MsgID:	1954
Date:	8/19/2021 4:37:19 PM
From:	Southeastern Idaho Public Health
To:	Multiple Recipients. See IDHAN Web Site for Complete Recipient list.
Subject:	Casirivimab/imdevimab (REGEN-COV) Authorized as COVID-19 Post-exposure Prophylaxis
Type:	Private
Priority:	Advisory
PHIN Status:	Actual
Severity:	Unknown
PHIN Type:	Alert
Delivery Time::	24 Hours

Health Alert Network Message for Healthcare Providers

Casirivimab/imdevimab (REGEN-COV) Authorized as COVID-19 Post-exposure Prophylaxis
August 18, 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. 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

Department of Health and Human Services (HHS), *Federal Response to COVID-19: Monoclonal Antibody Playbook*: https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Documents/USG-COVID19-Tx-Playbook.pdf

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

O'Brien, et al. (2021). Subcutaneous REGEN-COV Antibody Combination to Prevent Covid-19. *New England Journal of Medicine*, https://www.nejm.org/doi/full/10.1056/NEJMoa2109682

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

Updated Fact Sheet for Healthcare Providers on Emergency Use Authorization (EUA) of REGEN-COV (casirivimab/indevimab): https://www.fda.gov/media/145611/download