The Evolving Role of Therapeutics Against COVID-19

Colin Shepard, MD

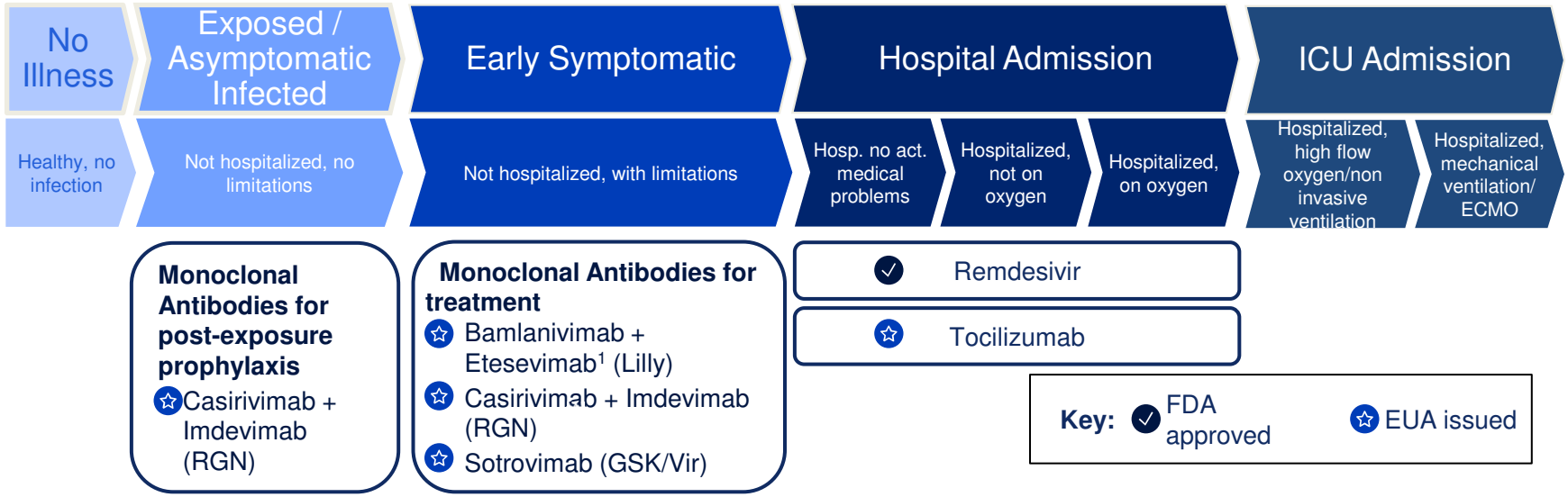
U.S. Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response

August 11th, 2021

Unclassified/For Public Use

As of 08/02/21

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

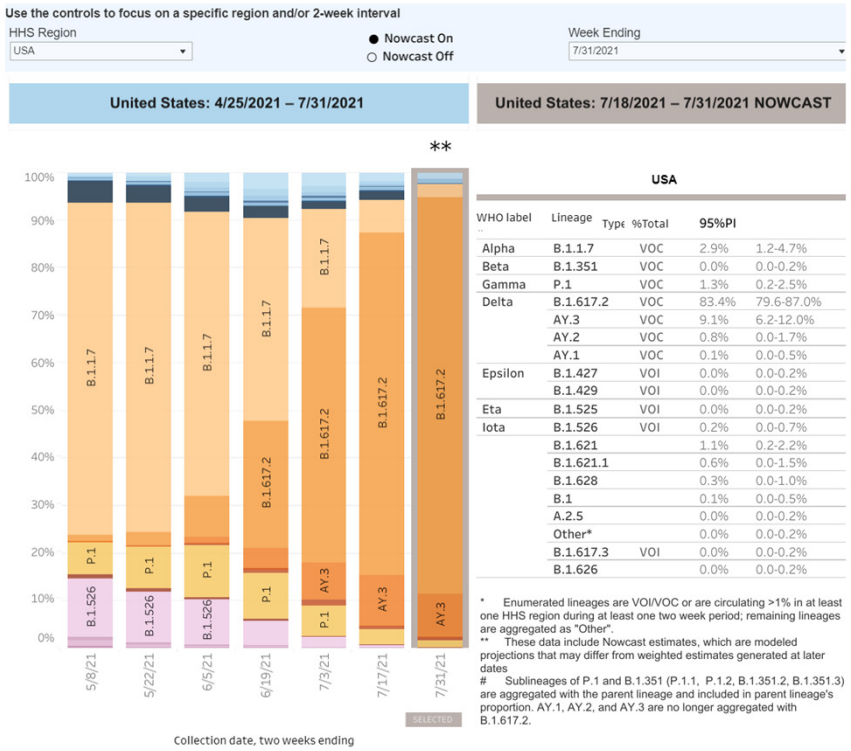
Limitations of authorized use:

- *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



USA

WHO label	Lineage	Type	%Total	95%PI
Alpha	B.1.1.7	VOC	2.9%	1.2-4.7%
Beta	B.1.351	VOC	0.0%	0.0-0.2%
Gamma	P.1	VOC	1.3%	0.2-2.5%
Delta	B.1.617.2	VOC	83.4%	79.6-87.0%
	AY.3	VOC	9.1%	6.2-12.0%
	AY.2	VOC	0.8%	0.0-1.7%
	AY.1	VOC	0.1%	0.0-0.5%
Epsilon	B.1.427	VOI	0.0%	0.0-0.2%
	B.1.429	VOI	0.0%	0.0-0.2%
Eta	B.1.525	VOI	0.0%	0.0-0.2%
Iota	B.1.526	VOI	0.2%	0.0-0.7%
	B.1.621		1.1%	0.2-2.2%
	B.1.621.1		0.6%	0.0-1.5%
	B.1.628		0.3%	0.0-1.0%
	B.1		0.1%	0.0-0.5%
	A.2.5		0.0%	0.0-0.2%
	Other*		0.0%	0.0-0.2%
	B.1.617.3	VOI	0.0%	0.0-0.2%
	B.1.626		0.0%	0.0-0.2%

* Enumerated lineages are VOI/VOC or are circulating >1% in at least one HHS region during at least one two week period; remaining lineages are aggregated as "Other".
** These data include Nowcast estimates, which are modeled projections that may differ from weighted estimates generated at later dates
# Sublineages of P.1 and B.1.351 (P.1.1, P.1.2, B.1.351.2, B.1.351.3) are aggregated with the parent lineage and included in parent lineage's proportion. AY.1, AY.2, and AY.3 are no longer aggregated with B.1.617.2.

- 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