



The Evolving Role of Therapeutics Against COVID-19

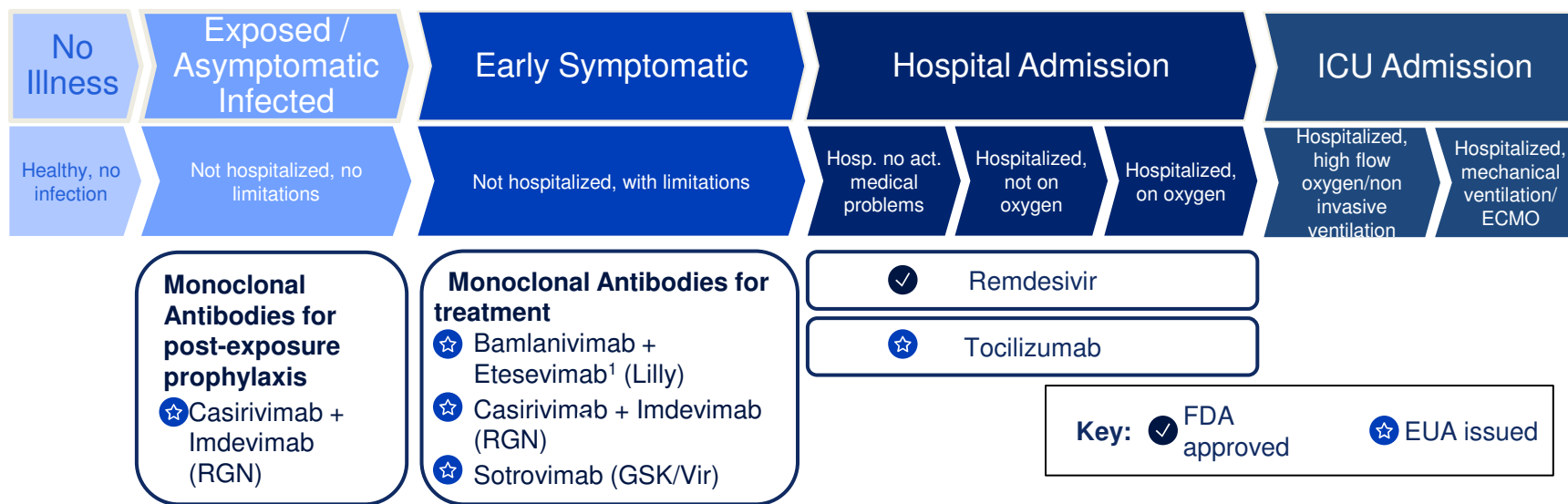
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Assistant Secretary for Preparedness and Response**

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Summary of COVID-19 Therapeutics



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

**REGEN-COV Emergency
Use Authorization(EUA)
expanded to include
post-exposure
prophylaxis**

- 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

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](#) ***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

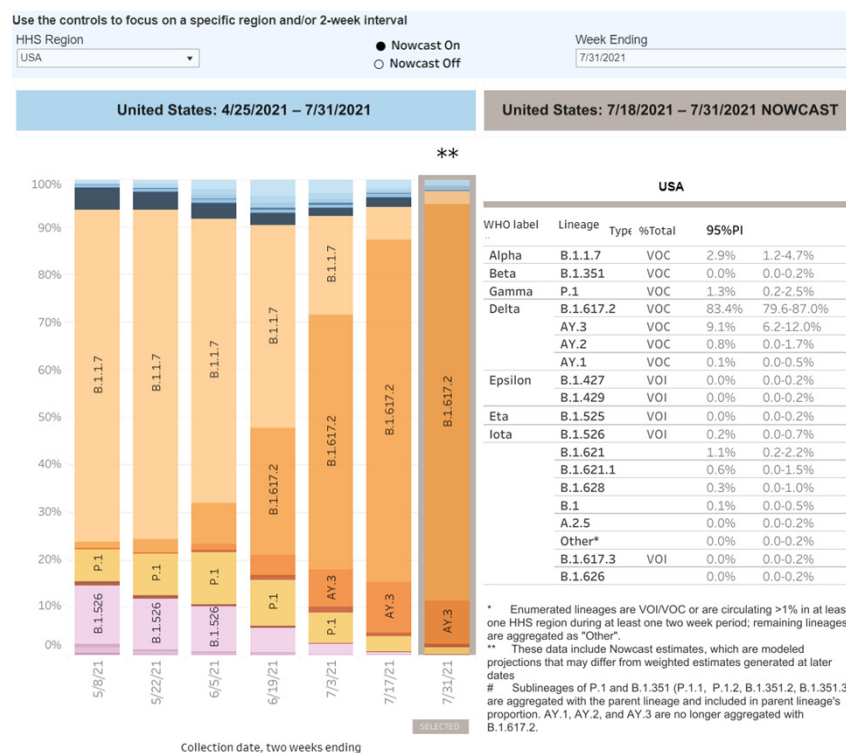
Limitations of authorized use:

- *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/>
Materials include links to EUA criteria, consolidated playbooks & educational materials