The Evolving Role of Therapeutics Against COVID-19

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Unclassified/For Public Use
Summary of COVID-19 Therapeutics

**No Illness**
- Exposed / Asymptomatic Infected

**Healthy, no infection**
- Not hospitalized, no limitations

**Exposed / Asymptomatic Infected**
- Not hospitalized, with limitations

**Early Symptomatic**

**Hospital Admission**
- Hosp. no act. medical problems
- Hospitalized, not on oxygen
- Hospitalized, on oxygen

**ICU Admission**
- Hospitalized, high flow oxygen/non invasive ventilation
- Hospitalized, mechanical ventilation/ECMO

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

**Monoclonal Antibodies for treatment**
- Bamlanivimab + Etesevimab (Lilly)
- Casirivimab + Imdevimab (RGN)
- Sotrovimab (GSK/Vir)

- 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.

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](mailto:COVID19therapeutics@hhs.gov)
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/daily-life-and-work/close-contact.html) **or**
    - 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