PENNSYLVANIA DEPARTMENT OF HEALTH 2022 – PAHAN – 634 –04-07-UPD



UPDATE: Therapeutics to Prevent and Treat COVID-19

DATE:	04/07/2022
TO:	Health Alert Network
FROM:	Keara Klinepeter, Acting Secretary of Health
SUBJECT:	Therapeutics to Prevent and Treat COVID-19
DISTRIBUTION:	Statewide
LOCATION:	n/a
STREET ADDRESS:	n/a
COUNTY:	n/a
MUNICIPALITY:	n/a
ZIP CODE:	n/a

This transmission is a "Health Advisory," which 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

- The SARS-CoV-2 <u>Omicron BA.2</u> variant is estimated to be the cause of more than 50% of COVID-19 cases in the United States, including in Pennsylvania.
- Vaccination (especially after receipt of a booster dose) is expected to protect against severe
 illness, hospitalizations, and deaths from infection with the Omicron variant.
- Therapeutics are also available for preventing and treating COVID-19 in specific at-risk populations.
- Providers are encouraged to consider COVID-19 treatment <u>options</u>, which are updated frequently.
- Due to <u>data</u> regarding the prevalence of the Omicron BA.2 variant and likely <u>ineffectiveness</u> against it, <u>Sotrovimab</u> is no longer authorized for treatment of COVID-19 in the United States.
- Details on how to obtain currently authorized treatment agents can be found at the <u>PA DOH</u> 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 supplemental to HAN 620 and includes updated information regarding Sotrovimab. Insurance coverage for treatment remains mandated by federal law. 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 BA.2 variant is estimated to be the cause of more than 50% of COVID-19 cases in the United States, including in Pennsylvania. Eligible individuals should get all vaccines and 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

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 <u>authorized</u> by the U.S Food and Drug Administration (FDA) for adults only or adults and certain pediatric populations.

B. Sotrovimab

In late 2021, the FDA issued an Emergency Use Authorization (EUA) for the anti-SARS-CoV-2 monoclonal antibody treatment, Sotrovimab.

However, due to the increased prevalence of Omicron BA.2 variant in the United States, and <u>data</u> that show that it is unlikely that the authorized dose of Sotrovimab will be effective against the SARS-CoV-2 Omicron BA.2 variant, the use of Sotrovimab is no longer authorized in any U.S. state or territory at this time.

Effective April 5, 2022, the Office of the Assistant Secretary for Preparedness and Response (ASPR) has paused Sotrovimab distribution in all U.S. states and territories. Additionally, the FDA has updated the EUA Fact Sheet for Sotrovimab to reflect restrictions in the product's use. Healthcare providers are encouraged to review the Antiviral Resistance information in Section 15 of the EUA Fact Sheet for Sotrovimab.

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

C. 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://www.phe.gov/emergency/events/COVID19/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/therapeutic-management/).

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

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).

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 April 7,2022 but may be modified in the future. We will continue to post updated information regarding the most common questions about this subject.