HEALTH ALERT NETWORK
HEALTH DISTRICT 4

CASIRIVIMAB/IMDEVIMAB (REGEN-COV) AUTHORIZED AS COVID-19 POST-EXPOSURE PROPHYLAXIS

August 19, 2021

Healthcare providers should be aware that on July 30, 2021, the FDA revised the emergency use authorization (EUA) for casirivimab/imdevimab (REGEN-COV) to include authorization for post-exposure prophylaxis for COVID-19. REGEN-COV also remains authorized for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death.

Casirivimab/imdevimab (REGEN-COV) may now be used as post-exposure prophylaxis for COVID-19 in adults and pediatric individuals (12 years and older weighing at least 40 kg) who are:

- at high risk for progression to severe COVID-19, including hospitalization or death, AND
- not fully vaccinated OR who are not expected to mount an adequate immune response to complete SARS-CoV-2 vaccination (for example, people 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 Centers for Disease Control and Prevention (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, nursing homes or prisons).

The data supporting the expansion of the EUA to include an indication for post-exposure prophylaxis are from a Phase 3 trial studying household contacts of individuals with SARS-CoV-2...
2. An 81% risk reduction in confirmed symptomatic COVID-19 cases was observed with casirivimab/imdevimab (REGEN-COV) compared to placebo in the primary analysis population.

This added indication expands the population of patients eligible for casirivimab/imdevimab (REGEN-COV). Healthcare providers may wish to identify and refer for post-exposure prophylaxis close contacts (including household contacts) of their patients diagnosed with SARS-CoV-2 infection if those contacts meet the criteria outlined above.

Healthcare providers are also reminded that casirivimab/imdevimab (REGEN-COV) can be administered by subcutaneous injection when intravenous infusion is not feasible and would lead to delay in treatment.

Resources


HHS Therapeutics Locator (map of locations that have received a distribution of monoclonal antibody therapeutics): https://protect-public.hhs.gov/pages/therapeutics-distribution


Ordering information for casirivimab/imdevimab (REGEN-COV) from the drug’s sole distributor AmerisourceBergen, Inc: https://app.smartsheet.com/b/form/255d164d67834793b4ab549e160941e8