PENNSYLVANIA DEPARTMENT OF HEALTH
2021 – PAHAN – 613 –12-23-UPD

This document has been archived. Please refer to PA-HAN-634 for updated information on the topic.

UPDATE: COVID-19 Treatment Options

DATE:	12/23/2021
TO:	Health Alert Network
FROM:	Keara Klinepeter, Acting Secretary of Health
SUBJECT:	**COVID-19 Treatment Update**
DISTRIBUTION:	Statewide
LOCATION:	n/a
STREET ADDRESS:	n/a
COUNTY:	n/a
MUNICIPALITY:	n/a
ZIP CODE:	n/a

This transmission is a "Health Update" provides important information for a specific incident or situation; may not 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

- On November 30, 2021, the U.S. government SARS-CoV-2 Interagency Group (SIG) classified **Omicron** (B.1.1.529 and BA lineages) as a Variant of Concern (VOC)
- Early in vitro data suggests that **the monoclonal antibody treatment, sotrovimab, retains activity against the Omicron variant.**
- Due to the ongoing threat of COVID-19, providers are encouraged to continue to consider the COVID-19 treatment options detailed in HAN 575.
    - The FDA has issued Emergency Use Authorizations (EUAs) for anti-SARS-CoV-2 monoclonal antibodies, combination therapies bamlanivimab plus etesevimab and casirivimab plus imdevimab (REGEN-COV), and monotherapy sotrovimab for use in non-hospitalized patients (age>12 and weighing>40kg), with laboratory confirmed SARS-CoV-2 infection and mild-to-moderate COVID-19 disease who are at high risk of progressing to severe disease and/or hospitalization.
- The federal government's current supply of sotrovimab is *extremely limited*. Continued use of bamlanivimab plus etesevimab and casirivimab plus imdevimab (REGEN-COV) monoclonal antibody products is recommended while reserving sotrovimab for treatment of eligible outpatients at *highest* risk who are either:
    - Diagnosed with a test that may identify a potential case of the Omicron variant (e.g., by S-gene Target Failure (SGTF) in the ThermoFisher TaqPath assay); or
    - Are present in local settings where reported prevalence of Omicron is greater than 20%; and
    - Meet criteria for administration of sotrovimab, per sotrovimab's EUA
- **Sotrovimab** is not a substitute for COVID-19 vaccination **and is not authorized for use as pre-exposure prophylaxis to prevent COVID-19.**
- 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 increase. 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 575 and includes additional information about sotrovimab. Since 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.

Genetic lineages of SARS-CoV-2 have been emerging and circulating around the world since the beginning of the COVID-19 pandemic. SARS-CoV-2 genetic lineages in the United States are routinely monitored through epidemiological investigations, virus genetic sequence-based surveillance, and laboratory studies. On November 30, 2021, the U.S. government SARS-CoV-2 Interagency Group (SIG) classified Omicron (B.1.1.529 and BA lineages) as a Variant of Concern (VOC).

At this time, differentiating cases of Omicron variant from other variants (e.g. Delta) requires specialized testing (e.g. ThermoFisher Taqpath assay) or testing that may take several days for results (e.g. genomic sequencing). Use of assays capable of detecting an SGFT (e.g.ThermoFisher Taqpath assay) may be used to differentiate the Omicron variant which triggers the SGTF on the assay. Additionally, cases of infection with Omicron variant appear clinically similar to cases of infection with other variants. Treatment options for COVID-19, as detailed in HAN 575, include three monoclonal antibody treatment regimens; Thus far, one of these treatments, sotrovimab, has proven effective against Omicron, while other treatment options have shown decreased effectiveness against Omicron. However, due to the limitations in both early detection of Omicron variant and in supply of sotrovimab, it is challenging to determine which patients shall receive sotrovimab.

B. Anti-SARS-CoV-2 Monoclonal Antibody Treatment

The FDA has issued Emergency Use Authorizations (EUAs) for certain anti-SARS-CoV-2 monoclonal antibodies, combination therapies bamlanivimab plus etesevimab and casirivimab plus imdevimab, and monotherapy **sotrovimab**. The EUAs allow for use of the agents in patients who meet the following criteria:

- Non-hospitalized patients.
- Age 12 or older, and weighing 40 kg or more [casirivimab plus imdevimab, and sotrovimab]
  - bamlanivimab plus etesevimab: *all ages*, including neonates
- Laboratory confirmed SARS-CoV-2 infection (PCR test).
- Mild-to-moderate COVID-19 disease who are at high risk of progressing to severe disease and/or hospitalization (see below).
- It is recommended that these drugs be administered as soon as possible after a positive SARS-CoV-2 test result, and within 10 days of symptom onset.

Unless there is another indication for use of these agents or use is part of a clinical trial, it is not recommended for patients hospitalized because of COVID-19 to receive the above monoclonal antibody treatments.

C. Sotrovimab

Sotrovimab is a recombinant human IgG1κ monoclonal antibody that binds to a conserved epitope on the spike protein receptor binding domain of SARS-CoV-2. Sotrovimab does not compete with human ACE2 receptor binding. This monoclonal antibody is administered intravenously as a one-time infusion of 500 mg.

Early in vitro data suggests sotrovimab retains activity against the Omicron variant.

The federal government's current supply of sotrovimab is *extremely limited*. Continued use of bamlanivimab plus etesevimab and casirivimab plus imdevimab (REGEN-COV) monoclonal antibody products is recommended while reserving sotrovimab for treatment of eligible outpatients at *highest* risk who are either:

- Diagnosed with a test that may identify a potential case of the Omicron variant (e.g., by S gene Target Failure in the ThermoFisher TaqPath assay); or
- Are present in local settings where reported prevalence of Omicron is greater than 20%; AND
- Meet criteria for administration of sotrovimab (listed above)
    - Are at high risk of progression to severe disease and/or hospitalization
        - These patients include:
            - Older age (≥65 years of age)
            - Obesity or being overweight (adults with BMI >25 kg/m2, or if 12 to 17 years of age, have BMI ≥85th percentile for their age and gender based on CDC growth charts
            - Pregnancy
            - Chronic kidney disease
            - Diabetes
            - Immunosuppressive disease or immunosuppressive treatment
            - Cardiovascular disease (including congenital heart disease) or hypertension
            - Chronic lung diseases (for example, chronic obstructive pulmonary disease, asthma [moderate-to-severe], interstitial lung disease, cystic fibrosis and pulmonary hypertension)
            - Sickle cell disease
            - Neurodevelopmental disorders (for example, cerebral palsy) or other conditions that confer medical complexity (for example, genetic or metabolic syndromes and severe congenital anomalies)
            - Having a medical-related technological dependence (for example, tracheostomy, gastrostomy, or positive pressure ventilation [not related to COVID-19])

Healthcare providers should consider the benefit-risk for an individual patient, with the above in mind.

Sotrovimab is not a substitute for COVID-19 vaccination **and is not authorized for use as pre-exposure prophylaxis to prevent COVID-19.**

The issuance of an EUA does not constitute FDA approval.

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 the Assistant Secretary for Preparedness and Response 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 NIH 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.

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 23, 2021 but may be modified in the future. We will continue to post updated information regarding the most common questions about this subject.