The Evolving Role of Therapeutics Against COVID-19

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Summary of COVID-19 Therapeutics

As of 08/02/21

- **Monoclonal Antibodies for post-exposure prophylaxis**
  - Casirivimab + Imdevimab (RGN)

- **Monoclonal Antibodies for treatment**
  - Remdesivir
  - Tocilizumab

Key:
- 🌟 FDA approved
- 🟢 EUA issued

1. National shipment pause due to variants, as of 06/25/2021
Bottom Line: monoclonal antibodies for treatment reduce relative risk of hospitalization

- COVID-19 monoclonal antibodies (mAbs) are intended for patients with mild to moderate COVID-19 who are at high risk of developing severe disease.
- mAbs are likely to be most effective when given early in disease course.
- Early evidence appears to suggest promise of mAb products in outpatient settings; products (bamlanivimab/etesevimab\(^1\) and REGEN-COV(casirivimab/imdevimab)) reduce the relative risk of hospitalizations by up to 70% in high-risk patients.

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1. National shipment pause due to variants, as of 06/25/2021
As of July 30, 2021, FDA has authorized post-exposure prophylaxis use of the COVID-19 monoclonal antibody therapeutic REGEN-COV (casirivimab and imdevimab)

REGEN-COV is expected to be effective against circulating variants, including the Delta variant. Please refer to the following for more information:

- FDA fact sheet and EUA Letter of authorization
- Regeneron press release

For additional information and approved materials, including information about ordering, please refer to the REGEN-COV webpage

Should you have any questions regarding the expanded indication for REGEN-COV, please contact us at COVID19therapeutics@hhs.gov

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**REGEN-COV post-exposure prophylaxis treatment eligibility**

REGEN-COV (casirivimab and imdevimab) is authorized for post-exposure prophylaxis of COVID-19:

- **in adult and pediatric individuals** (≥12 yrs+, weighing ≥40 kg) 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 SARS-CoV-2 vaccination (for example, individuals 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 CDC](https://www.cdc.gov/coronavirus/2019-ncov/your-health/close-contact.html)
  - Who are at high risk of exposure to an individual infected with SARS-CoV-2 because of occurrence of COVID-19 infection in other individuals in the same institutional setting (for example, nursing homes or prisons)

**New authorized use is in addition to the prior authorization of REGEN-COV to treat**

- **non-hospitalized patients w/ mild to moderate COVID-19** in adult and pediatric patients, aged 12 and older, w/ positive results of direct SARS-CoV-2 viral testing, and who are **at high risk** for progression to severe COVID-19

**Limitations of authorized use:**

- **Post-exposure prophylaxis w/ 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**
Guidelines for REGEN-COV repeat dosing for post-exposure prophylaxis

- 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

- Initial dose is 600 mg of casirivimab + 600 mg of imdevimab by subcutaneous injection or intravenous infusion

- Followed by subsequent repeat dosing of 300 mg of casirivimab and 300 mg of imdevimab by subcutaneous injection or intravenous infusion once every 4 weeks for the duration of ongoing exposure
Presence of Delta variant nationally

- B.1.617.2 (Delta) variant was at 31% nationally as of 6/19 and is **83.4% nationally as of 7/31** (pending data via Nowcast)

- States/territories encouraged to reach out with questions/concerns
Administration can occur across a wide variety of models

- Hospital
  - Hospital-based infusion centers
  - Emergency departments
  - Converted space within hospital for COVID infusion
  - Alternate care sites

- Ambulatory center
  - Infusion centers
  - Urgent care clinics
  - Dialysis centers
  - Alternate care sites

- Nursing homes
  - Skilled nursing facilities
  - Long-term care facilities

- Mobile sites
  - Bus/trailer
  - Other mobile sites

- Home
  - At patient’s home

Information support via [https://CombatCOVID.hhs.gov/](https://CombatCOVID.hhs.gov/)
Materials include links to EUA criteria, consolidated playbooks & educational materials