. DOI: http://dx.doi.org/10.15585/mmwr.mm7148e1.

Individuals interested in receiving further PA-HANs are encouraged to register at https://www.health.pa.gov/topics/prep/PA-HAN/Pages/HAN.aspx.

If you have questions about this guidance, please call your local health department or **1-877-PA-HEALTH** (**1-877-724-3258**).

Categories of Health Alert messages:
Health Alert: conveys the highest level of importance; warrants immediate action or attention.
Health Advisory: provides important information for a specific incident or situation; may not require immediate action.
Health Update: provides updated information regarding an incident or situation; unlikely to require immediate action.

This information is current as of December 15, 2022 but may be modified in the future. We will continue to post updated information regarding the most common questions about this subject.