california **pharmacists** association

REGEN-COV
generic name(s): Casirivimab and Imdevimab
band name(s): REGEN-COV

GROUP: Antiviral agent; monoclonal antibody

MECHANISM OF ACTION: Casirivimab and imdevimab are recombinant human (IgG1κ and IgG1λ, respectively) monoclonal antibodies (mAbs). Casirivimab and imdevimab bind to nonoverlapping epitopes of the spike protein receptor binding domain of SARS-CoV-2, blocking attachment to the human ACE2 receptor.

INDICATION AND PLACEMENT OF THERAPY: Emergency use authorization (EUA) for the treatment of mild to moderate coronavirus disease 2019 (COVID-19) in adult 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:

1. COVID-19, postexposure prophylaxis
    - Reserved for patients with SARS-CoV-2 exposure, or at high risk for exposure, who are not fully vaccinated or are not expected to mount an adequate immune response to complete vaccination and are at high risk for progression to severe disease or hospitalization
2. COVID-19, treatment, mild to moderate
    - Reserved for patients with positive SARS-CoV-2 direct viral testing who are at high risk for progression to severe disease or hospitalization

ROUTES OF ADMINISTRATION: Intravenous (IV) infusion (preferred) or subcutaneous (SQ) injection (alternative)

DOSAGE AND TREATMENT

1. COVID-19, postexposure prophylaxis
    - 600 mg of casirivimab and 600 mg of imdevimab administered by SQ injection or together as a single IV infusion as soon as possible following exposure to SARS-CoV-2
    - For individuals in whom repeat dosing is determined to be appropriate for ongoing exposure to SARS-CoV-2 for longer than 4 weeks and who are not expected to mount an adequate immune response to complete SARS-CoV-2 vaccination:
        - Initial dose of 600 mg of casirivimab and 600 mg of imdevimab by SQ injection or IV infusion followed by subsequent repeat dosing of 300 mg of casirivimab and 300 mg of imdevimab by SQ injection or IV infusion once every 4 weeks for the duration of ongoing exposure
2. COVID-19, treatment, mild to moderate
    - 600 mg of casirivimab and 600 mg of imdevimab administered together as a single IV infusion or by SQ injection as soon as possible after positive SARS-CoV-2 viral testing and within 10 days of symptom onset

POTENTIAL ADVERSE EFFECTS AND MONITORING PLAN: Hypersensitivity including anaphylaxis and infusion-related reactions (urticaria, pruritus, flushing, pyrexia, shortness of breath, chest tightness, nausea, vomiting, rash). Monitor for infusion-related reactions and hypersensitivity/anaphylaxis during infusion and for ≥1 hour following completion of infusion or SQ dosing.

CONTRAINDICATIONS: REGEN-COV is contraindicated in individuals with previous severe hypersensitivity reactions, including anaphylaxis, to REGEN-COV.

POTENTIAL DRUG INTERACTIONS: REGEN-COV consists of 2 mAbs, casirivimab and imdevimab, which are not renally excreted or metabolized by cytochrome P450 enzymes; therefore, interactions with concomitant medications that are renally excreted or that are substrates, inducers, or inhibitors of cytochrome P450 enzymes are unlikely.

REFERENCES: Fact Sheet for Health Care Providers Emergency Use Authorization (EUA) of Regen-COV. U.S. Food and Drug Administration. Updated November 2021. https://www.fda.gov/media/145611/download.

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