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Distributed via the WV Health Alert Network – **August 11, 2021**

WEST VIRGINIA Department of Health & Human Resources BUREAU FOR PUBLIC HEALTH

HEALTH ADVISORY #177

REGEN-COV Authorized by FDA for Post-Exposure Prophylaxis under Emergency Use Authorization

TO: **West Virginia Healthcare Providers, Hospitals and Other Healthcare Facilities**

FROM: **Ayne Amjad, MD, MPH, Commissioner and State Health Officer**
West Virginia Department of Health and Human Resources, Bureau for Public Health

DATE: **August 11, 2021**

LOCAL HEALTH DEPARTMENTS: Please distribute to community health providers, hospital-based physicians, infection control preventionists, laboratory directors and other applicable partners.

OTHER RECIPIENTS: Please distribute to association members, staff, etc.

On July 30, 2021, the US Food and Drug Administration (FDA) authorized an additional use for the COVID-19 monoclonal antibody therapy REGEN-COV (casirivimab and imdevimab). The REGEN-COV Emergency Use Authorization (EUA) has been expanded to include post-exposure prophylaxis. This new authorization is in addition to the prior authorization of REGEN-COV to treat non-hospitalized patients with mild to moderate COVID-19 in adult and pediatric patients, age 12 and older, with positive results of a direct SARS-CoV-2 viral test, and who are at high risk for progression to severe COVID-19, including hospitalization or death.

REGEN-COV is expected to be effective against circulating variants, including the Delta variant. It should be noted that post-exposure prophylaxis with REGEN-COV is not a substitute for vaccination against COVID-19 and REGEN-COV is not authorized for pre-exposure prophylaxis. For both non-hospitalized treatment and post-exposure prophylaxis use, the authorized dose is 600 mg of casirivimab and 600 mg of imdevimab. For treatment of mild to moderate COVID-19, a single intravenous infusion is strongly recommended; however, subcutaneous injection may be an alternative if infusion is not feasible or would significantly delay treatment. For post-exposure prophylaxis, REGEN-COV may be administered as either subcutaneous injection or a single IV infusion. Please refer to the following links for full details about dosing and administration.

The new authorization is for post-exposure prophylaxis use:

- In adult and pediatric individuals (12 years of age and older weighing at least 40 kg) for post-exposure prophylaxis of COVID-19 in individuals who are at high risk for progression to severe COVID-19, including hospitalization or death, and are:

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- Not fully vaccinated or who are not expected to mount an adequate immune response to complete SARS-CoV-2 vaccination (for example, individuals with immunocompromising conditions including those taking immunosuppressive medications) and

    - Have been exposed to an individual infected with SARS-CoV-2 consistent with close contact criteria per CDC, or

    - Who are at high risk of exposure to an individual infected with SARS-CoV-2 because of occurrence of COVID-19 infection in other individuals in the same institutional setting (for example, nursing homes, home health, or prisons).

Additional Resources

- Fact Sheet for Healthcare Providers: https://www.fda.gov/media/145611/download
- Clinical Management COVID-19 Treatment Guidelines: https://www.covid19treatmentguidelines.nih.gov/management/clinical-management/
- Contact the West Virginia Poison Control Center at (800) 222-1222

For questions about this advisory, contact the Office of Epidemiology and Prevention Services (OEPS) at 1-800-423-1271, ext. 1; 304-558-5358, ext. 2; or the 24/7 answering service at 304-342-5151.

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