REGEN-COV™ (casirivimab/imdevimab) – Emergency use authorization expansion

- On July 30, 2021, Regeneron announced the emergency use authorization approval of REGEN-COV (casirivimab/imdevimab), in adult and pediatric individuals (12 years of age and older weighing at least 40 kg) for post-exposure prophylaxis of coronavirus disease 2019 (COVID-19) in individuals who are at high risk for progression to severe COVID-19, including hospitalization or death, and are:
    - Not fully vaccinated or who are not expected to mount an adequate immune response to complete severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccination ***and***
    - Have been exposed to an individual infected with SARS-CoV-2 consistent with close contact criteria per Centers for Disease Control and Prevention ***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.

- Limitations of authorized use for REGEN-COV are:
    - Post-exposure prophylaxis with REGEN-COV is not a substitute for vaccination against COVID-19
    - REGEN-COV is not authorized for pre-exposure prophylaxis for prevention of COVID-19.

- Previously, REGEN-COV was authorized for the treatment of mild to moderate 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.

- The EUA approval is based on data from a randomized, double-blind, placebo-controlled study enrolling 1,505 patients who were asymptomatic and who lived in the same household with a SARS-CoV-2 infected patient. The primary efficacy endpoint was the proportion of subjects who developed RT qPCR confirmed COVID-19 through day 29.
    - There was an 81% risk reduction in the development of COVID-19 with REGEN-COV treatment vs. placebo (1% vs. 8%; adjusted odds ratio 0.17; $p < 0.0001$).

- The recommended dose of REGEN-COV for the expanded EUA use is 600 mg of casirivimab and 600 mg of imdevimab administered by subcutaneous (SC) injection or together as a single intravenous (IV) infusion.
    - Casirivimab and imdevimab should be given together as soon as possible following exposure to SARS-CoV-2.

- For individuals 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, the initial dose is 600 mg of casirivimab and 600 mg of imdevimab by SC injection or IV infusion followed by subsequent repeat dosing of 300 mg of casirivimab and 300 mg of imdevimab by SC injection or IV infusion once every 4 weeks for the duration of ongoing exposure.

Continued . . .

- Refer to the REGEN-COV EUA prescribing information for dosing for the treatment of COVID-19 and additional dosing recommendations.

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