Health Advisory: REGEN-COV Approved for Post-Exposure Prophylactic Use

Minnesota Department of Health, Mon, Aug 2 13:00 CDT 2021

Action Steps

Local and tribal health department: Please forward to hospitals, clinics, emergency departments, urgent care centers, and convenience clinics in your jurisdiction.
Hospitals, clinics and other facilities: Please forward to infection preventionists, infectious disease physicians, emergency department staff, hospitalists, primary care clinicians, and all other health care providers who might see patients with COVID-19.
Health care providers:

- Consider providing REGEN-COV monoclonal antibody therapy for post-exposure prophylaxis (PEP) to persons not fully vaccinated for COVID-19 or persons not expected to mount an adequate immune response to SARS-CoV-2 vaccination 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 SARS-CoV-2 infection in other individuals in the same institutional setting (for example, congregate care settings like long-term care or prisons)
- Offer subcutaneous injection if infusion is not feasible or would significantly delay treatment.
- Find out which monoclonal therapies are applicable to your patient and where they can get those therapies at Minnesota Resource Allocation Platform for COVID-19 Treatment https://www.health.state.mn.us/diseases/coronavirus/mnrap.html
- Call the MDH COVID-19 Provider Hotline at 651-201-5414 or 877-676-5414, option 3 for more information.

Summary

On July 30, 2021, the 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 direct SARS-CoV-2 testing, 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.

- HHS/ASPR: REGEN-COV Authorized by FDA for Post-Exposure Prophylaxis under Emergency Use Authorization https://www.phe.gov/emergency/events/COVID19/investigation-MCM/cas_imd/Pages/update-30July2021.aspx
- FDA: Fact Sheet for Health Care Providers Emergency Use Authorization (EUA) of REGEN-COV (casirivimab and imdevimab) https://www.fda.gov/media/145611/download
- MDH Therapeutic Options for COVID-19 Patients: https://www.health.state.mn.us/diseases/coronavirus/hcp/therapeutic.html
- MDH COVID-19 Medication Options: https://www.health.state.mn.us/diseases/coronavirus/meds.html

Higher Risk Patients

- CDC People with Certain Medical Conditions https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html
- CDC Underlying Medical Conditions Associated with High Risk for Severe COVID-19: Information for Healthcare Providers https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-care/underlyingconditions.html

For More Information

- FDA Drug and Biological Therapeutic Products https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#coviddrugs
- FDA Combating COVID-19 with Therapeutics (PDF) https://www.fda.gov/media/136832/download

A copy of this HAN is available at: MDH Health Alert Network (http://www.health.state.mn.us/han)
The content of this message is intended for public health and health care personnel and response partners who have a need to know the information to perform their duties.