PENNSYLVANIA DEPARTMENT OF HEALTH
2021 – PAHAN – 588 – 8-19-UPD

UPDATE: COVID-19 Post-Exposure Prophylaxis

DATE:	8/19/2021
TO:	Health Alert Network
FROM:	Alison V. Beam, JD, Acting Secretary of Health
SUBJECT:	**COVID-19 Post-Exposure Prophylaxis**
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," 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

- Due to the ongoing threat of COVID-19, providers are encouraged to continue to consider the COVID-19 treatment options detailed in HAN 575. Additionally, a post-exposure prophylaxis option is also currently available.
- In late fall 2020, the FDA issued an Emergency Use Authorization (EUA) for anti-SARS-CoV-2 monoclonal antibodies, **casirivimab** plus **imdevimab** (REGEN-COV) - for use in nonhospitalized 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.
- On July 30, 2021, the FDA expanded the EUA for casirivimab plus imdevimab to include use for **post-exposure prophylaxis** in the following individuals:
  - at high risk for progression to severe COVID-19, AND
  - are not fully vaccinated OR are not expected to mount an adequate response to vaccination (e.g. immunocompromised individuals), AND
  - have been exposed to a SARS-CoV-2 infected individual OR are at high risk of exposure to an infected individual because of infection occurring in the same institutional setting (e.g. nursing homes or prisons).
- **Casirivimab plus imdevimab is the only COVID-19 antibody therapy in the U.S. that is available for both treatment and post-exposure prophylaxis.** It is effective against COVID-19 variants, may be administered by *subcutaneous injection or intravenous infusion*, and *repeated dosing* may be given *monthly* to individuals with ongoing exposure.
- Casirivimab plus imdevimab 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**).

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

A. Casirivimab plus Imdevimab (REGEN-COV) for COVID-19 Post-Exposure Prophylaxis

The U.S. Food and Drug Administration (FDA) announced on July 30, 2021 an EUA expansion for anti-SARS-CoV-2 monoclonal antibodies, casirivimab plus imdevimab.
The EUA now includes post-exposure prophylaxis for the following individuals (age ≥12 and weighing ≥ 40 kg):

- at high risk for progression to severe COVID-19, AND
- are not fully vaccinated OR are not expected to mount an adequate response to vaccination (e.g. immunocompromised individuals), AND
- have been exposed to a SARS-CoV-2 infected individual OR are at high risk of exposure to an infected individual because of infection occurring in the same institutional setting (such as in nursing homes or prisons).

B. Additional Details

- Route of administration: *subcutaneous injection* or *intravenous infusion*.
- Repeat dosing: indicated for those with ongoing exposure (more than four weeks), to be administered *monthly*. See dosing specifics below.
- Variants: casirivimab plus imdevimab has been shown to retain potency against the main variants of concern circulating in the U.S., including Delta (B.1.617.2, first identified in India), Gamma (P.1, first identified in Brazil), and Beta (B.1.351, first identified in South Africa).
    - Studies regarding potency against emerging variants is ongoing.
- Casirivimab plus imdevimab is not a substitute for COVID-19 vaccination and is not authorized for use as pre-exposure prophylaxis to prevent COVID-19.

This EUA expansion is supported by multiple analyses, including Phase 3 clinical trial data which showed:

- *Reduced risk of symptomatic infections by 81%* in individuals who were close contacts of those infected with SARS-CoV-2, and who were themselves seronegative with a negative PCR test.

C. Indication and Dosing Clarification

Casirivimab (previously REGN10933) and imdevimab (previously REGN10987) are recombinant human monoclonal antibodies that bind to nonoverlapping epitopes of the spike protein RBD of SARS-CoV-2. The combination of these two antibodies blocks the binding of the RBD to the host cell.

Post-Exposure Prophylaxis:
The EUA for casirivimab plus imdevimab for use as post-exposure prophylaxis indicates use for *patients age 12 or older and weighing 40kg or more*, and in the scenarios detailed above in section A.

- For use as post-exposure prophylaxis, the initial dose of REGEN-COV is 1,200 mg (600 mg casirivimab and 600 mg imdevimab). If indicated, subsequent repeat dosing of 600 mg (300 mg casirivimab and 300 mg imdevimab) may be administered once every four weeks, for the duration of ongoing exposure.

Treatment:
The FDA issued EUAs for certain anti-SARS-CoV-2 monoclonal antibodies, including combination therapy casirivimab plus imdevimab, for treatment of COVID-19 infection. The EUAs for treatment of COVID-19 allow for use of the agents in nonhospitalized *patients age 12 or older and weighing 40kg or more, 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*.

- For use as COVID-19 treatment, REGEN-COV is administered intravenously together as a combined one-time dose of casirivimab 1,200 mg and imdevimab 1,200 mg.

The issuance of an EUA does not constitute FDA approval.

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 August 19, 2021 but may be modified in the future. We will continue to post updated information regarding the most common questions about this subject.